ANIA Associazione Nazionale fra le Imprese Assicuratrici

Alimentary products and the cold chain: *elements, insurance and loss prevention*

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Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004, laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004, on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

Commission Regulation (EC) No. 1216/2007 of 18 October 2007, laying down detailed rules for the implementation of Council Regulation (EC) No 509/2006 on agricultural products and foodstuffs as traditional specialities guaranteed

Decree dated 6th November 2007, No. 193, implementation of Directive 2004/41/EC *(in Italian)*

Commission Regulation (EC) No. 628/2008 of 2 July 2008, amending Regulation (EC) No. 1898/2006 laying down detailed rules of implementation of Council Regulation (EC) No. 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

FOREWORD

The ANIA Committee for the Global Safety in Transport Project, availing itself of the experience gathered in the insurance field at an international level, as well as of the suggestions put forward by external qualified operators (producers, shippers, carriers, surveyors), has collected, analysed and turned into an operative tool of ready reference a whole series of information, documents and law provisions concerning classification, correct preservation and distribution systems of alimentary perishable goods.

The aim pursued by the Committee through the present study consists, in particular, in offering colleagues working in the marine insurance sector guidance and recommendations of a practical nature and aimed to:

- examination and possible suggestion to shippers and carriers of optimal systems of prevention of damages in the processes of preservation and transport of the above products;
- correct evaluation of the risk according to the type of goods, to the packing and preservation system, to the characteristics of the voyage and of the carrying conveyance;
- activities relating to filing the claim and settling same, with particular reference to gathering relevant information and documents, choosing a surveyor and rapidly obtaining his intervention, singling out (directly or through external collaborators) possible liabilities and critical factors linked to the shipment.

As for the part relating to the analysis of loss prevention systems, emphasis has been given - within the scope of the entire production and distribution cycle – to the procedures of preservation and transport.

An essential reference made in the study is made to the rulings of the European Union which, with the free circulation of goods, has taken it upon itself (for the sector of alimentary products) to harmonize and maintain common levels of hygiene and safety.

The most recent directives are structured on the principle of self-control, i.e. making all the operators of the foodstuff chain responsible, comprising therefore bailees and the parties entrusted with transport.

The new disciplinary layout imposes on carriers the duty to acquire greater and deeper technical knowledge (especially for those who carry out transports on behalf of third parties, so far only marginally and passively involved in the control of alimentary products).

In spite of the fact that the rules now in force satisfy the requisites guaranteeing the safe transferral of products, the actual situation is very different from the one described on the self-control chart.

In order to try to remedy this shortcoming, insurers too are called upon to propose to operators, precisely, adequate and efficient solutions with a view to correct prevention.

Transport constitutes a very delicate phase in the production/distribution cycle of alimentary products which, in the same way as the life of a human being, requires particular attention in maintaining the optimal temperature.

This is why shipments are also named “transports under controlled temperature”.

In the insurance context perishable goods, besides being subject to the risks which other non perishable goods undergo (road accidents, thefts, armed robberies, fire, contamination etc.), need to be guaranteed against damages and losses deriving from the influence and the variations in temperature.

The lack or the excess of cold are the main effe cts of the influe nce of te mperature on the goods being carried, whil e the relevan t causes may be manifold , e.g. the br eakdown of t he refrigerating plant or its malfunctioning or its incorrect working order.

The time of intervention subsequent to the o ccurrence of an event is therefore fundam ental, as the longer or shorter duration of the failure may cause considerable damages or, more simply, a thermal anomaly remaining within the tolerances of the product.

The te mperature conditions which must be kept during the voyage are spec ific to each product and, therefore, the contemporary presence of products with non-homogeneous transport temperatures must surely be avoided.

The preservation techniques of an ali mentary product through the cold chain are based on biological principles. Cold has the advantage to keep food, even for a prolonged stretch of time, without altering its nutritional properties and its organoleptic characteristics.

This book ai ms to provid e useful suggestions to all those who are involved at various levels in the transport, preservation and insurance of alimentary goods along the cold chain. It is divided i n fi ve parts relat ing to: 1) alimenta ry goods and their nutr itional and organolepti c characteristics; 2) transport of goods; 3) prep aration for transport of go ods and means of transport; 4) coverage conditi ons ha bitually being offered; 5) the regulato ry schem e. The volume is provided, finally, with: specific records for each alimentary product; full text of so me laws; specimens of insurance conditions.

Hoping that this manual may become a useful tool for all insurers when evaluating risks and settling clai ms due to variation in tem perature, we wish to thank all those who have made possible its realization. P articular thanks to Capt. Paolo Costa, who passed on to us his enthusiasm in continuing his work.

Luca Florenzano, Giovanni Carlo Pietrangeli
Coordinators of ANIA Committee
Global Safety in Transport Project

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Part 1

Alimentary goods

CHARACTERISTICS OF ALIMENTARY PRODUCTS

Definition of alimentary product

A recent definition of alimentary product (Art. 2 of EC Regulation 178/2002) determines that by "alimentary product" we term any substance or product, whether it be transformed, partially transformed or not transformed, intended to be ingested, or which may reasonably be ingested, by human beings.

The perishableness of an alimentary product represents the possibility that the bio-chemical structure of the foodstuff may degenerate, owing to microbiological, enzymatic, chemical and physical-chemical phenomena linked to the composition of the product or to the preservation modalities and techniques. The topic of the perishableness of an alimentary product is closely linked to the one of the preservation techniques employed for it. In this connection it is useful to highlight that when speaking of preservation we mean the period of time elapsing between production and sale or consumption of foodstuffs. Temperature is one of the main factors influencing the quality of alimentary products. The law defines "perishable foodstuff" any product which needs thermal conditioning for its preservation (Art. 1 of the Ministry of Public Health Ordinance 2nd March 2000).

Foodstuffs provide our organism with the energy and the nutrients necessary to perform its vital functions. The nutrients having energetic contents are proteins, yielding 4 kcal/g, lipids or fats, providing 9 kcal/g, carbohydrates or sugars with a yield of 3.75 kcal/g, and alcohol, providing energy for the amount of 7 kcal/g. The other nutrients (vitamins and mineral salts, anti-oxidants, fibres, etc.) participate in biological processes. Foodstuffs also contain substances having negative effects, e.g. enzymatic inhibitors, fitates and oxalates, anti-vitamins etc., or toxic compounds. Many nutrients cannot be totally assimilated by our organism. The fraction which may be utilized, determining the biological quality of the foodstuff, is termed bioavailable. For our nourishment we also employ other substances such as sweeteners, natural or synthetic, salt and water.

The organoleptic characteristics of foodstuffs are those we perceive through our senses, such as colour, aroma, flavour, firmness. Sensorial stimuli linked to food are of great importance in determining alimentary behaviour. Characteristics like colour and shine are compared with images set in our memory, causing a reaction of acceptance or denial. The preferences for sweet substances, for fat foodstuffs or for salt are features which have prevailed through natural selection. The organoleptic characteristics of the various types of alimentary products are regulated by law.

Vegetable products

Nutritional characteristics

Cereals

Cereals represent the main alimentary resource for mankind. The most important ones are wheat or corn, rice, maize, barley, oat, rye, then millet, emmer, sorghum etc.

The water content is comparatively low (11.5 % of weight in durum wheat, 12 % in rice). The protein content, with low nutritional quality, ranges between 7 % of weight in rice, 10 % in maize and 12 % in wheat. Wheat and rye are suitable for bread baking because they are rich in gliadins

and glutenins (85 % of total proteins). Starch is present in large quantity: e.g. 55 % of weight in wheat, 65 % in maize, 70 % in rice.

Lipid content is scarce. Cereals are rich in alimentary fibres, which in wheat bran represent more than 40 % of weight, and provide a good yield in vitamins of the B group. Mineral salts are also present.

The energy content varies according to the type: durum wheat provides 312 kcal per 100 g, rice provides 332 of same, maize 353.

Vegetables, greens, pulses and mushrooms

Vegetables, greens and fresh pulses are made up from 80 % to 95 % of water, except a few cases, such as beans, for which water accounts for about 60 % of weight, they lack proteins (1-3 % of weight, with the exception of fresh pulses, which contain up to 20% of proteins) and lack lipids (0.5 %).

The yield in vitamins, like vitamin C, is good, especially in peppers or in broccoli sprouts, and in vitamin K, in carotenoids forerunners of vitamin A, abounding in carrots, in tomatoes, in spinach etc. or in other kinds of carotenoids, having anti-oxidant properties like lycopen, present in high quantities in tomatoes, and in mineral salts like potassium and calcium, abounding in chicory and spinach, and in iron, also present in spinach, even though some compounds limit its digestibility.

Fibres too are present, in particular in pulses.

The energy content is not usually high (e.g. 17 kcal per 100 g in tomatoes, 35 in carrots, 85 in potatoes, 133 in beans).

Mushrooms are included among vegetable products, but in actual fact they are organisms forming a group apart. They comprise, besides several edible species, also many poisonous types and moulds, the latter being one of the main causes, together with bacteria, of deterioration of alimentary products. On the whole, the nutritional yield of mushrooms is scant. Moreover, except for very few species, they must be cooked before being eaten. Fresh mushrooms are rich in water (more than 90 % of weight). They provide few proteins, not wholly assimilable, sugars and and fibres. They do not contain many fats. The yield in vitamins is fairly good, like the group B ones, vitamin C, vitamin PP, vitamin A and vitamin D, and so is the yield in mineral salts. The energy content is low: 31 kcal per 100 g in the case of truffles.

Fruit

Fruit has a high water content, up to 95% of weight, and lacks proteins and lipids. The quantity of sugars (glucose, fructose, sucrose) present in fruit grows greater and greater with the ripening of same. Starch is not present, except in bananas.

Fruit is an excellent source of vitamin C, abounding in citruses, in kiwis and in strawberries, and of carotenoids, contained for example in peaches and apricots. We also find mineral salts and fibres, which comprise pectins, important in the making of jams and marmalades. The energy yield is low: e.g. 15 kcal per 100 g in water melons, 34 in oranges, 53 in apples.

Olives, from which oil is derived, are a fruit whose nutritional composition is peculiar. In fact they provide a high yield of lipids, which constitute 25.1 % of weight in black olives, and are rich in energy: black olives offer 235 kcal per 100 g.

Dried fruit

Dried fruit (nuts, almonds, pine nuts etc.) presents a reduced water content: for example, 3.5 % of weight in nuts. It is very rich in proteins of fairly good quality, in mineral salts and in lipids, which constitute 50 % of weight in pine nuts and 70 % in nuts.

The energy yield is very high: for example, 595 kcal per 100 g in pine nuts, 603 in almonds, 689 in nuts.

Dried pulses

This group comprises the dried seeds of beans, chickpeas, lentils, horse beans, peas, soybeans, peanuts etc. These are the vegetables with the highest content of proteins, an average 20 % of weight, but 35 % in soy beans, the same amount as in meat. The protein content of soy beans is employed for the production of protein concentrates and isolates. The proteins in pulses, of fairly good biological quality, are complementary to those in cereals.

Starch too is present. There is a reduced yield in lipids (2 % of weight in beans), which contain a high percentage of unsaturated fats, easily subject to turning sour.

Pulses also provide a good yield in vitamins like vitamin B1, vitamin B2 etc., of mineral salts like iron, zinc, etc, and in fibres.

Soybeans and peanuts differ from other pulses because they have beans rich in oil (18 % and 50 % of weight respectively).

The energy yield is quite high: for example, 291 kcal per 100 g in lentils, 316 in chickpeas, 407 in soy beans.

Seasoning and spice

Potherbs and spice have been employed for thousands of years to better the flavour of food. They are devoid of nutritional value because they are ingested in extremely low quantities. Nevertheless, the essential oils giving these plants their flavouring properties are also capable of performing other functions in our organism, like for example stimulating digestion.

The most common potherbs are basil, marjoram, mint, oregano, parsley, sage, rosemary. Spice are nearly all derived from tropical plants. Among the main spice we may list pepper, mustard, nutmeg, saffron.

Organoleptic characteristics

Colour

The wide variety of the colours of vegetable products is due to pigments which carry out various functions in the organism of the plant. The main pigments are chlorophyll, carotenoids and anthocyanins. Chlorophyll fixes sunlight, allowing the photosynthesis process. It is present in two forms, chlorophyll A, blue-green, and chlorophyll B, olive green, and accounts for the green colour of vegetables.

The yellow, orange and red colours of various kinds of fruit and vegetables (e.g. citruses, tomatoes, greens, etc.) are due to carotenoids, also involved in photosynthesis, and which, resisting heat, maintain pigmentation in cooked products too, to anthocyanins who determine red, violet, pale blue colours, and to anthoxanthins which confer a yellow color.

In mushrooms red, orange, yellow colours are due to carotenoids, to quinones and to other molecules. Blue, brown, yellow, red and pink are due to the presence of several phenolic compounds.

Among cereals, wheat has a characteristic yellow colour, maize an orange-yellow colour.

As for greens, spinach are dark shiny green in colour, carrots are orange-yellow, tomatoes are red, more or less intense, beans have red pods spotted with cream colour or green and salmon-coloured or green seeds.

Among the various kinds of fruit, peaches have a red and yellow skin and yellow-paste or white-paste pulp according to the type, pineapples have a light yellow pulp, bananas have yellow or streaked skin and ivory yellow pulp, blueberries are violet blue in color, oranges, depending on type, have a skin ranging from light orange to red and orange or red pulp.

Alterations in colour or the appearance of spots or cracks on the skin are usually symptoms of deterioration.

As for spice, basil has shiny green leaves, saffron is bright yellow.

The colour of mushrooms varies according to species. It may range from white like amanita to yellow, to greenish yellow to violet-black for black truffle.

Smell and flavour

The flavour of vegetable products depends on substances like tannins, which have an astringent effect, on the balance between acids and sugars, which gives a sweet-and-sour taste, etc.

The astringent effect is the dry sensation we feel, for example, eating unripe fruit. Tannins present in the pulp interact with the proteins in our saliva and with the oral mucosa, reducing lubrication in our mouth.

The sweet-and-sour taste of vegetable products also depends on the degree of ripening. In unripe fruit there exist high concentrations of weak acids, which diminish as ripening proceeds, and the flavour switches from sour to sweet.

Aroma is determined by substances like ketones, alcohols, exthers etc. The various comparative concentrations of such substances confer to every product its distinctive aroma.

Spice and seasonings are particularly rich in substances like piperine, which gives pepper a hot taste.

Aroma and flavour of mushrooms depend on species. White truffle has a strong and pleasant smell, black truffle has a more delicate aroma.

Alterations in flavour and aroma are signs of deterioration.

Firmness

The degree of firmness is distinctive of the various types of vegetable products. Firmness is given by substances composing fibres, like pectins. Their deterioration, by ageing or mechanical damages, causes loss of turgidity and softening. Also the surface of the skin and of the leaves, which may be smooth or velvety, represents a characteristic aspect of vegetable products. Spots or cracks are symptoms of deterioration or poor quality.

The tissues of mushrooms are made up of intertwined filaments, hyphas, which confer a fleshy firmness to the pulp.

Products derived from cereals

Nutritional characteristics

Many other products are derived from cereals. The production processes which cereals undergo so as to obtain for example flour, then employed, together with other ingredients, to produce pasta, bread etc., cause loss of vitamins, but also an increased bioavailability of mineral salts and a gain in digestibility of starch,

The water content varies depending on type: 4.3 % of weight in pop corn, 11 % in durum wheat pasta, 14.2 % in 00 type durum wheat flour, 29 % of weight in 00 type bread. High is the yield in carbohydrates, ranging from 66.9 % of weight in 00 type bread to 82.3 % in rusk slices. These products are also rich in fibres, which represent 2.7 % of weight in durum wheat pasta, 6.5 % in wholemeal bread, 7 % in bran crackers, up to 28 % in wholemeal biscuits enriched with fibres.

Among the products obtained from cereals, 00 type bread provides 289 kcal per 100 g, durum wheat pasta 325, 00 type durum wheat flour 340, pop corn 378, breadsticks 431.

Organoleptic Characteristics

Cereals are employed to produce several other products. Here below are the organoleptic characteristics of some of the main cereal by-products, like bread and pasta.

Aspect

Bread presents a crumbly, homogeneous crust, dark yellow in colour, different according to the type of bread. The crumb is soft and resilient, light coloured.

Raw alimentary pasta is rigid, with a smooth, uniform surface devoid of impurities and foreign bodies, yellowish in colour. Some types of pasta (egg pasta, fresh pasta etc.) have a softer consistency.

Other products obtained from cereals are rusk slices, breadsticks etc.. These products are crisp, crunchy and their colour depends on the different brands, but it is always homogeneous.

Smell and flavour

The smell and the flavour of bread and of the other products obtained from cereals are pleasant and characteristic of the various types. They depend on the ingredients employed.

Transformed products based on fruit and vegetables

Nutritional characteristics

The various kinds of vegetables and fruit may undergo various processes to produce preserves, jams and marmalades, fruit in syrup, fruit juices, dressings (mustard, ketchup) etc.

The products so obtained have different nutritional characteristics from those of the originary species.

These foodstuffs present a highly variable water content according to type: 3.9 % of weight in freeze-dried vegetable soup, 21 % in candied pears, 70 % in tomato paste, 90 % of weight in deep-frozen cooked French beans. The protein yield also varies depending on the type of product: 0.5 % in jams, 3.9 % in tomato paste. The lipid content also varies: 0.4 % of weight in tomato paste, practically nil in jams. The yield in carbohydrates is fairly good: 20.4 % in tomato paste, 58.7 % in jams.

The energy content, too, is variable: 67 kcal per 100 g in deep-frozen products, over 200 in jams, 295 in candied pears, 289 in freeze-dried vegetable soup.

Organoleptic characteristics

The organoleptic properties of the products obtained from fruit and vegetables may reflect the ones of the originary products or may be influenced by the production process. For example, products which have undergone deep-freezing have a very similar flavour to the one of the primitive product. In jams, the high percentage of sugars employed in preparation increases the sweet flavour. Moreover, pectins contained in fruit are very important in determining the consistency of these products.

Finally, colourings may be added, which revive the chromatic shades of the product.

Meat

Nutritional characteristics

Meat consists in muscular tissues of animals. Nevertheless, when dealing with alimentary subjects, by meat we only mean the one of mammals and birds. Fish, shellfish and crustaceans are considered separately, as fishing products.

The average content in nutrients of fresh meat of mammals (cattle, swine, sheep, goats, equines, rabbits) and birds (yardbirds etc.) is similar.

The water content is about 70 % of weight. Proteins represent about 20 % of weight, and are of good nutritional quality as they are rich in essential amino acids (which the human body is unable to produce autonomously).

Lipids represent from 3 % to 10 % of the weight of meat. It should be kept in mind that the ever growing employment of fodder enriched in polysaturated fats for bred animals, in particular swine, has enhanced the decrease of lipid content of animal meat, and the increase of the percentage of unsaturated fats in animal tissues.

Meat has a scant content of carbohydrates, present as glycogen, which is consumed in the deterioration processes after death, except in horsemeat. Meat is also an important source of vitamins of the B group and in particular of vitamin B12, of which it is the sole alimentary source.

Meat also has a good yield in mineral salts, easily digestable by the organism: iron, zinc, copper and selenium.

Here following are the characteristics of the kinds of meat more commonly marketed.

Beef

The nutritional characteristics of beef vary with the age of the animal and the different cuts. In the adult bovine the water content ranges between 69 % of weight in the shoulder and 75 % in the geret. The protein content is about 20 %.

The lipid content is low: 2.7 % of weight in veal up to 6.1 % in the sirloin steak of the adult bovine. Carbohydrates are virtually absent.

The energy yield varies from 107 kcal per 100 g in veal to 134 in the loin of the adult bovine, and it is higher in liver: 142 kcal per 100 g.

Horsemeat

Horsemeat presents nutritional characteristics similar to those of other kinds of meat. However, differing from the others, it provides a small quantity of carbohydrates. It is particularly rich in iron. The water content is equal to about 70 % of weight. The protein content amounts to 19.8 %, the lipid content to 6.8 %. Carbohydrates constitute 0.6 % of weight. The caloric content of horsemeat is equal to 143 kcal per 100 g.

Pork

Also in swine the nutritional characteristics vary with the age of the animal and the various cuts of meat. The water content is equal to about 70 % of weight. The protein content is about 20 %: 19 % in the shoulder, 21.3 % in the steak.

The lipid content is higher than the one of beef: up to 9.9 % in the loin, but decreasing in the last years because of the employment of fodder lacking in fats. Carbohydrates are practically missing.

The energy yield is greater than in other meat and ranges between 157 kcal per 100 g of "light" pork steak and 172 of "heavy" pork loin.

Mutton

As in other species, also in mutton the nutritional characteristics vary according to the age of the animal and to the various cuts. The water content is about 70 % of weight, proteins amount to about 20 %, lipids vary between 5.0 % in kids and 8.8 % in lambs. Carbohydrates are almost absent. The caloric content is higher than in beef and horsemeat, and is equal to 122 kcal per 100 g in kids and 159 in lambs.

Poultry and rabbit meat

Meat of this kind is obtained from slaughtering of birds and other animals defined as farmyard animals: chickens, turkeys, rabbits etc., and game.

In these products too water constitutes about 70 % of weight. The protein content varies from 15.8 % of weight in geese to 19 % in chickens, 19.9 % in rabbits, 24.3 % in guinea hen legs. The lipid content varies according to species: 4.3 % in rabbits, 10.6 % in chickens, 34.4 % in geese. Carbohydrates are almost absent.

The energy yield also varies depending on species: 118 kcal per 100 g in rabbits, 171 in chickens, 373 in geese.

In the last few years a new kind of poultry has appeared on the market, ostrich meat, of the Ratitae group. This meat has a lipid content (0.9 %) and en energy yield (92 kcal per 100 g) lower than other kinds of meat.

Organoleptic characteristics

Organoleptic characteristics play a fundamental role when judging the quality of meat and meat by-products. The quality parameters of meat are: colour, smell, flavour, fineness, appearance, firmness and juiciness.

Colour

The colour of meat is due to the respiratory pigment of muscles, myoglobin, and to haemoglobin present in red blood cells. These protein molecules contain iron. Iron, binding itself with oxygen, gives tissues and blood the typical red colour. The muscles which are richer in myoglobin have a darker appearance. They are those which need more oxygen because employed to a greater extent.

The colour of meat also depends on the age of the animal (in oxen, meat is bright red, in pigs pinkish red, in goats dark red, while in young individuals, e.g. calves or piglets, it is pinkish white), on the level of activity of muscles (typical is the dark red colour of game), on sex (the meat of male animals is of a brighter red than the meat of females) and on feeding.

The colour of muscles after slaughtering is employed to classify the various types of meat: calf, lamb, kid and rabbit meat and poultry (excluding goose meat) are considered “white” meat because they present light shades of colour, while the meat of adult animals like bullocks, goats, pigs is termed “red” meat because it is red-coloured, from bright to dark red. Game meat is generally defined “black” meat.

Smell

The smell of meat varies depending on the type of animal, on its age, sex and feeding. Fresh meat, irrespectively of the species of origin, generally has a mild smell, similar to lactic acid, in which different gradations due to feeding may be perceived. However, in certain animals aroma is stronger, as for instance in goat meat, which has a musky smell, and in game meat, presenting what we in fact term a “gamy” smell.

Meat which has been kept too long has a musty smell. The deterioration processes of proteins cause a putrid smell, those of fats determine a rancid smell.

Flavour

The flavour of meat varies from species to species and depending on the age of the animal. It is determined by various substances: proteins, lipids, carbohydrates, various other nitrogenous substances, fat oxidation products, sulphurated products, ammonia etc.

The meat of young animals has a more delicate taste than the one of adult individuals.

Fineness

The fineness of meat depends on the quantity and on the type of connective tissue which is present in muscles. Cutting meat crosswise one may observe the appearance of the muscular bundles tied in lobules by the connective tissue (grain). Meat is considered very fine, like in horses or calves, being soft and velvety, fine, like in bullocks and young beef, rough if it is coarse and dry like in oxen.

The fineness of meat is also determined by texture, which shows when examining a muscle cut lengthwise and evaluating the arrangement of muscular bundles and the quantity of connective tissue between them. Bull meat has a very thick texture, bullock meat a thick one, cow meat a not very thick one, calf meat a decidedly loose texture.

Firmness

This parameter depends on the age of the animal. The younger the individual, the lesser the firmness of muscles. The muscles of young animals, in fact, are richer in water and less rich in myofibrils than the ones of older animals. The lower content in muscular fibres implies a lesser quantity of myoglobin and therefore confers a lighter colour. Fat also contributes to firmness of meat.

In adult animals, like oxen, pigs, goats, horses, meat is firm, while in younger ones meat is tender.

Juiciness

Juiciness is due to water released by meat during mastication. It depends on the state of muscular proteins, on the degree of acidity, on the duration of hanging, on the quantity of fat.

Meat by-products

Nutritional characteristics

Many products are derived from meat, like forcemeat, whether cooked or raw (obtained from pork, except "bresaola", which is produced with beef), tin-canned meat, etc. The production procedures envisage adding seasonings, spice, additives, etc.

These products have a widely varying water content, depending on type: for instance, approximately 35 % of weight in processed pork meat, 83.2 % in tinned jellied beef etc. They are very rich in proteins: 12 % of weight in tinned jellied beef, 27 % in dry-cured ham, 30 % in salami. The yield in lipids is more variable: 4 % in lean cooked ham, 30 % in salami, 41 % in liver sausage. Only some also provide a low yield in carbohydrates, like Hungarian salami, in which they account for 0.7 % of weight, or pork Bologna sausage, in which they reach 1.5 %.

The vitamin and mineral salts content depends on the one of the meat employed in preparation: for example, in tinned jellied meat the production process causes a considerable decrease of the vitamin content.

The energy content too varies according to type. In tinned jellied beef it is equal to 67 kcal per 100 g, 268 in dry-cured ham, 392 in Milan type salami, 424 in liver sausage.

Organoleptic characteristics

The colour of products obtained from meat is dependent on the one of the species of origin, though it is influenced by the production process, For example, in forcemeat colourings may be added, and sodium nitrite and nitrate are added to tinned jellied meat to maintain the red colour of meat, which the production process would render dark grey.

In forcemeat aroma and flavour are strongly influenced by the addition of other ingredients, like salt and spice. In cooked meat these characteristics are influenced by the substances which are created during cooking.

Fresh fishing products

Nutritional characteristics

Fishing products comprise the various species of fish, molluscs and crustaceans.

Fish

The composition of the flesh of fish differs widely depending on species and on place of origin.. Fish presents a variable water content according to species, from 60 % of weight in herrings to 80 % in codfish.

Fishing products are also rich in proteins, about 20 % of weight, have a high nutritional quality and are very easily assimilated by our organism. The lipid content is particularly variable, and goes from about 1 % or even less in fish considered lean like soles or codfish to 14 % and over in those considered fat like herrings and eels. Among fats there is a prevalence of poly unsaturated ones: in particular, fish is the main alimentary source of omega three fats, which are very important in decreasing the risk of brain and cardiovascular diseases. The cholesterol content is similar to the one of the meat of terrestrial animals. Fishing products are a plentiful source of vitamins A and D and of mineral salts, mainly iodine and fluorine.

The energy yield is also variable depending on species: sea-basses provide 82 kcal per 100 g, giltheads 121, herrings 216.

Molluscs

Molluscs comprise several species, subdivided into various groups. Molluscs provided with tentacles (cuttlefish, octopuses, squids) are termed cephalopods. They are predators, able to swim and travel even across long distances. Those provided with a muscular foot and with an external shell, in which they find refuge, are termed gastropods (limpets, snails etc.). Other types instead present a shell divided in two valves and are termed lamellibranchiates or bivalves (mussels, clams etc.). Bivalves spend their whole lifetime on the sea- floor or fixed to rocks, filtering the nutrients present in seawater.

Molluscs present a high water content, equal to approximately 80 % of weight. The protein yield goes from 11 % of weight in mussels to 13 % in squids. Moreover, they provide a scant yield in lipids, up to about 3 % of weight, but with a high cholesterol content. They contain very few carbohydrates. They are a fairly good source of vitamins. Certain species, like mussels, have a high iron content.

The energy yield varies depending on species: from 68 kcal per 100 g in squids to 84 in mussels.

Crustaceans

Crustaceans comprise several forms, all of them characterized by the number of limbs, ten, and by the division of their bodies in two parts: cephalothorax and abdomen. They may be classified on the basis of the position of their abdomen, which in Macruria, like cray fish and lobsters, is flat, while in Brachyura, like crabs, it is folded under the body.

Crustaceans have a high water content, equal to about 80 % of weight. Protein yield goes from 13.6 % of weight in crayfish to 16 % in lobsters . Crustaceans are poor in fats, which constitute up to about 3 % of weight, but they present a high cholesterol content. Carbohydrates are very scant.

Crustaceans provide a good yield of vitamin A and vitamin D and of mineral salts like iodine and fluorine.

The energy content varies depending on species: e.g. 71 kcal per 100 g in crayfish, 85 in lobsters.

Organoleptic characteristics

Fish

Fish presents a different flesh from the one of terrestrial animals, white in colour, except for some species (tuna, salmon etc.) in which it is pink. The flesh is also less firm, owing to the low content in connective tissue.

The white colour of the flesh of fish is due to the different arrangement of muscular proteins, which form fibres suitable for quick and intense efforts (quick fibres) which do not employ oxygen. These muscles therefore lack myoglobin, which renders red the flesh of terrestrial animals. Fish species which present pink flesh, instead, have muscles with a different type of fibres, suitable for prolonged efforts (slow fibres), in which myoglobin is present.

The lesser firmness is due to the different anatomy of muscles, which are made up not of longitudinal bundles but of segments of fibres (myotomes) separated by layers of connective tissue.

The organoleptic characteristics which determine the degree of freshness of fish are: smell, stiffness, firmness and appearance of the eye, of the skin, gills and abdomen.

Smell

The smell of fresh fish is a sea smell, salty , brackish and faint. A more intense and unpleasant smell is a sign of deterioration.

Stiffness

Fresh fish must maintain the rigor mortis which appears shortly after its catch and lasts for a few hours, depending on the preservation temperature. This is evaluated by holding the fish by its head in a horizontal position: the body of the animal must be only slightly curved.

Firmness

The flesh of the various species of fresh fish are firm and elastic.

The appearance of the eye, skin, gills and abdomen

The eye of fresh fish is bright, brilliantly coloured, convex towards the outside. In some species, like in grey mullets, it is slightly veiled.

The skin is shiny , brilliant and taut, with scales (in species in which they are present) well adherent to the body. The whole surface of the body must be covered by a layer of translucent mucus.

Gills must have the operculum (if present) well closed. Lamellas must be pinkish-red, intact, closed and covered by transparent mucus.

The abdomen must be full, undamaged and elastic. Possible bulges or a flabby consistency are signs of deterioration.

Molluscs

Appearance

In cephalopods (cuttlefish, squids, octopuses etc.) the body must be turgid, shiny and covered by a layer of mucus. Eyes must be bright and tentacles adhering to the body , with suckers still retaining adhesive power.

Bivalves (mussels, clams etc.), to be sold when still alive, must present their valves perfectly closed; if the animal is in water it must immediately close its valves when touched. The body must be adherent to the valves.

Smell

In fresh cephalopods molluscs smell, which must be judged near one's mouth, must be fresh and brackish. An ammonia smell is a sign of deterioration. The smell of fresh bivalves has a pleasant aroma, salty or brackish.

Colour

The colour of clean cephalopods must be white, without any shade. A reddish colour indicates deterioration. In bivalves colour must be brilliant and vivid.

Crustaceans

Appearance

As in other fishing products, also in crustaceans vitality is a very important requisite for freshness. Some types, like lobsters, crabs etc. must be therefore sold alive and able to react to stimuli. Others, like crayfish, must anyway be sold when they are very fresh.

Smell

Fresh crustaceans have a smell of saltiness, without any ammonia tinge.

Colour

The colour of the flesh of crustaceans is generally white. The appearance on the trunk of a dark spot, or variations in the colour of the carapace are signs of deterioration. In frozen crustaceans sulphites are added as preservatives, sulphites which must be anyway indicated on the label.

Preserved fishing products

Nutritional characteristics

Fishing products may undergo various processes, like being salted, smoked, tinned and deep-frozen.

The products so obtained present nutritional characteristics which are somewhat different from those of the species of origin.

Water content is somewhat reduced in products like salted stockfish, obtained from cod (12 % of weight). In caviar (sturgeon eggs) it is equal to 46 % and in frozen fishfingers, obtained from codfish, to 61 %. The protein yield is usually considerable: 25.9 % of weight in anchovies in oil, 29 % in dried salt cod, obtained from codfish, 80.1 % in stockfish.

The content in fats depends both on the production process and on the characteristics of the species of origin: for instance, it is equal to 1% of weight in soaked salt cod and to 21.9 % in pickled eel. The yield in carbohydrates is generally scant.

The energy yield is also variable: 95 kcal per 100 g in soaked salt cod, 255 in caviar, 356 in stockfish.

Organoleptic characteristics

The organoleptic characteristics of these products may differ from those of the original products because of the production processes.

Colour is similar to the one of the original species but, for example, in fish preserved in brine substances like red ochre may be added to liven the shade of colour. In caviar the eggs must be vitreous, brilliant and uniform in colour.

Flavour is characteristic of the various products. Salt employed in the preservation of fish deeply influences flavour. Caviar must have a delicate taste, not too sweet nor too sour.

Milk and milk by-products

Nutritional characteristics

Milk

Milk is the product of mammary glands of female mammals. "Alimentary" milk is defined as the product of the regular, complete and continuous milking of udders of animals in good health and feeding condition.

From the physical point of view milk is a colloidal system in which three phases may be identified: in emulsion are lipids and fat-soluble vitamins; in dispersed phase are proteins with high molecular weight; in solution are lactose, proteins with low molecular weight, water-soluble vitamins and mineral salts.

By the term milk we only indicate cow's milk, even though other types of milk (sheep milk, goat milk etc.) are also employed as food.

The milk which is more commonly marketed undergoes pasteurization, a procedure by which the product is heated at temperatures varying between 72° C and 85° C for a few seconds (for instance 72° C or 75° C for 15 seconds).

The water content of milk is obviously high (between 87 % and 90 % of weight). Milk provides proteins of high biologic quality, which account for about 3.2 % of weight. They are subdivided into caseins (80 %) and serum proteins (20 %). Caseins may form precipitates by acidification (at 4.6 pH) or by enzymatic action. Serum proteins only coagulate because of heat.

Lipids constitute approximately 3.5 % of weight of milk and triglycerides account for about 97 % of the total lipidic fraction.

The sugar in milk, lactose, made up of glucose and galactose, is digested in the small intestine. Other than being a nutrient, it facilitates the assimilation of mineral salts like calcium and contributes to the growth of intestinal flora.

Milk also provides B group vitamins, carotenoids, vitamin D etc. Among mineral salts very important is calcium, of which milk is one of the main alimentary sources.

By reducing the content in fats partially skimmed milk is obtained, the lipid yield of which is equal to 1.5 % - 1.8 % of weight, and skimmed milk, in which fats are no more than 0.3 %. They therefore provide a reduced energy yield.

From milk, through various processes, sterilized milk, UHT milk, powdered milk etc. are obtained.

The energy content of pasteurized full-cream cow's milk is 64 kcal per 100 g. Goat milk (76 kcal per 100 g) and sheep milk (103 kcal) are richer in energy.

Milk by-products

Various other products are derived from milk, like yoghurt, cheese and butter, the latter though considered as belonging to the group of alimentary fats.

Yoghurt has the same nutritional composition as the milk of origin.

Milk cream or whipped cream, obtained through separation of fats, presents a high lipid content, from 10 % to 50 % of weight. Proteins present are caseins. The content in carbohydrates is similar to milk. Cream is a fairly good source of vitamins of group B (B1 and B2), of vitamins A and D and of mineral salts like calcium and phosphorus. The energy content is more than 300 kcal per 100 g.

There exist very many types of cheese, approximately one thousand, even though they may be grouped in about 20 fundamental types.

Cheese may be classified in several ways. On the basis of the milk of origin we have cow's milk, goat's milk and sheep's milk cheese. Considering the consistency of the paste we have: creamy cheese, with a water content over 40 % of weight; soft cheese, with a water content also over 40 %; hard cheese, with a water content below 40 %, like "fontina" or parmesan.

On the basis of the production techniques cheese may be divided into: raw paste cheese like "provola" or "gorgonzola"; semicooked paste cheese like "fontina"; cooked paste cheese like parmisan; threaded paste cheese like "provolone" or "mozzarella".

On the basis of length of seasoning and ripening we have: fresh cheese like cream cheese; brief ripening cheese like "taleggio"; medium-long ripening cheese like "gorgonzola"; long ripening cheese like parmisan.

Less and less employed nowadays is the classification on the basis of content in fats, which considers low-fat cheese the ones with a percentage of lipids under 20 % of the dry product, semifat cheese those with fat content between 20 % and 42 %, and full-fat cheese the ones with a percentage of lipids over 42 %.

The water content of cheese varies considerably depending on the production process. Nutritional characteristics depend on the milk of origin, even though cheese usually presents a high protein content (almost only caseins, and therefore of low biological quality, as they lack certain amino acids vital for our organism) and a high content in fats. The carbohydrates content is irrelevant.

Furthermore cheese provides ample quantities of vitamins A and D and of mineral salts, in particular calcium and phosphorus.

The concentration of nutrients varies widely depending on the type of cheese. For example in dairy products like cow "mozzarella" proteins and fats account for about 19 % of weight, while in seasoned cheese like parmisan these nutrients represent respectively 33 % and 28 % and in cream cheese proteins constitute 7.6 % of weight, while fats represent 47 %.

The energy yield, therefore, also varies noticeably: from 253 kcal per 100 g in cow "mozzarella" to 387 in parmisan and 455 in cream cheese.

Organoleptic characteristics

Milk

Colour

Milk is usually opalescent white, though sometimes it may present yellowish reflections. Serum, obtained after separation of proteins, has a yellowy color.

Smell

The smell of milk is not strong. It depends on feeding of the animal, but may be also influenced by smells in the external environment, as for example the smell of fodder, of materials in the stable, of detergents etc.

Flavour

The flavour of milk is at the same time sweet and salty, owing to the presence of sugar (lactose) and salt (sodium chloride).

Yoghurt

Appearance

Its colour is milky white, homogeneous, and can also depend on the flavourings which may be added.

The external surface is smooth and glazed in the full coagulum.. The full coagulum is firm, the other one is creamy.

Smell

The smell of yoghurt is characteristic, and depends also on the flavourings which are possibly added.

Flavour

The flavour of yoghurt ranges from fairly acid to slightly acid. Flavourings which are possibly added also contribute to determine it.

Whipped cream

Appearance

Whipped cream has a compact consistency, white in colour.

Cheese

There exist about twenty kinds of cheese from which, through various production processes, the approximately 1,000 known types are obtained. Here following are listed the organoleptic characteristics of the main types.

Appearance, colour and flavour

Fresh cheese, like crescenza or robiola, have a soft consistency, white coloured paste and delicate flavour, which in some types may take a slight acidulous tinge.

Cheese with a medium-long ripening period, for example "gorgonzola", "caciotta", "taleggio" etc. have a soft, flaky paste, straw-coloured, more or less intense, and a flavour ranging from sweet to sharp. In some types ("gorgonzola") characteristic moulds are present, necessary to produce them, which confer colour green-blue stripes and render aroma and flavour very strong.

Cheese with a long ripening period, like parmisan and pecorino, presents a paste the consistency of which varies between finely grainy and compact, with a colour from straw yellow to white, with a marked flavour, sweeter in parmisan, sharp in pecorino.

Cheese with threaded paste, like "mozzarella" or "provolone", presents a paste with consistency from elastic to compact, colour from yellow to milky white and flavour from sharp to sweet.

Eggs

Nutritional characteristics

Eggs are produced by oviparous animals. An egg is practically a cell and contains everything necessary for the development of an embryo.

The term "egg" is employed only for hen eggs. However, the latter do not present significant differences compared with eggs of other species of birds, except for weight. The structure of an egg comprises the shell (weighing about 8 g), made up of calcium carbonate, the albumen or egg white (37 g), made up especially of proteins, and the yolk or yellow (16 g), made up of lipids and proteins and rich in vitamins and mineral salts.

Eggs provide an important quantity of nutrients. Proteins (12 % of weight) are the ones with the best nutritional quality and have been taken for a long time as a term of comparison for the qualities of other proteins, Lipids represent 9 % of weight of eggs. The cholesterol content is somewhat high. Carbohydrates are present as traces.

Eggs are also an important source of vitamins of group B, vitamin D, carotenoids, retinol etc. The energy content is 128 kcal per 100 g.

Eggs of other species (ducks, geese, turkeys) have similar nutritional characteristics, even though the higher yield in lipids causes an increase of the energy content (190 kcal per 100 g in duck eggs).

Various other products are obtained from eggs, like powdered eggs, which are widely employed in pastry-making, or mayonnaise, used as a dressing. The nutritional composition of these products is different and the energy content is much higher, for the same quantities, in comparison with eggs.

Organoleptic characteristics

Appearance

Eggs present an acute pole and an obtuse one, form which is typically termed ovoid. Volume and weight vary according to race, age and diet of the animal.

Eggs are divided in two parts, albumen and yolk, enclosed in a porous shell. The colour of the shell depends on the race of the animal and is not indicative of quality.

Under the shell there is a membrane made up of two thin layers. With time these two layers detach and form a space (air chamber) under the obtuse pole of the egg. Air allows the egg to float: therefore, an egg which floats is not fresh.

Albumen is colourless. Yolk presents an orange yellow colour, due to the presence of carotenoids and vitamin A. The colour of the yolk is influenced by diet: chickenfeed rich in fats, and therefore in vitamin A and carotenoids, gives a more intense colour.

Smell

Fresh eggs are odourless. The shell though, being porous, allows the filtering of the smell of the substances with which the egg has come in contact. The diet of animals can also determine the smell of eggs.

Flavour

Fresh eggs have an agreeable taste, even though it may deteriorate easily. Eggs of other species, as ducks and geese, have a more intense flavour than hen eggs.

Alimentary fats

Nutritional characteristics

Alimentary fats (oils, butter, lard etc.) may be both of vegetable and animal origin. Irrespective of origin, if they are liquid at ambient temperature (20° C) they are termed oils, if they are solid they are called fats. The melting point varies according to the composition in fatty acids. Lipids, from a chemical point of view, are hydrophobic, that is, not soluble in water. In products like oils (olive oil, seed oil etc.), made up only of lipids, water is practically absent, while it is present in butter, in margarine etc.

Vegetable fats

Vegetable fats comprise oils, derived from olives, from maize etc., margarine and other products like peanut butter, coconut butter etc.

The most important alimentary vegetable fat is olive oil, of which various categories may be identified. The finest ones are those of virgin olive oils, termed on the basis of the degree of acidity: extra virgin olive oil, with acidity not higher than 1 %; virgin, with acidity not higher than 2 %; common virgin, with acidity not higher than 3.3 %; lamp virgin, with acidity higher than 3.3 %. There are then other olive oils of inferior quality (olive pressings oil etc.).

Margarine is a solid emulsion of fats. In the past it was produced also with animal fats, but nowadays in its preparation only vegetable fats are employed, like soy oil, peanut oil, maize oil etc.

Vegetable alimentary fats are almost entirely made up of lipids, in the form of triacylglycerols, with a percentage of phospholipids. The composition in fatty acids shows a greater percentage of unsaturated fatty acids, the consumption of which, if not excessive, seems to be important for a good state of health. Among unsaturated fatty acids are linoleic acid and linolenic acid, termed essential, that is not synthesizable by the human body, of which oils represent the main alimentary source. Vegetable fats are furthermore a source of liposoluble vitamins (tocopherols) and of several other compounds.

The energy yield depends on composition. Made up almost entirely by fats, 100 g of olive oil provide about 900 kcal.

Other products comprise, besides water, percentages of proteins and carbohydrates, and present a lower energy content: for instance, margarine provides 760 kcal per 100 g.

Animal fats

Animal fats comprise butter (obtained from cow's milk), bacon fat, lard or bacon (made up of pig fat), cod-liver oil, employed in the past as a tonic, and other products of industrial use (whale oil etc.).

Animal alimentary fats too are made up almost entirely by lipids, in the form of triacylglycerols, phospholipids and cholesterol, exclusive of animal products. The composition in fatty acids has a considerable percentage of saturated fats, an excessive consumption of which brings to becoming overweight, to circulation disorders etc. These products also provide liposoluble vitamins (carotenoids, vitamin D etc.) and other substances.

The energy yield of these products depends on composition. Lard, made up almost entirely of fats, provides 891 kcal per 100 g.

Products like butter, which also contain water, proteins and carbohydrates, provide less energy: 758 kcal per 100 g.

Organoleptic characteristics

Vegetable fats

Appearance

Olive oil usually has a veiled appearance. A turbid oil must instead be considered flawed.

Seed oils (peanut, rapeseed, sunflower seed, maize, soy, palm oil) generally have a limpid appearance.

Margarine has a hard, medium or soft consistency depending on its composition in fats. Peanut butter appears as a grainy paste, while coconut butter is solid.

Colour

The colour of olive oil is influenced by the zone of origin and from the production techniques, and varies from straw yellow to gold yellow to greenish. Colours ranging from yellow to grey, to reddish or brown indicate a scarce consistency. A bright green colour may depend on the employment of unripe olives or from the zone of origin and does not necessarily indicate low quality.

Seed oils are instead generally yellow in colour, in various shades, from very light to golden yellow. Palm oil, instead, has a colour ranging from orange to brownish red.

In margarine colour depends on the oils employed in its production. Coconut butter is yellowish white.

Smell and flavour

Olive oil has a fragrant, agreeable, fruity aroma. Flavour is characteristic, pleasant. Aroma and flavour of oil, too, are influenced by the zone of origin.

The aroma of margarine varies according to the oils employed in its preparation. Coconut butter has a distinctive aroma and a fresh taste.

Animal fats

Appearance

Butter appears compact, glossy and homogeneous. The distribution of water must be uniform and when cutting butter no drops must show up.

Consistency

Butter in blocks must not lose its shape under its own weight.

Colour, smell and flavour

Butter is yellowish white, colour which may vary depending on the period when it is produced (a lighter colour in winter, a darker one in summer) and on the feeding of animals. It may be corrected with adequate colourings. Smell and flavour are light and delicate.

Bacon fat has a colour varying from white to yellowish, depending on feeding and age of animals. Lard is white-coloured. A yellowish colour indicates that it has turned rancid or any way that it is a poor quality product.

Sweetmeat

Nutritional characteristics

Sweets comprise several alimentary products, different in origin and composition. They are not essential from the nutritional point of view, they are extremely agreeable thanks to their sweet

flavour. Sugar and honey are commonly employed as sweeteners. Confectionery products, sweets, ice cream, chocolate are widespread sweet products.

Sugar and honey

Common sugar, made up of saccharose, is obtained from canes and from beet. It provides about 390 kcal per 100 g.

Honey, employed since ancient times as sweetener, is produced by bees. Besides various sugars, it also contains other substances, different according to the zone of origin, Many components of honey perform functions which are positive for our organism (antibiotic, demineralizing, detoxicant etc.). Energy content is equal to approximately 300 kcal per 100 g.

Confectionery products, sweets and ice-cream

This group of alimentary products comprises the ones obtained by adding to flour other ingredients like eggs, milk, flavourings etc. (biscuits, dry, fried and fresh confectionery products, leavened sweets, snacks etc.), candies (bonbons, chewing gums), ice-cream (ready-made or handmade), chocolate etc.

The nutritional characteristics of these foodstuffs are heterogeneous, given the very ample range of ingredients and production processes.

The water content is widely variable (0.5 % of weight in bitter chocolate, 2.2 % in dry biscuits, 33.7 % in cream horns, 63.5 % in vanilla ice-cream). They are characterized by a high caloric content, generally provide a low yield in proteins and are rich in fats and sugars.

For example, dry biscuits have a 6.6 % of weight protein content, a 7.9 % lipid content and a 84.8 % carbohydrate content and provide 416 kcal per 100 g, cream horns contain 6.2 % of proteins, 20.7 % of lipids and 41.9 % of carbohydrates and provide 368 kcal per 100 g. Stuffed snacks have a 6.2 % of weight protein content, a 15.1 % lipid content and a 67.3 % carbohydrate content and provide 413 kcal per 100 g. Chewing gums are made up of 70 % of carbohydrates and provide 263 kcal per 100 g.

In ready-made ice-creams (ice lollies) carbohydrates represent 36.5 % of weight and, practically by themselves, account for the whole energy yield, equal to 137 kcal per 100 g.

In milk ice-cream proteins make up 4.2 % of weight, lipids 13.7 %, carbohydrates 20.7 % and the energy yield is 218 kcal per 100 g.

One of the most widespread confectionery products is chocolate, of which there exist many types.

It contains several substances which have healthy effects for our organism. Bitter chocolate has a protein content equal to 6.6 % of weight, a lipid content equal to 33.6 % of weight and a carbohydrate content accounting for 49.7 % of weight. It provides 515 kcal per 100 g. The nutritional composition of the various types of chocolate is influenced by the ingredients employed, firstly milk.

Organoleptic characteristics

Sugar and honey

From a commercial point of view we should consider two types of sugar: unrefined sugar, deriving from canes and beet, and refined sugar. The refining process affects the organoleptic parameters of the product.

Organoleptic characteristics of honey are mainly determined by the flowers from which bees have drawn nectar.

Appearance

Unrefined cane sugar has a colour var ying from yellow to brown with big cr ystals. Unrefin ed beet sugar also has a colour ranging from yellow to brown with hard, quite big crystals.

Refined sugar is white with lig ht bl ue shades an d is sold i n cakes weig hing 8-12 k g or granulated, i.e. co mmon sugar, or again in lum ps, i n grains, cry stalline, liquid (62 % solution of cane sugar) etc.

Raw honey has a tendency to cr ystallize, form ing grains, and t o take on opaque shades. This process can take quite a long tim e, as for exam ple in acacia or chestnut hone y. Pasteurized honeys are instead fl uid. Separation between the cry stallized part and the liquid one, the presence of froth on the surface or of small gas bubbles in the mass, of foreign bodies etc. indicate poor quality.

The colour of honey is det ermined by the flowers fr om which nectar derives. So acacia giv es a very light coloured or golden yellow honey, a darker honey is obtained from chestnut trees etc.

Smell and flavour

Unrefined cane sugar has an agreeable flavour and smell.

Unrefined beet sugar, instead, does not have a nice taste and must be refined in order to be marketed.

The smell and flavour of honey are determined by the flowers of origin of nectar. Some types of honey, like the ones derived from acacia, from orange trees etc., have a fairly strong sm ell, others, like the one obtained from lucerne, a milder aroma. A pungent, fermented s mell or a sm ell similar to smoke, or again a sour taste indicate poor quality.

Confectionery products, sweets and ice-cream

Confectionery products have a smell and a tast e distinctive of the various t ypes and which depend on the ingredients employed.

Sweets and cakes are of course characterized by their sweet flavour, an d their appearance and colours are extremely varied, according to type.

The organoleptic characteristics of dry confectione ry products and biscuits are similar to those of other products derived from cereals. They generally present a cru mbly, brownish y ellow crust, with different shades of colour depending o n th e type. Ingredien ts, like sugar , cream , whipped cream, jam etc, also contribute to taste and smell, sweet and fragrant.

These products are strongly affected by light, m oisture and tem perature conditions of the pla ce in which they are kept. To maintain their fragrance and consistency dry products must b e hermetically sealed and kept in fresh, dr y places, away from lig ht. Fresh confectionery pr oducts, which are highl y perishab le, must be kept under controlled tem perature. Read y-made ice-crea m must be kept in the freezer.

In the structure of hand-made ice-cream a small percentage remains liquid up to the temperature of –20° C. Also present are small ice crystals, milk fat glo bules and air bubbles. A grainy consistency, due to sugar (lactose) crystals, denotes low quality.

Cocoa, from which chocol ate is obtained, has a yellow-red colour, depending on the degree of ripening. The pulp has a bitter taste.

Aroma, flavour and co lour t ypical of chocolate are due t o the correct preservation of th e product. Fats in fact tend to turn rancid because of h umidity and heat, for ming whitish spots and giving off a bad smell.

Alcoholic drinks

Nutritional characteristics

Alcoholic drinks comprise products like beer and wine, obtained through alcoholic fermentation, spirits, obtained through fermentation and distilling, or liquors, obtained by mixing alcohol, sugars and flavourings.

Alcohol has various effects, not all of them positive, on our organism. In moderate quantities it appears to have a protective effect against cardiovascular ailments, while an excessive consumption causes an increase of the fat accumulation in the organism and concurs to the arising of various diseases. At the level of the central nervous system alcohol may cause excitement, but in large doses it leads to drunkenness, loss of control when driving etc.

Through fermentation of wine vinegar is obtained, employed as a dressing.

Beer

Beer is a drink with a low alcohol content, obtained through alcoholic brewing of musts prepared with barley malt, water and hop. There are many kinds of beer. The alcohol content varies from 1 % in volume in some non-alcoholic beers to 4 % in "double malt" beers. Certain beers have a 12 % alcohol content.

From a nutritional point of view, besides alcohol in beer there are sugars, proteins, vitamins of group B and mineral salts. Carbon dioxide gives beer thirst-quenching properties, while hop stimulates digestive functions.

The energy content of beer is on average 30 kcal per 100 ml.

Wine

Probably originating in the ancient Mesopotamia, wine has been a well-known alimentary product for millenniums, produced nowadays in hundreds of different kinds all over the world. It is obtained through the total or partial alcoholic fermentation of fresh grapes, pressed grapes or of must derived from fresh grapes, fruit of vines.. There are many different wine-making methods, depending on the type of wine one intends to obtain. Many additives are also employed in producing wine.

Wine is a solution of various substances, like water, alcohols, proteins, vitamins, mineral salts, esthers, polyphenols, pigments, acids, carbon dioxide, the composition of which may vary according to the vine employed or the wine-making technique.

A characteristic of wine is the alcohol proof, which must not be less than 3/5 of overall proof. There exist various types of proof: alcohol proof (percentage of ethyl alcohol in wine, not less than 6°), potential alcohol proof, total alcohol proof (sum of the preceding ones, not less than 10°), overall proof (overall alcohol proof, not less than 8°).

The energy yield depends on the alcohol percentage, it is equal to about 70 kcal per 100 ml.

Vinegar

Vinegar is obtained through acetic fermentation of wines caused by certain micro-organisms, which oxidize ethyl alcohol turning it into acetic acid, giving the product its distinctive aroma and taste. There are many kinds of vinegar, according to the wines employed in preparation. The alcohol content of vinegar must be equal to or less than 1.5 % and acidity, expressed in acetic acid, must be equal to or more than 6 %.

The caloric yield of vinegar is negligible.

Sweet wines and flavoured wines

Sweet wines are produced from particular vines. They have an alcohol proof varying between 16 % and 22 %. One of the main sweet wines is "Marsala", of which there are several kinds. The energy content of this wine is 150 kcal per 100 ml.

Flavoured wines have an alcohol proof not higher than 21 %. They are produced from wine to which sugar, alcohol and other substances are added. Flavoured wines are Vermouth, for the preparation of which sagebrush is employed, giving it a distinctive taste, egg Marsala, obtained from Marsala by adding to it at least 60 grams of egg yolk per litre, etc.

The energy yield of these wines depends on the percentage of alcohol and on the other ingredients employed, and is equal to 139 kcal per 100 ml in sweet Vermouth, 203 in Marsala etc.

Sparkling wine

Sparkling wine is prepared through alcoholic fermentation of grapes, must or wine. There are many kinds of sparkling wine, depending on the wine and the production technique employed.

Spirits

These drinks have a minimum alcohol proof of 21 %. They comprise distillates or aqua vitae and liquors.

Distillates are obtained from wine (Cognac, Brandy etc.), from apple cyder (Calvados), from marcs (Grappa), from barley malt (Scotch Whisky), from barley, oat, corn, rye (Irish Whisky), from maize, barley, rye (Bourbon), from corn (Vodka), from cane sugar (Rum), from agave (Tequila), from rice (Saké) etc.

Liquors are produced from mixtures of spirits with water, flavourings, sugar. They comprise fruit liquors like Cherry, "Strega", Maraschino etc.

The nutritional content of distillates depends on their alcohol proof. Cognac and Brandy have an alcohol proof between 30° and 42°, Irish Whisky and Bourbon 43°, Rum and Vodka 40°, Tequila 46°, Saké 15 °. Among liquors, Cherry brandy has an alcohol proof equal to 30°, "Strega" 45°, Maraschino 32°.

The energy yield of spirits is higher than 200 kcal per 100 ml: 230 in Brandy, 245 in Whisky.

Organoleptic characteristics

Beer

Appearance

Beer generally has a clear and bright appearance, or a slightly opaline one. In some fermented beers yeast deposits are visible. Colour of beer varies from light yellow to dark brown.

Smell and flavour

Beer has a pleasant smell, with a hop and malt aroma. In this case too strength and shades of aroma vary depending on type. The flavour of beer goes from bitterish to sweetish to acidulous, according to type.

Wine

The analysis of the organoleptic characteristics of wine is fundamental for evaluation of the quality of same, and is carried out through visual, olfactory and taste examinations.

Visual examination

Characteristics analysed in this examination are consistency or fluidity, clearness, colour and fizziness, all of them distinctive of the various types of wine.

Olfactory examination

The aroma of wine depends on the grapes of origin, on fermentation, during which leavens produce substances (superior alcohols and esthers) which give fruity, marasca and flowery aromas, and on maturation and seasoning, during which the final aroma of wine is formed.

Taste examination

Wine has a sweet taste. The presence of sugars (glucose, fructose), ethanol and glycerol determines the various nuances of flavour. A bitter taste is due to substances like tannins. Saline and acid compounds confer salty nuances. An acid taste is determined by the acids present in wine, in particular: tartaric, malic, citric, lactic, acetic acid.

Vinegar

Vinegar has distinctive aroma and taste, determined by its composition.

Sweet and flavoured wines

Marsala is one of the best known sweet wines. Colour, which is employed to classify the various types, has golden, amber or ruby shades.

Smell and taste are given by the ingredients which are added, liked cooked must, ethyl alcohol etc. and, in egg Marsala, also yolks.

In Vermouth, aroma and taste are given by the ingredients employed in its preparation, like sagebrush, always present, and other herbs (thyme, sage, cinnamon etc.).

Sparkling wine

The organoleptic characteristics of sparkling wine, too, widely differ depending on type. General characteristics of sparkling wine are: appearance of the foam, which must be white, profuse and evanescent; bubbles, which must have a fine, continuous and lasting grain; colour, which varies between pale gold to bright gold; smell, intense, with a leaven aroma; taste, which must be dry, strong, keen and elegant, with a persistent aftertaste of almonds or hazelnuts.

Spirits

The organoleptic characteristics of spirits depend on the products of origin and on the production process. Distillates like Cognac and Brandy have an amber colour, Scotch Whisky and Irish Whisky a golden amber colour, Bourbon has golden brown shades, Grappa is colourless, with straw-coloured shades, Rum is straw white, Tequila, Vodka and Saké are colourless.

Among liquors, Cherry Brandy has an amaranth red colour, Curaçao a dark orange colour, Maraschino is colourless, Mint is green, “Strega” is golden yellow.

Soft and nervine drinks

Nutritional characteristics

Soft drinks, fizzy or not, are prepared with water and other ingredients (infusions, saccharose, citric acid, flavourings etc.). They comprise colas (Coke, Pepsi), soda waters etc.

Nervine drinks comprise extensively used products like coffee, tea, chocolate, which is classified under sweets, camomile tea, tisanes. These products contain alkaloid substances which exert exciting or relaxing effects on our nervous system.

Soft drinks

They are products rich in calories, almost all though provided by simple sugars. A drink like cola has a 10.5 % sugar content and yields 39 kcal per 100 g.

Nervine drinks

Roasted coffee contains 10.4 % of proteins, 15.4 % of fats and 28.5 % of sugars and provides about 287 kcal per 100 g. Tea leaves contain 19.6 % of proteins, 2 % of fats and 3 % of sugars, and the energy yield is equal to about 108 kcal per 100 g.

Organoleptic characteristics

Soft drinks

The high sugar content gives these drinks an excessively sweet flavour, which is mitigated by adding acids, like citric acid. Colour is determined by added substances, like caramel (bitter-orange drinks, colas) or a chemical yellow colouring (citron drinks) etc.

Nervine drinks

Each of these drinks has a distinctive appearance and aroma. In coffee, a rancid taste, due to the oxidization of fats, indicates incorrect keeping, in damp places.

Tea is classified into two main categories, black tea and green tea. Black teas have pieces with uniform dimensions, while green teas are subdivided on the basis of the age of leaves. About 20 different types of tea are marketed, obtained by mixing the various varieties and adding other seasonings. Tea, too, must be kept away from dampness.

Sweeteners, salt, water

Sweeteners

Besides sugar and honey, other products, both natural and artificial, are employed to enhance the sweet flavour of foodstuffs. Natural sweeteners are simple sugars like glucose, fructose and alcohols like sorbitol, mannitol, xylitol. They have a rather low calory content. Artificial sweeteners, like saccharin and aspartame, do not provide any energy.

Salt

Salt is the common name for sodium chloride, employed both to savour and to preserve foodstuffs. Salts with addition of other minerals, like potassium or iodine, or of aromatic herbs are also available on the market. Salt does not provide energy but is a source of minerals. However, in a balanced diet it must be employed in moderate quantities as the yield in mineral salts is sufficiently guaranteed by the various foodstuffs.

Water

Water is a fundamental element for life. The human body is made up of 60 % of water and the daily need of it of an individual is on average 2.5 litres. Drinking water must meet certain microbiological, chemical, physical and organoleptic requirements.

Bacteria indicating contamination must be within the limits set by law. The temperature at the spring must be between 9° C and 12° C. Water must not be too hard (percentage of salts) and must be clear, odourless, tasteless.

Many kinds of mineral water are marketed. They may be classified on the basis of their mineral salts content (with a low, medium or high mineral content) or of their therapeutical properties (diuretic, digestive, purgative etc.).

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ALIMENTARY PRODUCTS QUALITY POLICY

Organic product

Organic agriculture is a method of farming and breeding which is based on respect for the environment, avoiding both the excessive exploiting of air, water and soil and the employment of synthetic substances (manure, weedkillers, insecticide, hormones, antibiotics).

It is a production method defined at EC level by EEC Ruling 2092/91 and in Italy by Ministerial Decree 220/1995.

The best definition of organic agriculture appears to be the one set down by the *Codex alimentarius* on the basis of contributions by experts of worldwide renown. The *Codex* considers organic agriculture a global system of agriculture production (vegetable and animal) which favours husbandry practices rather than resorting to production factors of external origin. In view of this, growing, biological and mechanical methods are preferably employed instead of chemically synthesized products.

In accordance with the guiding lines of the *Codex*, organic agriculture must contribute to the achievement of the following goals:

1. enhancing the biological variety of the system as a whole;
2. maintaining the fertility of soil in the long run;
3. recycling waste of animal or vegetable origin, so as to restore nourishing elements to the soil, reducing as far as possible the use of non-renewable resources;
4. exploiting renewable resources in locally organized agricultural systems;
5. promoting a correct fruition of soil, of water resources and of the atmosphere and reducing as far as possible any form of pollution which may derive from agricultural and zootechnical practices;
6. manipulating agricultural products, taking great care over transformation methods, with a view to maintaining the biological integrity and the essential properties of products along all the various phases;
7. being practised in an existing farm, after a period of conversion the length of which must be calculated on the basis of factors specific to the site, such as past information on the area and types of growing and breeding which are envisaged.

As for breeding, the organic production method is based upon the principle of a close connection between animals and agricultural areas. The need for this connection involves therefore that animals may graze on ample open areas and that fodder given to them not only must be organic but must be preferably produced in the same farm. This aspect of organic agriculture is, by the way, regulated in detail by a number of regulations concerning well-being of animals and veterinary treatments.

Whether it be animal or vegetable products, the aims of organic production are the same: applying restrictive practices from an environmental viewpoint, occupying country spaces in a more harmonious way, respecting the well-being of animals, producing high-grade agricultural products.

Organic products are conquering wider and wider shares of the market, in consideration of consumers' demand for superior quality products. In fact, a revision of the existing studies on the characteristics of organic products and products obtained through conventional methods (Bourne and Prescott, 2002) indicates that there is no substantial difference as to both nutritional values and organoleptic characteristics and furthermore it appears that organic products are not more prone to microbiological contamination than conventional ones. However, there is no established data on the

concentration of residues of pesticides in organic products, although it would appear reasonable that the latter present lower levels of chemical contaminators.

With a view to harmonizing rules and production manners, some organizations have arisen which group the "organic" farms. IFOAM (International Federation of Organic Agriculture Movements) founded in 1972 is presently the most representative federation as it groups various organizations which operate worldwide in matters like production, certification, research, training and promotion of organic agriculture.

Another organization which is representative in this connection is the Committee of the *Codex alimentarius* which operates in the joint program FAO/OMS, which in June 1999 has adopted the guiding lines in matters like production, storing, labelling and sale of foodstuffs derived from organic production. Furthermore, since 1999 FAO has adopted a work program in the sector of organic production with a view to promoting this type of production in developing countries.

In order to give the aims of organic production, which are difficult to measure, a solid content, so as to clearly distinguish organic agriculture from the traditional one, it was necessary to codify practises which were to be considered acceptable. This has been made possible at first through private rules and then through official regulations and guiding lines, both at a national and international level.

By the adoption of (EEC) Regulation no. 2092/91 the Council has defined an unitary scheme throughout the European Community with a view to defining conditions to be kept so that an agricultural product or a foodstuff may bear an indication of its organic production method.

It regulates transformation, inspection, labelling and commerce of organic products circulating within the Community, as well as import from third Countries, in order to protect consumers from the many frauds existing in commerce, also because of the considerable confusion present in connection with this matter up to this moment.

In March 2000 a Community logogram, too, has been defined, with a view to allowing a greater improvement of organic products (both animal and vegetable) and strengthening protection from frauds.

Labelling of foodstuffs

EEC Regulation no. 2092/91 confirms the general rules provided for by community law on traditional agriculture in matters like production, preparation, labelling, marketing and controls of agricultural products and of foodstuffs, aimed at safeguarding consumer health. Its scope refers to non-transformed animal and vegetable products, transformed products intended for human consumption and animal fodder.

It fixes precise ways to intervene both as to the organic production method which is applicable to vegetable products (encl. I, part A of the regulation) and the conversion from traditional to organic agriculture. The same regulation establishes the minimum rules regarding animal organic production (encl. I, part B) and apiculture (encl. I, part C). Transformation of organic agricultural products in foodstuffs, too, is regulated. (encl. A of EEC Regulation 2092/91 – technical enclosures of the regulation).

Labelling is a guarantee for consumers that they are dealing with a product deriving from organic agriculture. The label must bear the following indications:

1. name of the authorized control organism along with its code, with the initials IT before it;
2. code of the firm being controlled;
3. authorization number (both for agricultural products and for transformed ones);
4. wording "control organism authorized by Ministerial Order of the Agricultural, Environment and Forest Resources Ministry no. ….. dated …… enforcing EEC Regulation no. 2092/91".

The following are instead optional:

1. wording “Organic agriculture – EC control system”;
2. European mark.

There are three types of organic agriculture:

1. products with at least 95 % of ingredients deriving from organic agriculture;
2. products with at least 70 % of ingredients de riving from organi c agriculture. In this case reference to organic agriculture is allowed onl y in the list of ingr edients and not in the sale mark;
3. products in conversion (t he wo rding “product in conversion t o organic ag riculture” is compulsory).

The European logogram which the reg ulation refers to is facultative and is int ended to i dentify products with at least 95 % of co mponents deriv ing from organic agriculture. It is therefo re still advisable to check that the label bears th e reference to one of the ni ne control organisms which are presently operating in Ital y, fact which does not necessarily exclude the presence of the logogram (encl. C of EEC Ruling 2092/91 – various versions of the community logogram).

All the prod ucts which meet the requirem ents provided for by comm unity rules may freely circulate wit hin the European Co mmunity whether they are produced in the Union or they are imported fro m third Countries. Therefore member States may n ot in an y way lim it their commercialization.

Through the regulation, the Euro pean Community sets up an uniform Control S ystem throughout t he territory of the Euro pean Uni on, co mprising a public authorit y an d private accredited organisms. The public authority has the duty to supervise such organisms with a view to ascertaining their qualifica tion to perform contro l an d guarantee f unctions. The control measures must be guaranteed at various levels:

1. farms;
2. preparation units of foodstuffs containing organic products;
3. importers of products obtained through organic production methods;
4. transport.

The same principles are applied to products being i mported by t hird Cou ntries, in respect of which the Committee carries out a t horough evaluation of the rules applied and of the effectiv eness of the control measures which are b eing taken. The Co mmittee, once equivalence ha s bee n ascertained, enters the third Country in a list of Countries, and consequently the organic agriculture products coming from such Countries may be im ported and m ay freely circul ate in the Eu ropean Union (encl. B of the EEC Regulation 2 092/91 – lis t of the third Countries the o rganic agriculture products of which are imported in the European Union).

What operators must know:

1. They m ust c heck that the label bears the wording “ organic agriculture” acco mpanied by one of the marks rele ased by the control Or ganisms authorized by the Agriculture and Forest Policies Ministry . The label must also s how the name and add ress of th e manufacturer and of the preparers of transformed products.
2. On a facultative basis, the producer may also insert the EU logogram on organic products.
3. If the percentage of organic co mponents is be tween 95 and 70 % such percentage must be indicated besides the ingredient.
4. The label may also bear the wording “ product i n co nversion to o rganic agriculture” for those far ms which have been em ploying or ganic production methods for at least 12 months.

The organisms of certification of organic agricultural products presently operating in Italy are the following:

- ICEA (Ethical and Environmental Certification Institute, ex AIAB);
- BIOAGRICERT – Bioagricoop;
- BIOS;
- CCPB (Organic Products Control Consortium);
- CODEX;
- ECOCERT Italia;
- IMC (Mediterranean Certification Institute);
- QC&I International services;
- SUOLO E SALUTE (Soil and Health);
- BIOZERT.

Brand products

Organic agriculture falls within the ambit of the quality policy regarding agricultural products, which through specific rules embraces products protected by DOP (Protected Origin Denomination) and IGP (Protected Geographical Indication) marks, disciplined by (EC) Reg. 510/06, which repeals Reg. 2081/92, and STG (Guaranteed Traditional Speciality) mark disciplined by (EC) Reg. 509/06, which repeals Reg. 2082/92.

Application of these Regulations is in turn disciplined by subsequent acts: (EC) Reg. 1898/2006, as modified by (EC) Reg. 628/2008 as for (EC) Reg. 510/2006, while as for Reg. 509/2006 the application rule is Reg. 1216/2007.

Setting up these forms of protection allows producing firms to develop an economically profitable system based on enhancement of the product, which may so be distinguished from similar products available on the market. The Control Organisms, unrelated to the companies and authorized by the Ministry of Agricultural, Alimentary and Forest Policies, are then appointed to verify the correspondence between the characteristics of the product and the production specifications or conformity to the Regulation. The consumer is so enabled to purchase products which are effectively original and protected.

The DOP mark indicates a product which is closely linked to the production zone; in particular the ruling law imposes that characteristics and properties of the product are due essentially or exclusively to the geographical site, and ensures that all raw materials and transformation processes are carried out in the geographical place of origin.

IGPs have been set up to indicate products which have a close tie with the territory where they are produced. However, such a tie may be less strict : in fact in this case an origin from the zone from which the product gets its denomination is required, but unlike the DOP mark, it is sufficient that only one of the production phases is carried out in the zone of origin.

STG is a denomination which does not refer to origin, but defines a product whose raw materials, composition or recipe, production or transformation method are of a traditional type: it deals with the enhancement of a traditional composition or production method.

An STG product may be manufactured in any Country of the European Union, as long as this is done abiding by the relevant production specifications according to (EC) Regulation 509/2006.

Products bearing a double certification, i.e. those conforming to EC Regulation 2092/91 for organic and to production specifications drawn up for typical products, make up the qualitative excellence.

Products affected by marks

Products affected by (EC) Regulations nos. 509 and 510/2006:

- fresh meat;
- meat preparations;
- cheese;
- other products of animal origin (eggs, honey, milk and cheese products of various types excluding butter etc.);
- fats (butter, margarine, oils etc.);
- fruit, vegetables and cereals, whether raw or transformed;
- fresh fish, molluscs, crustaceans;
- beer;
- drinks made of plant extracts;
- baking, confectionery, biscuits products;
- other agricultural products

Products affected only by (EC) Regulation no. 509/2006:

- chocolate and other alimentary preparations containing cocoa;
- pasta, also if cooked or stuffed;
- composite dishes;
- ready-made dressing sauces;
- soups or broths;
- ice-creams and sherbets.

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Regulation references

Geographical indications (IGP) and origin denominations of agricultural and alimentary products (DOP)

- (EC) Regulation 510/2006
- (EC) Regulation 1898/2006
- (EC) Regulation 628/2008

Specificity certifications of agricultural and alimentary products (STG)

- (EC) Regulation 509/2006
- (EC) Regulation 1216/2007

PRESERVATION AND TRANSPORT OF FOODSTUFFS

Preservation techniques

When speaking about products undergoing controlled temperature we usually identify goods which, in order to maintain unspoilt their organoleptic, nutritional and wholesomeness characteristics for a predetermined stretch of time, need to be kept at a certain temperature by employing refrigeration systems.

The preservation techniques of foodstuffs through the cold chain may be listed as follows:

- Refrigeration (0/+2 °C; humidity 85%)
  The meat of slaughtered animals (cattle, sheep and swine) keep for about 30 days in optimal conditions, while poultry keeps for 6-7 days if without bowels; furthermore, this technique is employed in the carriage of fruit and vegetables (slightly higher temperatures, 2-4° C).
- Freezing
  It consists in subjecting the foodstuff to low or very low temperatures (-12° C or less) with ensuant crystallization of water (which accounts for about 70- 80 % of each alimentary product, animal and/or vegetable) and solidification of the product. The freezing process lasts many hours.
- Deep-freezing
  It is the same technique set out above, with the difference that refrigeration and consequent solidification of the product must take place in a very short time (within 4 hours) with a temperature not exceeding –18° C.

Preservation and possible carriage of products which, owing to their organoleptic characteristics, need to be preserved under controlled temperature present various problems which must always be kept in mind by those who work in the insurance field, beginning from the phase of risk underwriting up to the phase of evaluating the occurrences giving rise to damage.

The aim of this paper is to indicate certain essential features which must be thoroughly observed and analysed.

Preserved products typologies

Each product must be kept at a specific temperature which does not vary whatever the means of transport employed and however long the voyage is.

Not only is it fundamental that the optimal preservation temperature is kept during each phase of transport but it is also necessary that no thermo-hygrometric variations take place, variations which, though slight, may give rise to undesired and detrimental phenomena (e.g. frost, dehydration, sweat, formation of ice macrocrystals).

Refrigerated foodstuffs

These products must be kept slightly above their freezing point or their physiopathologic thermal threshold in the case of fresh vegetables.

It should be reminded in this connection that the values of the temperature of intake air of refrigerating plants always oscillate by defect and by excess up to $\pm$ 1° C in comparison with the

value set on the thermostat. Therefore the set point (value of temperature at which the thermostat is set) must be evaluated keeping in mind what the best preservation temperature is for the product, depending also on its freezing point.

For instance the freezing point of most foodstuffs is around –1° C/ -2° C and therefore the ideal temperature for carriage of same is 0° C.

In the particular case of fresh vegetable products the value of their physiopathologic thermal threshold must also be considered when assessing the set point. The physiopathologic thermal threshold is the temperature value under which fresh vegetables undergo the first alterations of their organoleptic characteristics and is slightly higher than the freezing point.

Frozen and deep-frozen foodstuffs

Through freezing and deep-freezing foodstuffs are preserved at very low temperatures, even –40° C.

The law defines "deep-frozen" foodstuffs which undergo a special freezing process, which allows to keep the temperature of the product at –18° C or less (art. 1 of Statute 110/1992). During transport, local distribution and sale, variations of the temperature upwards no higher than 3° C are permitted (art. 4 of Statute 110/1992).

For frozen foodstuffs there are no precise regulations: the internal temperature of products must be –12° C or less, and must not exceed –9° C during transport and sale.

When freezing foodstuffs the desired temperature is reached in quite long periods of time (e.g. freezing of half a pig takes up to ten hours). When deep-freezing, or fast freezing, the preservation temperature is instead attained in a maximum time of four hours.

The quickness of the process allows therefore to deep-freeze only small- sized foodstuffs, whether animal or vegetable (16 mm thick), while larger products are frozen.

When deep-freezing small ice crystals form in the foodstuff. This process permits to maintain the normal nutritional and organoleptic properties of products.

When freezing, larger crystals form, which damage the tissue of the foodstuff. Once thawed the latter loses, along with its intracellular liquid, mineral salts and vitamins, so resulting altered as to organoleptic characteristics and impoverished from a nutritional point of view.

Freezing and deep-freezing eliminate most micro-organisms, even though some species of bacteria, as well as spores and some viruses may resist low temperatures.

Almost all deep-frozen products may be kept for twelve months.

TT-PPP Factor

The factors concurring to deterioration and damage to refrigerated or frozen goods are:

- Temperature (storage temperature)
- Time (storage period)
- Product (nature and quality of the product at the time of refrigeration or freezing)
- Process (preparation processes including cooling)
- Packaging (method and means of packing and boxing/wrapping)

Now, it is evident that the above-mentioned elements all concur to determine the PSL (Practical Storage Life), that is to say the index which identifies and defines the period during which the organoleptic characteristics of a product remain unaltered or acceptable.

PSL is usually expressed in days or weeks for refrigerated products and in months for frozen products.

Each product included in the two categories presents its own diagram (of which we shall offer a few examples in the following paragraphs) which indicates times and temperatures recommended for a successful shipment.

Recommended temperatures during transport of alimentary products

Maintaining a correct temperature is one of the main guarantees of safety and quality of foodstuffs. This condition must be met also during transport.

The law therefore sets the temperature values which must be kept during transport of the various products, in particular of the fresh ones of animal origin, the characteristics of which make them more perishable, such as meat, fishing products, milk, eggs and their by-products, as well as deep-frozen products.

As for other products, instead, such as fruit and vegetables, semipreserved food, gastronomy ready-made dishes or cooked food, ruling laws do not require specific temperatures during transport.

Preserved products, finally, do not need to be kept at a controlled temperature, although it is anyway advisable to keep them away from heat.

Temperature control may also be employed jointly with techniques which modify the atmosphere of the place where goods are kept, by varying the concentration of oxygen and carbon dioxide (preservation in controlled atmosphere) or by introducing certain gases in the packing of food (preservation in modified atmosphere).

In the following paragraphs the temperatures set by law for transport of the various typologies of foodstuffs are listed. As for the products for which no specific transport temperatures are fixed, for fruit and vegetables recommended temperature values allowing to maintain their characteristics for a few weeks are indicated, while for other products the storage temperatures are shown.

Where available, the temperatures set by the most recent Community or national laws have been listed. For the other products the values fixed by previous regulations, even though repealed, have been indicated.

Temperatures during transport of fruit and vegetables

For fresh, unpacked fruit and vegetables the European Union rules do not require a specific temperature during transport. A storage temperature lower than +10° C is recommended. The optimum for most fresh vegetable products is 0° C. Temperatures below +5° C prevent the growth of pathogenic bacteria.

The United States Department for Agriculture (USDA), instead, indicates the temperatures, however not greatly differing from those recommended in Europe, and the conditions to maintain during transport of fruit and vegetables, as well as the length of the preservation period which on the contrary is not precisely fixed by European regulations. Furthermore, it is here also specified which species may or may not be preserved together to avoid phenomenons of ripening or damaging of the products.

The tables here following list the temperatures and the preservation conditions for fruit and vegetable products.

Product	Temperature (relative humidity)
Apricots	from -1 to 0°C
Oranges	+ 6°C
Asparagus	0°C
Bananas	+12°C
Artichokes	0°C
Carrots	from -1 to +1°C
Cucumbers, melons, courgettes, peppers	from +7 to +10°C (over 95%)
Cherries	from -1 to 0°C

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Product	Temperature (relative humidity)
Onions	from 0 to +3°C
Watermelons	from +7 to +10°C
French beans	0°C
Strawberries	0°C
Lettuce	0°C
Lemons	+12°C
Apples	from -1 to +4°C
Nuts and almonds	from -3 to 0°C (from 65% to 75%)
Potatoes	+7°C (from 90% to 95%)
Pears	from -2 to +1°C
Peaches	from -1 to +1°C
Peas	0°C
Tomatoes	0°C (85%)
Spinach	0°C
Grapes	from -1 to 0°C

To ensure a correct preservation, a relative humidity equal to about 90% should be maintained. These conditions allow to keep products for periods ranging from a few days to a few months.

In certain cases, with a view to slowing down the ripening processes and the growth of moulds, vegetable products are kept under controlled temperature, diminishing the percentage of oxygen and increasing the percentage of carbon dioxide in the atmosphere in which they are preserved.

Indicatively, the following tables list the temperatures and the preservation conditions relevant to the transport of fruit and vegetable products established by the United States Department for Agriculture. Obviously such rules are not mandatory in the European Union.

Product (variety)	Temperature (°C)	Temperature (°F)	Relative humidity (%)	Period of preservation
Garlic	0	32	from 60 to 70 (ventilation)	from 6 to 7 months
Apricots	from -0.5 to 0	from 31 to 32	from 90 to 95	from 1 to 2 weeks
Pineapple	from 7 to 10	from 45 to 50	from 85 to 90	from 2 to 3 weeks
Watermelon	from 10 to 16	from 50 to 60	90	from 2 to 3 weeks
Anise	from 0 to 2	from 32 to 36	from 90 to 95	from 2 to 3 weeks
Oranges (CA)	from 5 to 7	from 41 to 45	from 85 to 90	from 2 to 6 weeks
Oranges (AZ, March)	9	48	from 85 to 90	from 6 to 8 weeks
Oranges (AZ, June)	3	37	from 85 to 90	from 6 to 8 weeks
Oranges (FL e TX)	from 0 to 1	from 32 to 34	from 85 to 90	from 8 to 12 weeks
Oranges (Jaffa)	from 8 to 10	from 46 to 50	from 85 to 90	from 8 to 12 weeks
Asparagus	from 0 to 2	from 32 to 36	from 95 to 98	from 2 to 3 weeks
Avocado (Fuerte, Hass)	7	45	from 85 to 90	from 2 to 3 weeks
Avocado (Lula, Booth-1)	4	40	from 85 to 90	from 4 to 8 weeks
Avocado (Fuchs, Pollock, Waldin)	13	55	from 85 to 90	2 weeks
Green Bananas	from 13 to 14	from 56 to 58	from 90 to 95	from 1 to 4 weeks
Broccoli	0	32	from 95 to 98	from 10 to 14 days (from 4 to 6 weeks in controlled atmosphere)
Persimmon (Japanese)	from 0 to 2	from 32 to 36	from 90 to 95	from 2 to 4 months
Artichokes	from -0.5 to 0	from 31 to 32	from 95 to 100	from 2 to 3 weeks
Artichokes (Jerusalem)	from -0.5 to 0	from 31 to 32	from 90 to 95	from 4 to 5 months
Carrots (ripe)	0	32	from 98 to 100	from 7 to 9 months
Carrots (unripe)	0	32	from 98 to 100	from 4 to 6 weeks
Brussels sprouts	0	32	from 95 to 98	from 3 to 5 weeks
Cauliflower	0	32	from 95 to 98	from 2 to 4 weeks
Cabbage (early)	0	32	from 98 to 100	from 3 to 6 weeks

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Product (variety)	Temperature (°C)	Temperature (°F)	Relative humidity (%)	Period of preservation
Cabbage (late)	0	32	from 98 to 100	from 5 to 6 months (from 7 to 9 momths in controlled atmosphere)
Citron (Citrus medica)	13	55	from 85 to 90	from 6 to 8 weeks
Cucumber	from 10 to 13	from 50 to 55	from 90 to 95	from 10 to 14 days
Cherries (unripe)	0	32	from 90 to 95	from 3 to 7 days
Cherries (sweet)	from -1 to -0.5	from 30 to 31	from 90 to 95	from 2 to 3 weeks
Onions (green)	0	32	from 95 to 100	4 weeks
Onions (Bermuda)	0	32	from 65 to 70	from 1 to 2 months
Onions (Globe)	0	32	from 65 to 70	from 6 to 8 months
Onions (Spanish)	0	32	from 65 to 70	from 3 to 6 months
Clementines	4	40	from 90 to 95	from 2 to 4 weeks
Dates	0	32	75	6 months (soft) 12 months (semisoft)
Beans (dry)	from 4 to 10	from 40 to 50	from 40 to 50	from 6 to 10 months
Beans (green)	from 4 to 7	from 40 to 45	from 95 to 98	from 7 to 10 days
Figs (fresh)	0	32	from 85 to 90	7 days
Figs (dried)	from 0 to 10	from 32 to 50	from 50 to 70	1 year
Strawberries	from -0.5 to 0	from 31 to 32	from 90 to 95	from 5 to 10 days
Passion fruit	from 7 to 10	from 45 to 50	from 85 to 90	from 3 to 4 weeks
Mushrooms	from 0 to 1.1	from 32 to 34	from 90 to 95	from 3 to 5 days
Yam	16	61	from 60 to 80	from 3 to 6 months
Endive (Belgian)	from 2 to 3	from 36 to 38	from 95 to 100	from 2 to 4 weeks
Kiwis	from 0 to 0.6	from 32 to 33	from 90 to 95	from 3 to 4 months
Raspberries	from -0.5 to 0	from 31 to 32	from 90 to 95	from 2 to 3 days
Lettuce (Iceberg)	from 0 to 1	from 32 to 34	from 95 to 100	from 2 to 3 weeks
Lemons	from 7 to 10	from 45 to 50	from 85 to 95	from 2 to 3 months
Lychees	from 0 to 2	from 32 to 36	from 90 to 95	from 3 to 5 weeks
Maize (sweet)	0	32	from 95 to 98	from 4 to 8 days
Mandarines	from 3 to 4	from 38 to 40	from 85 to 90	from 3 to 4 weeks
Mango	13	55	from 85 to 90	from 2 to 3 weeks
Apples (quince)	from -0.5 to 0	from 31 to 32	90	from 2 to 3 months
Apples (cold-resistant varieties)	from -1 to 0	from 30 to 32	from 90 to 95	from 2 to 7 months
Apples (cold-susceptible varieties)	from 3 to 4	from 38 to 40	from 90 to 95	from 2 to 7 months
Aubergines	from 8 to 12	from 46 to 54	from 90 to 95	from 1 to 2 weeks
Melon (sour)	from 12 to 13	from 53 to 55	from 86 to 90	from 2 to 3 weeks
Melon (Casaba)	from 7 to 10	from 45 to 50	from 90 to 95	from 4 to 6 weeks
Melon (Crenshaw)	from 7 to 10	from 45 to 50	from 90 to 95	2 weeks
Melon (Honeydew)	from 7 to 10	from 45 to 50	from 90 to 95	from 2 to 3 weeks
Melon (Persian)	from 7 to 10	from 45 to 50	from 90 to 95	2 weeks
Bilberries (first harvest)	from -0.5 to 0	from 31 to 32	from 90 to 95	from 12 to 15 days
Bilberries	from 3.3 to 4	from 38 to 40	from 80 to 85	from 2 to 4 months
Blackberries	from -0.5 to 0	from 31 to 32	from 90 to 95	from 2 to 5 days
Coconut	from 0 to 1.5	from 32 to 35	from 80 to 85	from 1 to 2 months
Olives	7	45	from 85 to 90	from 2 to 4 weeks
Papaya (partially ripe)	from 10 to 13	from 50 to 55	from 85 to 90	from 1 to 3 weeks
Papaya (ripe)	from 4 to 10	from 40 to 50	from 85 to 90	from 2 to 3 days
Potatoes	from 10 to 18	from 50 to 65	95	from 10 to 14 days
Sweet Potatoes	from 13 to 16	from 55 to 60	from 85 to 90	from 3 to 10 months
Hot peppers (dried)	from 0 to 10	from 32 to 50	from 60 to 70	6 months
Pears (Anjou)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 6 to 7 months
Pears (Asian)	1	34	from 90 to 95	from 5 to 6 months
Pears (Bartlett)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 2 to 3 months
Pears (Bosc)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 3 to 4 months
Pears (Comice)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 4 to 5 months
Pears (Hardy)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 2 to 3 months

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Product (variety)	Temperature (°C)	Temperature (°F)	Relative humidity (%)	Period of preservation
Pears (Kieffer)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 2 to 3 months
Pears (Packham Triumph)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 5 to 6 months
Pears (Seckel)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 3 to 3.5 months
Pears (Winter Nelis)	from -1.5 to -0.6	from 29 to 31	from 90 to 95	from 7 to 8 months
Peaches	from -0.6 to 0	from 31 to 32	from 90 to 95	from 2 to 4 weeks
Peas	0	32	95	1 week
Tomatoes (ripe)	from 7 to 10	from 45 to 50	from 90 to 95	from 3 to 5 days
Grapefruit (CA e AZ)	from 14 to 15	from 58 to 60	from 85 to 90	from 6 to 8 weeks
Grapefruit (FL e TX)	from 10 to 15	from 50 to 60	from 85 to 90	from 6 to 10 weeks
Parsley	0	32	95	from 2 to 3 weeks
Plums (Angelino)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 3 to 5 weeks
Plums (Black Amber)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 3 to 5 weeks
Plums (Casselman)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 5 to 6 weeks
Plums (El Dorado)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 3 to 5 weeks
Plums (Friar)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 3 to 4 weeks
Plums (Kelsey)	from -0.6 to 0	from 31 to 32	from 90 to 95	2 weeks
Plums (Laroda)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 3 to 4 weeks
Plums (Late Santa Rosa)	from -0.6 to 0	from 31 to 32	from 90 to 95	3 weeks
Plums (Nubiana)	from -0.6 to 0	from 31 to 32	from 90 to 95	2 weeks
Plums (President)	from -0.6 to 0	from 31 to 32	from 90 to 95	3 weeks
Plums (Queen Ann)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 3 to 4 weeks
Plums (Red Beaut)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 1 to 2 weeks
Plums (Roysum)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 3 to 4 weeks
Plums (Santa Rosa)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 3 to 5 weeks
Plums (Simka)	from -0.6 to 0	from 31 to 32	from 90 to 95	3 weeks
Plums (Wickson)	from -0.6 to 0	from 31 to 32	from 90 to 95	4 weeks
Prunes (Italian)	from -0.6 to 0	from 31 to 32	from 90 to 95	from 2 to 3 weeks
Rhubarb	0	32	95	from 2 to 4 weeks
Red lettuce	from 0 to 1	from 32 to 34	95	from 2 to 3 weeks
Radish	from -1 to 0	from 30 to 32	from 98 to 100	from 10 to 12 months
Turnip	0	32	95	from 4 to 5 months
Radishes (winter)	0	32	95+	from 3 to 4 months
Radishes (spring)	0	32	95+	from 3 to 4 weeks
Celery	0	32	from 98 to 100	from 1 to 3 months
Celeriac	0	32	from 95 to 99	from 6 to 8 months
Spinach	0	32	from 95 to 100	from 1 to 2 weeks
Grapes (Vitis vinifera)	from -1 to -0.5	from 30 to 31	from 90 to 95	from 2 to 6 months
Grapes (Virginia vine)	from -0.5 to 0	from 31 to 32	from 85 to 90	from 3 to 8 weeks
Sultanas	from -0.5 to 0	from 31 to 32	from 90 to 95	from 1 to 4 weeks
Gooseberry	from -0.5 to 0	from 31 to 32	from 90 to 95	from 3 to 4 weeks
Pumpkin	from 10 to 13	from 50 to 55	from 60 to 70	from 2 to 3 months

Fruit and vegetable products susceptible to refrigeration

The following table lists some products which may be damaged by temperatures below those recommended for preservation.

Pineapple	Lemons	Papaia
Oranges (CA and AZ)	Mango	Tomatoes
Avocado	Aubergines	Hot Peppers
Bananas	Melon	Grapefruit
Cucumber	Sour melon	Potatoes
Beans	Bilberries	Sweet potatoes
Passion fruit	Olives	Pumpkin
Yam		

Fruit and vegetable products which are susceptible to freezing

The tables here following show some products which may be damaged by freezing temperatures.

Highly susceptible products	Apricots, asparagus, avocado, bananas, beans, berries (bilberries excluded), cucumbers, aubergines, lemons, lettuce, peaches, plums, potatoes, sweet potatoes, tomatoes
Quite susceptible products	Oranges, broccoli, carrots, cauliflower, cabbage (early), onions (dried), apples, bilberries, pears, peas, grapefruit, celery, parsley, radishes, spinach, grapes
Slightly susceptible products	Brussels sprouts, cabbage, dates, turnips

Fruit and vegetable products which release ethylene or are susceptible to it

Ethylene is a hormone of vegetable origin which stimulates the ripening processes. It is therefore appropriate not to keep the vegetable species that release ethylene together with those susceptible to this hormone, to avoid phenomenons of early ripening or deterioration. The following tables show some products grouped on the basis of release or sensitivity to ethylene.

Products which release ethylene	Apricots, bananas (ripe), persimmon, figs, passion fruit, kiwis (ripe), mango, apples, papaya, pears, peaches, tomatoes, plums
Products which are susceptible to ethylene	Watermelons, bananas (unripe), broccoli, carrots, cauliflower, Brussels sprouts, cabbage, cucumbers, green beans, yam, endive, kiwis (unripe), lettuce, aubergines, sweet potatoes, hot peppers, parsley, peas, spinaci

Grouping methods on the basis of characteristics of various species of fruit and vegetable products

Fruit and vegetable products differ according to characteristics such as tolerance to low temperatures, relative humidity they need etc. It is therefore necessary, to avoid damaging the products, that species having different characteristics are not stocked together.

The following tables show a few examples of grouping of various species of fruit and vegetables on the basis of their characteristics.

Products requiring preservation temperatures between 0 and 2°C and relative humidity between 90 and 95%. Many of these species produce ethylene	Apricots, oranges (FL e TX), cherries, figs (not to be kept together with apples), berries (except bilberries), mushrooms, lychees, apples, quinces, coconut, pears, peaches, plums (fresh and prunes), radish, turnip, radishes, grapes (without sulphurous anhydride, SO_2)

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Products requiring preservation temperatures between 0 and 2°C and relative humidity between 95 and 100%. Many of these species are susceptible to ethylene	Anise, asparagus, broccoli, artichokes, carrots, Brussels sprouts, cauliflower, cabbage, cherries, onions (green; not to be kept together with figs, mushrooms, maize and grapes), endive, berries (except bilberries), mushrooms, kiwis, lettuce, maize (sweet), peas, parsley, red lettuce, radish, turnip, radishes, celery, spinach, grapes (without sulphurous anhydride, SO_2)
Products requiring preservation temperatures between 0 and 2°C and relative humidity between 65 and 75%. Many of these species are damaged by humidity	Garlic, onions (dried)
Products requiring a preservation temperature of 4.5°C and relative humidity between 90 and 95%	Oranges (CA e AZ), clementines, lemons, lychees, mandarines, bilberries
Products requiring a preservation temperature of 10°C and relative humidity between 85 and 90%. Many of these species are susceptible to ethylene and to low temperatures	Cucumbers, beans, aubergines, potatoes (in stock) hot peppers, olives
Products requiring preservation temperatures between 13 and 15°C and relative humidity between 85 and 90% Many of these species produce ethylene and are susceptible to low temperatures	Pineapples, avocado, bananas, passion fruit, lemons, mango, melons, coconut, papaya, potatoes (new), tomatoes (ripe), grapefruit, pumpkin
Products requiring preservation temperatures between 18 and 21°C and relative humidity between 85 and 90%	Watermelon, yam, potatoes (sweet), pears (for ripening), tomatoes

Products for which no specific transport temperature is set

Like for fruit and vegetables, also for other food products (preserves, cooked food or wines etc,) regulations do not fix a specific transport tem perature. As an indication, preservation temperatures are listed below.

Product	**Temperature**
Cooked foodstuffs to be eaten hot (ready-made dishes, snacks, chickens etc.)	higher than + 65°C
Cooked foodstuffs to be eaten cold (roast meat, roast-beef etc.)	up to + 10°C
Packed greens and vegetables (IV Range products)	from + 4 to + 6°C
Ripe cheese with rind	up to + 15°C
Delicatessen products with jelly covering, non-sterilized milk-based soft drinks	up to + 4°C
Stable products and preserves (1), seasoned raw salami and ham	from +15 to + 18°C
Cooked salami and ham	up to + 10°C
Semipreserves (excluding fish-based ones) (2)	from 0 to + 5°C
Stomach, bladder and processed intestine (3)	up to + 3°C
Liquid eggs (4)	up to + 4°C

(1) Foodstuffs which have undergone a technological treatment apt to guarantee the absence of micro-organisms capable of developing during preservation: pasteurized, dried, sterilized, preservative-added etc. products

(2) Foodstuffs which have undergone a technological treatment which enhances their preservation qualities but which need an adequate conditioning: wines, salami and ham, sliced salami and ham in bags etc.

(3) Temperature needed to preserve in particular products which are neither salted nor dried. In any case, stomach, bladder and processed intestine which may not be preserved at ambient temperature must be stored in a refrigerated condition, employing specifically designed equipment, until they are shipped.

(4) This temperature not higher than +4°C must be maintained if processing is not carried out immediately after breaking and anyway for no longer than 48 hours; these requirements do not apply to products bound to be deprived of their sugars, as long as such process is carried out at the earliest.

Temperatures during transport of flour products and pasta

Product	Temperature
Fresh unpacked pasta (1)	up to +4 °C
Fresh pasta in pre-made packing (2)	up to +4 °C

(1) For fresh unpacked pasta a 3°C tolerance on the set temperature value is allowed during transport.
(2) For fresh pasta in pre-made packing a 2°C tolerance on the set temperature value is allowed during transport.

Temperatures during transport of meat and meat-based products

Product	Temperature
Beef (includine Bubalus and Bison species) mutton, pork, horsemeat (1) (2) (3)	up to + 7°C
Poultry (bred birds, excluding Ratitae: ostriches, emus, rheas) (1) (3)	from -2 to + 4°C
Rabbits, hares and rodents (1) (3)	up to + 4°C
Offal (1)	up to + 3°C
Bred game (Ratitae) (1) (3)	up to + 4°C
Bred game (Cervids, Swine) (1) (3)	up to + 7°C
Small-sized wild game (birds, hares, wild rabbits)	up to + 4°C
Large-sized wild game (wild land mammals not classified as small-sized wild game)	up to + 7°C
Minced meat	up to + 2°C
Meat preparations	up to + 4°C
Mechanically divided meat	up to + 2°C

(1) As they are not in contrast with any subsequent rule, whether at national or at Community level, listed, indicatively, are the temperature tolerances set by Encl. C, art. 51 of Presidential Ruling by Decree 327/80 and later amendments, allowed during the period of fractioned distribution – to be effected by means of transport built and technically equipped adequately for refrigerated transport – which involves, in order to carry out delivery to final sale points, several openings of the doors of such conveyances, temperatures when beginning the voyage unchanged, as fixed in the following table:

meat	+ 10 °C
poultry and rabbits	+ 8 °C
offal (in general)	+ 8 °C
game (in general)	+ 8 °C

(2) Awaiting specific rules at national or Community level, indicatively listed are the provisions dealing with compulsory refrigeration immediately after post mortem examination: fresh meat may be carried not yet refrigerated as long as transport does not last more than two hours and provided that such transport is carried out by vehicles classified as refrigerators according to Law 264/77 and also in possession of sanitary authorization as provided by Art. 44 of Presidential Ruling by Decree 327/80 (Art. 1 of Ministerial Order 14th November 1996).
(3) Meat packed in modified atmosphere must be kept at a temperature not exceeding +4°C as to rabbit and bred game meat and at a temperature not exceeding + 7°C as to other types of meat.

Temperatures during transport of fishing products

Product	Temperature
Edible lamellibranchiate or bivalve molluscs, alive	Temperature must not impair alimentary safety and the vitality of animals
Edible lamellibranchiate or bivalve molluscs, packed, including those unshelled belonging to “Chlamys” (scallops) and “Pecten” (clams) genus	+ 6°C
Fresh fishing products, not processed thawed, crustacean and mollusc products cooked and refrigerated	Temperature close to the melting point of ice
Fresh fishing products (always to be carried in ice) (1)	from 0 to + 4°C

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Product	Temperature
Fishing products preserved on board of vessels equipped with appliances fit for storage for more than 24 hours (2) (3)	up to + 3°C (b) up to 0°C (c)
Fresh fishing products	From 0 to +4 °C (always to be carried in ice) (1)

(1) Indicatively, shown here is the temperature relevant to fresh fishing products always to be carried in ice, temperature set by Encl. C, Art. 51 of Presidential Ruling by Decree 327/80 and subsequent amendments, anyhow not in contrast with subsequent regulations, at national or Community level. Water due to melting of the ice must not remain in contact with the products.
(2) Temperature the product must reach within 6 hours after loading.
(3) Temperature the product must reach within 16 hours after loading.

Temperatures during transport of milk and milk-based products

Product	Temperature
Colostrum	up to + 10°C
Raw milk (1) (2)	up to + 10°C
Pasteurized milk, carried in tanks or packed in small vessels or in drums (3)	up to + 6 °C
Pasteurized milk carried in tanks from a thermal treatment plant to another plant for thermal treatment and packing for direct consumption (2) (4)	from 0 to + 4°C
Pasteurized milk, packed (5)	from 0 to + 4°C
Milk and cheese products (fermented milk, whipped cream or milk cream, fresh cheese, cottage cheese) (5)	from 0 to + 4°C
Butter (5) and condensed butter (anhydrous) (6)	from +1 to + 6°C
Liquid anhydrous butter	higher than + 32°C

The table shows the temperatures for transport of raw milk and colostrum set by (EC) Regulation 853/2004 and later amendments, as well as those regarding pasteurized milk set by Presidential Ruling by Decree 54/97, the latter not having been replaced by subsequent provisions at national or Community level.
Also shown (notes from 1 to 6) are the temperatures, with corresponding tolerance limits, and the type of vehicles which must be employed for transport at various distances of milk and other milk-based products indicated by Presidential Ruling by Decree 327/80 and later amendments, not having been repealed by subsequent rulings at national or Community level.

(1) For voyages longer than 150 Km isothermal vehicles (IN or IR) are required.
(2) For voyages longer than 200 Km isothermal vehicles (IN or IR) are required.
(3) The veterinary service may allow departing from the set temperature, in connection with door to door delivery, and authorize a +2° C tolerance during delivery to retailers.
(4) For voyages longer than 200 Km a maximum 2°C increase in temperature as against the value set in the table is allowed.
(5) During the period of fractioned distribution – to be carried out by means of transport built and technically equipped adequately for refrigerated transport – which involves, in order to carry out delivery to final sale points, several openings of the doors of such conveyances, temperatures when beginning the voyage unchanged, as fixed in the table, the following maximum temperature values are allowed:

Product	Temperature
Pasteurized milk, packed	+ 9 °C
Whipped cream or pasteurized milk cream, packed	+ 9 °C
Cottage cheese	+ 9 °C
Butter made with pasteurized milk cream	+ 14 °C
Yoghurt and other fermented milk, packed	+ 14 °C
Fresh cheese (cream cheese and the like, cow or she-buffalo **mozzarella** and the like, unseasoned goat's milk cheese, **crescenza**, cheese with prevailing lactic or acid-rennet clotting and high humidity percentage, of ready consumption, such as **robiola**, *petit suisse*, **(cottage cheese)**, **quark** etc.), as long as produced with pasteurized milk	+ 14 °C

(6) Condensed butter (anhydrous) may be carried also at a temperature ranging between +6°C and +18°C.

Temperatures during transport of eggs and egg-based products

Product	Temperature
Eggs (A category) (1)	temperature, preferably constant, must be adequate to guarantee the optimal preservation of hygienic characteristics
Egg-based products (2)	+ 4 °C

(1) "A" category eggs must not be refrigerated in premises or plants in which temperature is artificially kept under +5°C. Anyhow, eggs kept at a temperature lower than + 5°C during transport, which must last no longer than 24 hours, are not considered refrigerated.
(2) Indicatively, for egg-based products the set temperature is the one indicated by Law by Decree 65/93, recently repealed by Law by Decree 193/2007. Such temperature value is anyhow identical to the one provided for by (EC) Regulation 853/2004 for the storage of egg-based products.

Temperatures during transport of frog legs

Product	Temperature
Frog legs	temperature close to the melting point of ice

Temperatures during transport of frozen and deep-frozen products

Product	Temperature
Frozen meat (1)	up to – 12°C
Frozen minced meat, meat preparations, mechanically divided meat	up to – 18°C
Frozen fishing products (2)	up to – 18°C
Frozen fishing products in brine	up to – 9°C
Butter or other frozen fat substances (3)	up to – 18°C
Fruit ice-creams and frozen fruit juices (3)	up to – 10°C
Other ice-creams (3)	up to – 15°C
Frozen egg-based products (4)	up to – 12°C
Deep-frozen egg-based products (4)	up to – 18°C
All other frozen alimentary products (3)	up to - 10°C
All deep-frozen alimentary products (3)	up to – 18°C

(1) The temperature fixed by repealed rulings is shown, in the absence of specific provisions at national or Community level.
(2) The temperature of – 18°C must be kept in every part of the mass; brief upward fluctuations, no higher than 3°C, are allowed.
(3) During transport of these products brief upward temperature fluctuations are allowed, as long as they are not higher than 3° C (Encl. C, Art. 51 of Presidential Ruling by Decree 327/80 and later amendments). This indication, confirmed by art. 4 of Law by Decree 110/92, is quoted as it is not in contrast with subsequent rulings, whether national or of the European Union.
(4) Indicatively, the table shows the provisions of Encl., Chapter X, art. 6 of Law by Decree 65/93, recently repealed by Law by Decree 193/2007.

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Regulation references

Fruit and vegetable products

- the current regulations do not indicate a specific carriage temperature for these products.

Other products for which no specific carriage temperature is set

- cooked foodstuffs, delicatessen products with jelly covering, non-sterilized milk-based soft drinks: art. 31 of Presidential Ruling by Decree 327/80 and later amendments.
- stomachs, bladders and processed intestines: Encl. III, Section XIII (EC) Regulation 853/2004

Flour products and pasta

- fresh pasta: art. 9 of Presidential Ruling by Decree 187/2001.

Meat

- beef (including Bubalus and Bison species), pork, mutton, horsemeat and offal: Encl. III, Section I, Chapter VII of (EC) Regulation 853/2004;
- poultry: Encl. XIV, Part B, Point II 3) of (EC) Regulation 1234/2007;
- bred birds (excluding Ratitae: ostriches, emus, rheas), rabbits, hares and rodents: Encl. III, Section II, Chapter V of (EC) Regulation 853/2004;
- bred game: Ratitae (ostriches, emus, rheas), cervids, swine: Encl. III, Section III of (EC) Regulation 853/2004;
- small-sized wild game (birds, hares, wild rabbits): Encl. III, Section IV, Chapter III of (EC) Regulation 853/2004;
- large-sized wild game (wild land mammals not classified as small-sized wild game): Encl. III, Section IV, Chapter II of (EC) Regulation 853/2004;
- minced meat, meat preparations, mechanically divided meat: Encl. III, Section V, Chapter III of (EC) Regulation 853/2004;
- note (1) – Encl. C, art. 51 of Presidential Ruling by Decree 327/80 and later amendments;
- note (2) – carriage of fresh, non-refrigerated red meat: art. 1 of Ministerial Decree 14th November 1996;
- note (3) – rabbit and bred game meat packed under modified atmosphere: art. 5 of Ministerial Decree 49/88;

Fishing products

- live edible lamellibranchiate and bivalve molluscs: Encl. III, Section VII, Chapter VIII of (EC) Regulation 853/2004;
- packed
- edible lamellibranchiate and bivalve molluscs: artt. 4 and 5 of Ministerial Decree 4th October 1978;
- fresh fishing products, not processed thawed, crustacean and mollusc products, cooked and refrigerated: Encl. III, Section VIII, Chapter VIII of (EC) Regulation 853/2004;
- fishing products (always to be carried in ice): Encl. C, Art. 51 of Presidential Ruling by Decree 327/80 and later amendments;
- fishing products preserved on board of vessels equipped with appliances suitable for storage for over 24 hours: Encl. III, Section VIII, Chapter I of (EC) Regulation 853/2004.

Milk and milk by-products

- colostrum: Encl. II of (EC) Regulation 1662/2006
- raw milk: Encl. III, Section IX, Chapter I of (EC) Regulation 853/2004
- pasteurized milk: Encl. C, Chapt. V, art. 5 of Presidential Ruling by Decree 54/97;
- products indicated by notes (2) to (6): Encl. C, Art. 51 of Presidential Ruling by Decree 327/80 and subsequent amendments.

Eggs and egg-based products

- eggs: Encl. III, Section X, Chapter I of (EC) Regulation 853/2004;
- egg-based products: Encl., Chapter X, art. 6 of Law by Decree 65/93;
- note 1: art. 2 of (EC) Regulation 557/2007.

Frog legs

- frog legs: Encl. III, Section XI of (EC) Regulation 853/2004.

Frozen and deep-frozen products

- red meat (beef, pork, mutton, domestic solipeds meat): Encl. I, Chapt. XV, art. 3 of Law by Decree 286/94;
- poultry: Encl. XIV, Part B, Point II 3) 4) of (EC) Regulation 1234/2007;
- yardbirds meat and offal thereof: Encl. I, Chapt. XV, art. 3 of Presidential Ruling by Decree 495/97;
- rabbit meat and bred game meat, offal thereof: art. 6 of Presidential Ruling by Decree 559/92;
- meat of game shot during hunting and offal thereof: Encl. I, Chapt. XI, art. 3 of Presidential Ruling by Decree 607/96;
- minced meat, meat preparations, mechanically divided meat: Encl. III, Section V, Chapter III of (EC) Regulation 853/2004;
- frozen fishing products: Encl. III, Section VIII, Chapter VIII of (EC) Regulation 853/2004;
- egg-based products: Encl., Chapter X, art. 6 of Law by Decree 65/93;
- products indicated by notes (2) and (3): Encl. C, art. 51 of Presidential Ruling by Decree 327/80 and subsequent amendments and art. 4 of Law by Decree 110/92;

Enclosure

Conversion table Celsius-Fahrenheit

Conversion from Celsius to Fahrenheit

C	F
50	122,0
49	120,2
48	118,4
47	116,6
46	114,8
45	113,0
44	111,2
43	109,4
42	107,6
41	105,8
40	104,0
39	102,2
38	100,4
37	98,6
36	96,8
35	95,0
34	93,2
33	91,4
32	89,6
31	87,8
30	86,0
29	84,2
28	82,4
27	80,6
26	78,8

C	F
25	77,0
24	75,2
23	73,4
22	71,6
21	69,8
20	68,0
19	66,2
18	64,4
17	62,6
16	60,8
15	59,0
14	57,2
13	55,4
12	53,6
11	51,8
10	50,0
9	48,2
8	46,4
7	44,6
6	42,8
5	41,0
4	39,2
3	37,4
2	35,6
1	33,8

C	F
0	32,0
-1	30,2
-2	28,4
-3	26,6
-4	24,8
-5	23,0
-6	21,2
-7	19,4
-8	17,6
-9	15,8
-10	14,0
-11	12,2
-12	10,4
-13	8,6
-14	6,8
-15	5,0
-16	3,2
-17	1,4
-18	-0,4
-19	-2,2
-20	-4,0
-21	-5,8
-22	-7,6
-23	-9,4
-24	-11,2

C	F
-25	-13,0
-26	-14,8
-27	-16,6
-28	-18,4
-29	-20,2
-30	-22,0
-31	-23,8
-32	-25,6
-33	-27,4
-34	-29,2
-35	-31,0
-36	-32,8
-37	-34,6
-38	-36,4
-39	-38,2
-40	-40,0
-41	-41,8
-42	-43,6
-43	-45,4
-44	-47,2
-45	-49,0
-46	-50,8
-47	-52,6
-48	-54,4
-49	-56,2

DETERIORATION OF FOODSTUFFS

Fresh foodstuffs, if not correctly kept, undergo, more or less quickly, transformation processes both chemical and physical which render them no more edible. It is clear that in order to fight such phenomena it is necessary to know the causes of the alteration of foodstuffs.

As far back as the IX century, as a result of the studies and discoveries of several scientists, micro-organisms were found to be the main agents causing alteration and transformation of organic matters. Subsequently it became clear that microbial activity is mediated by enzymes, molecules of protein nature present in the cells, which acting as catalysts are essential for any metabolic reaction to take place.

Other factors contributing to deterioration of foodstuffs are chemical reactions, not mediated by enzymes, and physical agents.

Summing up, the concepts set forth above may be schematized as follows:

- biological causes: enzymes present in the food itself
  micro-organisms
- chemical-physical causes: oxygen
  radiations
  heat
  variations in the water content

Biological causes

Biological causes are by far the most important ones among the degradation reactions and are catalysed by enzymes present in the food or belonging to the micro-organisms which contaminate the food itself.

Natural foodstuffs are organisms of animal or vegetable origin, or derive from them, and they maintain their enzymatic heritage. The enzymes involved in the degradation mechanisms of both animal and vegetable tissues are mostly those of lysosomic origin. Lysosomes are endocellular micro-organisms present in the cells of upper organisms and constitute the endocellular alimentary system, with an array of more than 50 enzymes, able to split both intra- and extra-cellular molecules. With the death of the organism the enzymes leak out of lysosomes, triggering cellular self-digestion phenomena, which cause, among other things, the processes occurring when hanging meat (cathepsins).

Alimentary substances, especially those of animal origin, richer in fermentable substrata, are an excellent ambience of growth for micro-organisms, which proliferate causing degradation of the foodstuff. The action of micro-organisms brings about:

1. alteration of organoleptic characteristics and nutritional yield;
2. impairment of wholesomeness.

Alterations in the composition of a foodstuff differ depending if germs are aerobes or anaerobes. However, these two kinds of alterations may not be easily distinguished and often one is associated with the other.

Generally speaking it can be said that putrefaction is mediated by anaerobe germs and is a phenomenon which involves mostly protein substrata, while fermentation is mediated by aerobe germs and involves mainly glucosidic substrata. Oxidization phenomena, also mediated by aerobe germs, affect lipids.

The final outcome is characterized by more or less considerable changes in organoleptic characteristics: unpleasant flavours, smells, softening, rotting. Alterations in the natural pigmentation of food also take place, along with growth of mucilages due to development on the surface of microbial species provided with a polysaccharide capsule and along with surface moulding.

Food in alterated state may cause more or less serious problems especially for people at risk, such as children, elderly people, sick people. The more pathogenic for man the agent causing alteration is, the greater the risk. Pathogenic micro-organisms may be carried through the food (infection) or may use the food to produce toxins (intoxication). Invasion of moulds may also be dangerous, mainly because of the production of metabolites of same, which may cause severe intoxication phenomena, both in animals and in men.

It must be highlighted that not always micro-organisms are noxious for foodstuffs, often they give rise to fermentation phenomena, necessary from a technological point of view to obtain the final foodstuff (yoghurt, wine, beer, bread etc.).

The main pathogenic organisms giving rise to diseases carried by food are described in the following table.

DISEASES CARRIED INGESTING FOODSTUFFS

Micro-organism	Food	Alteration	Incubation	Symptoms
Salmonellas	- eggs - milk and milk-made products - smoked fish - chocolate	none	from 2 to 48 hours	- fever - cephalea - abdominal pain
Staphylococcus aureus	- milk and cheese - sweets with cream - meat and poultry dishes - sauces - meat sauces	none	from 2 to 3 hours	- nausea - salivation - abdominal pain - diarrhea
Clostridium botulinum	- jams and home-made preserves - home-made sausages - dry-cured ham - pickled or fermented fish	sometimes smell of butter	from 12 to 36 hours	- dryness of fauces - paralysis of facial muscles - gastroenteric spasms
Bacillus cereus	- creams and cereal-based dishes	none	from 30 minutes to 48 hours	similar to intoxication by Staphylococcus
Clostridium perfringens	- cooked meat - poultry - meat sauces - meat pies	none	from 8 to 24 hours	- abdominal pain - diarrhea
Listeria monocytogenes	- raw minced meat - poultry - raw and salted forcemeat - fresh vegetables	none	from 4 to 21 days	- fever - cephalea - meningitis - abortion
Escherichia coli	- cheese - salmon - minced meat	none	48 hours	- fever - soreness - diarrhea
Vibrio cholerae	- seafood - mussels - raw or not cooked enough shrimps - raw vegetables - non-drinkable water	none	from 2 to 3 days	- bouts of diarrhea - dehydration - strong thirst - weakness
Vibrio parahaemolyticus	- seafood, fish, not cooked enough crustaceans	none	from 2 to 48 hours	- abdominal pain - diarrhea - fever - cephalea - weakness

Chemical-physical causes

Oxygen is the main inorganic agent causing alteration in foodstuffs, in particular in the fat fraction of same. In fact, it brings about rancidity of unsaturated fats besides deactivation of vitamins and loss of aroma. Together with enzymes, it causes darkening of vegetable juices and of fruit and vegetables when cut to pieces.

The quantities of oxygen needed to bring about changes in the sensorial properties of foodstuffs are very small:

1. fruit juices	10	ppm
2. roasted coffee	15	ppm
3. UHT milk	1-8	ppm
4. beer	1-4	ppm

The radiations of light and UV rays trigger radical chain reactions such as oxidative rancidity or deactivation of certain vitamins with loss of their nutritional value. Light and oxygen, jointly or severally, cause sensorial changes in many foodstuffs (anomalous flavours and smells). IR rays damage foodstuffs as they bring about an increase in temperature.

The variation in water content due to excessive evaporation causes dehydration and withering of vegetables, especially wide-leaved ones, or, in the case of frozen products, the so-called **"**burning**"**. The absorption of dampness, on the contrary, is detrimental for all desiccated foodstuffs: fresh baked products lose freshness and fragrance, dehydrated food clot, desiccated vegetables change taste and colour. Furthermore, the excess of humidity favours the development of moulds, leavens and bacteria, makes fats turn rancid (through hydrolysis) and transforms enzymes.

The increase in temperature, due to malfunctioning of the refrigeration machinery, is the main cause of deterioration of foodstuffs.

Low temperatures block the proliferation of micro-organisms (bacteriostatic action) as well as the metabolic processes which occur in the deterioration of food: as a consequence the interruption in the cold chain allows microbial proliferation and the degradation processes therewith associated, with alterations of the organoleptic characteristics and of the nutritional value of products.

The transport phase is crucial to the purpose of preserving foodstuffs as for both organoleptic and nutritional properties and hygienic-sanitary aspects.

Part 2

Transport of alimentary goods

MEANS OF TRANSPORT

Containers

The evolution of the technique of transport of alimentary products has introduced already since the '70s the employment of containers dedicated to the optimal keeping of temperature (reefer containers). These containers act as a "moving hold" and allow to carry out fast multimodal carriages avoiding loading and unloading operations when changing the means of transport.

To maintain temperature a container may be: fed directly by its means of transport or equipped with a self-contained power unit; thermally insulated; carried by any conveyance.

The International Organization for Standardization (ISO), organization which fixes the structural and dimensional building characteristics to which a container must conform to allow its employment on an international scale, defines it as an "element of the transport system" characterized as follows:

b) with permanent characteristics sufficiently sturdy to render it suitable for repeated use;
c) purposely designed to facilitate transport of goods by one or by several transport systems, without the need of intermediate reloadings;
d) integrable with devices which permit its easy handling, in particular from one transport system to another;
e) designed in such a way as to be easily stuffed and destuffed.

ISO divides containers into the following categories:

- for general cargo
- thermal
- tank
- for materials in bulk
- flat
- special
- for air transport

The container, to be employed, must be provided with special certifications. Such documents give evidence that the means has been built according to certain technical specifications and that the efficiency conditions of same are good.

The certifications required for containers are the following:

Certificate of conformity to ISO rules

The certificate attests that the container has been built according to ISO specifications. It is released by international agencies, or by national agencies acknowledged at an international level. In Italy this certificate is released by RINA (Italian Shipping Register).

Certificate of conformity to International Convention for Safe Containers

The aim of the International Convention for Safe Containers (CSC) is to render official and binding the rules relating to container building so as to guarantee the safe handling and transport of same in normal operating conditions.

Refrigerator trucks

The means of transport employed for road transport of perishable foodstuffs may vary according to perishableness of product and distance to be covered, but anyhow they must be heat insulated. The variability factor consists mainly in the structure employed for carriage, with the following broad division:

- Ventilated structure
  for carriage of not highly perishable agricultural products (e.g. potatoes) over short distances in temperate climates.
- Refrigerator structure
  equipped, that is, with cold producing machinery and intended for transport of perishable products, whether fresh, frozen or deep-frozen, over any distance with temperatures which may vary from +12°C to –25°C.

The refrigerating units have different potentials depending on the volume of the structure within which it is necessary to guarantee a controlled temperature.

Some refrigerator structures are equipped for transport under controlled temperature, which improves keeping of the product being carried (mainly fresh fruit and vegetables) as, besides controlling temperature, such a device also controls humidity, avoiding dehydration of the product and allowing safe delivery of cargo at final destination.

For international carriage refrigerator trucks must be in possession of the Certificate of Conformity to the *Accord Transport Perishables* (ATP). The ATP agreement, European convention signed in Geneva on 1st September 1970 by Austria, France, Italy, Yugoslavia, Luxembourg, Netherland, Germany, Spain, Switzerland, Russia, fixes the technical characteristics of the "special means of transport" intended for carriage of perishable products, with a view to improving the preservation conditions of cargo during transport.

With an empty loading space and external temperature of 30 ° C they allow to keep the following temperatures:

class A	between + 12 °C and 0 °C	Fna or Fra abbreviation
class B	between + 12 °C and - 10 °C	Fnb or Frb abbreviation
class C	between + 12 °C and - 20 °C	Fnc or Frc abbreviation
class D	less than + 2 °C	Fnd and Frd abbreviation
class E	less than – 10 °C	Fne or Fre abbreviation
class F	less than – 20 °C	Fnf or Frf abbreviation

This general scheme of autonomous devices for the production of cold is valid for all refrigerator units.

According to the goods being carried (e.g. potatoes, chocolate, butter, cheese), for brief transports at constant temperature heat insulated means of transport are employed, such as:

1. *normal isothermal vehicles*	K 0.7	In abbreviation
2. *reinforced isothermal vehicles* (with more effective insulation)	K 0,4	Ir abbreviation

For very brief transports of more easily perishable products (e.g. town distribution of frozen or deep-frozen products), *special refrigerated vehicles* may be employed with sources of cold constituted by ice, dry ice, liquid nitrogen, eutectic plates. With an empty loading space and an external temperature of 30° C they allow to keep the following temperatures:

class A	+7 °C	Rna or Rra abbreviation
class B	-10 °C	Rrb abbreviation
class C	-20 °C	Rrc abbreviation

Refrigerator wagons

Railway is effective especi ally in long distance tr ansports when bo th collection a nd deliv ery o f goods are each concentrated in onl y one location. Instead in cases in which the products t o be carried are sc attered over very am ple z ones the ra ilway sy stem t ends to lose operating efficiency and econom ic convenience. In ot her words railway is able to carry out only a "station to station" service, not a "door to door" service as required by the modern distribution of goods.

The wagons for transport under cont rolled tem perature are divided into "i sothermal" and "refrigerated" vans:

– *isothermal wagons*
they are not equipped with cells for ice, but they have a loading area with a better insulation in comparison with refrigerated vans and they are employed for transport of foodstuffs which need a special protection from heat and cold.

– *refrigerated wagons*
they are fitted with cases intended to contain i ce. Some vans are provided with hooks for transport of fresh or frozen meat. Certain models of wagons are equipped with an electroventilation system able to allow circulation of air between the ice cells and the interior of the wagon.

– *refrigerator wagons*
they are fitted with autonom ous refrig erating units, fed by a diesel engine, able to maintain temperatures ranging from +20° C to – 25° C.

Ships

The traditional ships int ended for transport of deep-frozen. frozen or refrigerated in hold products, in particular along international routes, comprise:

- *ships with ventilated holds* (intended for example for carriage of potatoes), therefore with insulated holds or holds built interposing insulating materials but anyway structured so as not to block circulation of air. This technique is necessary in particular to keep th e temperature constant and anyhow within a range varying generally between +5° C and +15° C.
- ships *specialized* for trans port of fresh fruit (bananas in cluded) a ble to keep a te mperature varying betw een -1° C an d +15.5° C. Moreover a constant and continu ous ch anging of air must be guaranteed so as to avoid accum ulation of the products of metabolism of fruit which quicken ripening or decay of the product.
- ships with refrigerated holds for transport of frozen perishable products (such as meat) and deep-frozen ones (like fish). Th ey are ships equipped with holds designed to reach and maintain temperatures as low as -25° C.
  All refrigerator ships are t hermically insulated so as to allow the mini mum possible loss o f heat through the walls of the holds and are fitted with hold ventilation plants able to maintain optimal transport conditions throughout the loading space.
  Production o f cold is carried out b y s pecial air refrigeration pla nts which work thro ugh expansion of a cold-generating gas or l iquid in pr oper evaporators throug h wh ich air to be cooled and to be let in the loading areas is forced by the ventilation plant. The temperature of the air which must be brought in the holds is regulated by special valves.

- *multipurpose* (multiple employment) ships, for instance of VCR type (*Versatile Conflat Reefer*), which are fitted with refrigerated holds, tanks for oil in bulk and may also carry reefer containers.

Aircrafts

There do not exist aircrafts specially meant for transport of alimentary goods under controlled temperature. Airlines employ isothermal containers with a maximum capacity of 10 cubic metres, inside which goods are stowed, sometimes further contained in special packings such as polystyrene boxes or sunk in dry ice. Such precautions are taken according to the type of goods and the length of transport.

TECHNICAL CHARACTERISTICS OF CONVEYANCES

The characteristics which reefer containers, refrigerator trucks, refrigerator wagons or refrigerator ships must have in order to carry perishable goods consist in "thermic insulation", that is means of transport with characteristics allowing the walls to represent a valid barrier to passage of heat between outside and inside and avoiding passage of air with the outside when doors are closed.

The efficiency of the thermic insulation of the loading area is indicated by a quantity called "K coefficient" which represents the global thermic conductivity coefficient.

"K" is expressed in "kcal", per hour, per square metre, per degree centigrade and represents the quantity of heat passing through a square metre of wall, in an hour, when between outside and inside ambience there is a difference in temperature of one degree centigrade.

Therefore the more efficient the insulation the lower the "K" factor. Usually the walls are insulated with a "sandwich" technique, through which insulation is obtained by placing panels which achieve the complete "padding" of surfaces within the metallic structure, doors included.

The panels are built with a "sandwich" technique, consisting mainly in coating surfaces with a sheet of insulating material.

To achieve thermic insulation particular materials are employed, among which the most widely used is "polyester resin", but also employed are cork and materials of mineral origin, Resin is reinforced with fiberglass to provide a better mechanical endurance.

The thermic conditioning units of the various conveyances (container /truck/holds) generally work by electric driving of a compressor, of evaporation fans and of the condenser.

Energy necessary for the electric engine to work is provided by the carrying vehicle's engine or by the electric plant to which it is plugged. In some models the electric engine may be fitted with an autonomous internal combustion generator, so as to ensure continuous feeding.

All the conveyances for transport of foodstuffs are equipped with an internal ventilation system which must ensure keeping of optimal conditions of transport throughout the internal ambience.

Air, after having been cooled, is distributed in the whole area where cargo is contained.

Often, in trucks, in order to facilitate air distribution, the feeding intake is linked to a canalization which runs lengthwise along the ceiling and is provided with openings which distribute air in different points of the cargo.

Cold air flows through the cargo, which must be permeable particularly as for stowing so allowing circulation of air everywhere, and absorbs its heat growing less and less cold as it proceeds towards the "return".

Then the air proceeds towards the intake of the conditioning unit and from here it is conveyed to the evaporator to which it transfers the heat brought away from the cargo.

The principle by which the holds of a ship are cooled is absolutely analogous and consists in an air cooling system which distributes such air throughout the stow by a forced ventilation plant.

There also exist plants of conditioning under controlled temperature which may be used successfully when carrying fruit and vegetable products. Such plants combine the cooling system and an unit intended to regulate and maintain the concentration of oxygen (O_2), carbon dioxide (CO_2) and ethylene (C_2H_4). The employment of this technique is due to the findings that a control of these gases permits to slow down the metabolism of fruit and vegetable products postponing the ripening/ageing processes which cause spoiling of such products.

Instruments and methods of temperature recording

The constant recording of temperatures within the loading area during transport is of particular importance to bring about an uniform and continuous keeping of optimal temperatures for preservation of cargo. Presently the temperature recording systems are performed by electronic appliances the detectors of which are placed within the loading areas and/or in the zone where cold is produced and transmit recorded temperatures to external displays/printers/recorders.

Such a device displays the trend of temperatures and possible anomalies like for instance duration and frequency of the openings of the doors of the loading space.

Some of the set temperature recording appliances are also able to monitor the percentage of humidity present in the loading area so as to verify keeping of the ideal conditions of carriage. This is of particular importance in the carriage of fruit and vegetable products which in some cases, in consideration of their organoleptic characteristics, need a constant percentage of humidity.

Modern technology further allows to employ special devices able to monitor and record instances when temperature and humidity exceed minimum or maximum limits previously chosen in accordance with the product which is being carried so permitting to verify, at the end of transport, that the cooling systems of the vehicle has been constantly in working order and, as a consequence, to make sure that the product has reached its final destination without undergoing temperatures inadequate for preservation of same.

Other sophisticated instruments may be placed inside the loading areas, such as indicators which show variations in temperature through the irreversible change in colour of the liquid they contain or electronic or electro-mechanical (Ryan) appliances placed by the shipper inside the loading area so as to verify, at the end of voyage, jointly with the carrier, possible thermic anomalies of the product, and the duration of the anomalies which products may have undergone.

The instruments allow to store collected data for a period which may be as long as one year and even more. Transfer of data may be on paper as well as through computer. Data so collected must be constantly verified by the operators (drivers, container yard managers, ocean carriers etc.).

Only for refrigerator trucks equipped with satellite telesurveillance systems it is possible to remotely handle all the data, that is to say the telesurveillance centre can record the anomalies ascertained and transmit them instantly to the driver of the truck.

EC regulation no. 37/05 dated 12th January 2005 provides rules regarding temperature recording on vehicles and in foodstuffs storerooms, previously laid down by national rulings (Ministerial Decree no. 493/1995).

The regulation, come into force on 2nd February 2005 but operative as from 31st December 2005, provides that thermo-recorders responding to the previous rules may be installed and employed up to 31st December 2009; as from 1st January 2006 all thermo-recorders being installed will have to conform to EN rules 12830, 13485 and 13486.

Also railway wagons for refrigerated transport will have to abide by the same regulation.

Comprised in this scope are isothermal vehicles of ATP class, which are FRC for carriage at -20° C and over, and in Italy the ruling law provides for derogation for vehicles with a loading capacity up to 7 tons for the local distribution of deep-frozen products.

For voyages of 24 hours or less temperature must be recorded at regular intervals of 5 minutes. For voyages over 24 hours temperature must be recorded at regular intervals of 20 minutes.

It is well known that in Italy Ministerial Decree no. 493/1995 fixes a 20 minute recording interval, independently from duration of the voyage, and the tolerance on temperature must not exceed the limit of +3° C for frozen and deep-frozen products.

The detectors of the thermo-recorder must be placed so as to measure the air temperature, not the temperature of the product, as provided for refrigerating units.

It is very important for insurance purposes that carriers must keep temperature recordings for one year.

Part 3

Preparation for transport of alimentary goods and conveyances

PREPARATION FOR TRANSPORT OF ALIMENTARY GOODS

Packing

For all types of foodstuffs, particular care must be taken in the choice of packing, which essentially must have the following characteristics:

- allow an easy handling of the shipments of goods and their correct stowage inside the carrying conveyance;
- absorb shocks, whether dynamic (due to transport) or static (due to stowage);
- concur to safe preservation of the product, also allowing airing of goods.

Packing must also be built with material as "non-hygroscopic" (not holding humidity) as possible.

Apparently packing and boxing could seem secondary in the top list of recommendations or situations which must be monitored, but it should be kept in mind that the product will "live" within its second protective skin for a period which may be long and in handling or keeping conditions which are not always optimal. We therefore suggest to verify whether packing and product therein contained can be considered compatible, adequate and customary.

By the term *machinability* we mean the capability of the packing and of the material making up the packing of being produced, shaped, filled up and closed by fast-working machines and at a low cost. In order to be employed with boxing machinery packing must be compatible with "mechanization". Packing must periodically undergo tests regarding its employment by machines to verify its "machinability".

Packing of foodstuffs is divided into two categories:

- internal packing
  Internal packing is in direct contact with the product. It may be a packing for the final consumer; common terms are consumer pack, sales packaging, retail packaging. It also includes packing intended for catering and great consumers such as canteens, hospitals etc. It is also used to pack food for further processing.
- external packing
  External packing usually contains a certain number of internal packings: Common terms are outer cases, transport packaging, transport carton, shipping container, secondary packaging etc.

Internal packing

Packing products in boxes for consumers has advantages and disadvantages:

- Advantages
  It protects against contamination, reduces or prevents dehydration, facilitates the sales distribution. It is necessary for hygiene of food sold in self-service shops, such as supermarkets, besides being needed for marking on the labels of prescribed information. It is convenient to apply information and instructions for the consumer.

- Disadvantages
  Disadvantages are the cost and the possibility that the cooling process is slowed down if the foodstuff has not reached the correct temperature before being packed.

The choice of the type of packing should be based first of all on the requisites of the individual product. The nature of the foodstuff, the composition of the product, the probable temperatures to be set, the storage period should also be borne in mind.

There is a wide variety of materials and forms of packing and the most common ones for consumers are cellulose or plastic trays wrapped in plastic film (foodtainers).

Important qualities of material for internal packing

The most important properties regarding material for internal packing of foodstuffs are:

– *Physical properties*

- permeability to steam
  Permeability to steam (Water-Vapour Transmission Rate, WVTR) of the packing material, and of the packing itself, must be low or very low (e.g. aluminium foil for foodstuffs).
- permeability to gas
  Permeability to gas refers especially to oxygen and carbon dioxide. For a certain number of frozen products it is necessary to use a packing material with a low permeability to oxygen, so as to prevent or reduce development of rancidity. Rancidity is an oxidizating process.
  When vacuum packaging is employed it is necessary to use a packing material with a permeability to oxygen of less than 70-90 ml/m2/day per bar, measured at ambient temperature. for goods which require an "extra" protection against oxygen, packing materials with a permeability to oxygen of 10 ml/m2/day per bar or lower.
  As for packing material employed for MAP (Modified Atmosphere Packaging), permeability to oxygen and to carbon dioxide must be even lower that the one of the plastic materials used for vacuum packaging.
- migration
  Some countries have in force legislation regarding packing which includes maximum allowable limits for the migration of additives from the packing materials to the foodstuffs.

– *Mechanical/technological properties*
  These comprise several characteristics such as resistance to explosion, endurance to breakages, stretching and elasticity. The packing material employed must resist to conditions taking place in the cold chain, such as lowering of temperature, blows and vibrations.
  The methods and characteristics of the main packages for alimentary products are standardized at international level by precise rules. In the particular case of frozen goods the material must withstand temperatures of –40° C without becoming friable. In cases where liquid nitrogen or solid carbon dioxide are employed as refrigerants the packing material must withstand temperatures of –50° C or even less. An ever increasing number of packing materials, besides bearing low temperatures, must also withstand high temperatures (e.g. 100° C or 200° C or even more for the packing of food cooked in the oven). For some foodstuffs hot "stuffings" are employed. This means that food (usually liquid or semi-liquid) is put in the package when it is still hot, often at a temperature exceeding 90° C. Obviously the packing material must resist such process.

Packing materials

For refrigerated and frozen food, the materials more commonly used are:

– *Plastic materials*
  - polyethylene (PE)
    The low density (*Low Density Polyethylene*, LDPE) has a comparatively low WVTR, but a great permeability to oxygen. The resistance to heat is excellent and polyethylene is not expensive. It is frequently used with laminated sheets when the internal layer touches alimentary products.
  - polyamide (PA) or nylon
    This plastic material has a good resistance and a comparatively low permeability. It is employed with many laminated sheets, for example when using vacuum-packaging..
  - polyester (PET)
    This film resists high temperatures, certain types up to about 240 °C. Its mechanical properties are very good, but it is quite expensive.
  - polyvinyl chloride (PVC)
    This film has good mechanical and optical properties and it is quite cheap. Light PVC has a great permeability. Plastified PVC is employed for certain kinds of food, e.g. meat, poultry, fruit. Other types of plastified PVC are used for rigid or semirigid containers, often thermic ones.

– *Laminated sheets*
  A laminated sheet contains various layers, usually made of different materials.
  In very many cases all layers are made up of plastic materials, but aluminium sheet may well be one of the layers. Also paper is used as a layer in certain laminated sheets. The various layers may be kept together by glues. Using laminated sheets it is possible to combine the characteristics of different plastic materials at reasonable costs. Nowadays packing materials are produced with the desired properties of permeability.
  - Aluminium sheet
    Aluminium sheet, in the form of trays, is employed for a variety of foodstuffs, for example for "ready-made" dishes which must then be heated in the oven.
  - Paper and cardboard
    Paper is employed as a layer in various laminated sheets, for example in tins, used for frozen concentrated juices. "Fat-proof" paper is employed for products such as butter and margarine, and for animal fats like bacon fat. Frozen food packed for consumers, ice-creams, milk etc. are often packed in cartons which are internally coated with plastic.
  - Barrier layers
    The two best known barrier materials are PDVD and EVOH.
    Both plastic materials have a very low permeability to oxygen and are used as barrier layers in laminated sheets for products where the dispersion of oxygen must be minimal.

– *Metal tins*
  Metal tins, often internally coated with a layer of inert plastic material, are used for some perishable products which must or must not be kept under controlled temperature for a period of time which is not usually brief.

Preservation in modified atmosphere

The techniques of preservation in modified atmosphere are:

– *Vacuum packaging*
  When packing has been filled with alimentary products, air is extracted and packing is sealed (usually by heat). With a flexible packing, the plastic material adheres to foodstuffs.

As mentioned above, a packing material with a low permeability to oxygen must be employed. In such a way food is protected against oxygen in the atmosphere and the decaying process should slow down, giving as a result a better preservation.
It is recommended that at least 95% of air is extracted from packing during the vacuum process. The small quantity of air remaining within the packing will have its oxygen used up by the enzymes and by the micro-organisms with a by-product of carbon dioxide.
For food like fresh meat the concentration of carbon dioxide is often well higher than 50% in the small part of air remaining in the packing, so contributing to the long period of preservation of vacuum packed meat.

– *MAP*
After having let out the air from the packing, an altered atmosphere may be introduced before sealing the container with heat. As a consequence, the packed food will be surrounded by a mixture of gas which is different from the normal atmosphere. This is sometimes termed gas flushing. Usually the modified atmosphere is without oxygen, simply because oxygen is involved in many processes of degradation of the quality of products. A variety of combinations of nitrogen and carbon dioxide are employed, for instance 50% nitrogen and 50% carbon dioxide; the oxygen content must always be low, for some foodstuffs the oxygen content must be kept under 0.5%.

– *CAPTECH*
This system was developed in New Zealand to help in the transport of meat over long distances. Meat is packed in an "alufoil" laminated sheet with a permeability to oxygen and to carbon dioxide which nears zero. The air in the packing is replaced by carbon dioxide and the oxygen content in the packing must be null or very low. When the stowage temperature during the voyage is kept at about –1.5° C with slight variations the preservation period, for instance of a lamb, could reach twenty weeks or more. Packing may contain whole animals, pieces for wholesale selling or packets for consumers. The system was developed for containerized transport of frozen lamb from New Zealand to Europe, but could be employed for other kinds of meat.

External packing

For very many frozen foodstuffs wrapped in an internal packing also external packings are employed. A correct transport packing is essential to maintain the quality of products and to reduce claims. The external packing encloses the product and during the voyage must resist:

– rough handling during loading and unloading
Rough handling may take place at the production plant, during storage, during transport and at final destination. The external packing must be sufficiently strong to withstand such shocks.

– compression due to weight of superimposed cartons
Compression caused by external packagings stacked above goods may be an important factor during storage.

– impacts and vibrations during transport
Impacts and vibrations during transport depend on the carriage modality, by road, sea or railway.

Many external packagings may be negatively influenced by an excess of humidity forming inside refrigerating cells and means of transport.

External packagings include:

1. cartons, boxes;

2. plastic trays, films;
3. wooden drums, crates etc.

Nowadays the most widely used external packagings for transport of alimentary products under controlled temperature are cartons and boxes.

Cardboard is the most used material for external packages. Cardboard is a material deriving from the assembly of three or more layers of material (e.g. linerboard, fibreboard). The building of cartons usually provides for the presence of a corrugated layer (corrugated board) within two smooth layers of linerboard, fibreboard etc.

The carton in its meaning of container (containerboard) is made folding and glueing/clipping the cardboard sheets which have been previously cut.

By fibreboard we mean a material principally made up of wooden fibres with a minimum density amounting to 1000 g/**m2** while we term linerboard a material made up of high density crepe paper.

Corrugated board consists in a sheet of fibreboard or linerboard which is purposely creased and waved to form *flutes* of various dimensions and compactness. According to the dimensions and density of *flutes* in the unit of measurement there will be a more or less high capacity of endurance to crushing, of rigidity of packing.

Types of *flutes* which have become standard:

- A-*flute* is the thicker one (4.6 mm), with the least number of *flutes* (110-120 per m) and the greater protection and absorbing properties.
- B-*flute* is 2.6 mm thick and has 160-170 *flutes* per m.
- C-*flute* falls between A and B *flutes*.
- E-*flute* is 1.15-1.50 mm thick and has 250-300 *flutes* per m. It has the best capacity of resisting crushing and a lesser capacity to absorb blows. E-*flute* is widely employed for cartons containing liquors and for delicate foodstuffs which require both protection during transport and good presentation.

Usually external packagings are made up of flutes which run vertically. In this direction they provide the stronger force of resistance to amassment.

Boxboard is the term by which we define a container built with the same method as containerboard but also with materials not deriving from paper and anyway with a weight in grams per square metre of less than 400 g/**m2**.

A folding boxboard is a container made of a great variety of raw materials, fit for production of foldable cartons. The carton must possess a force allowing its folding and characteristics apt for printing.

A type of folding boxboard consists in special cartons for foodstuffs. This group comprises solid cartons of cellulose, like cartons for frozen food, cartons for ice-cream and for milk.

Frozen foodstuffs are sometimes covered with thin plastic before being inserted in cartons. Some frozen foodstuffs are sold in foldable cartons without any extra protection and are therefore not prone to dehydration or oxidization.

There are many types of packing made with card board, for example one piece cartons, two pieces cartons with a cover etc. The external packing for fresh fruit and vegetables should permit an adequate circulation of air, so that goods contained therein may keep the desired temperature and the elimination of products of breathing/sweating.

This is not necessary for food, such as frozen meat, which do not “breathe” and do not produce metabolic heat.

For some products an external packing with holes in its walls is employed because cooling takes place after internal packagings are placed in the external ones.

For external packagings which may be subject to dampness and/or wetting a treated carton should be employed, that is to say a carton imbued with materials which render it waterproof or semi-waterproof (wax, plastic materials etc.). Cartons assembled with glue should be produced using a waterproof adhesive.

Resistance to compression of non-treated cartons is much lower when there is absorption of humidity. Absorption of dampness may be caused by sweat, for instance when cartons containing frozen products undergo thermo-hygrometrical variations.

Everything which has been discussed up to now may be summarized in a few parameters which should be verified:

- temperature (goods and means of transport);
- adequacy of packing considering the material which must be carried;
- verification of possible dispersions (handling, transhipment, loading and unloading);
- check of the means of transport;
- compatibility of the product with the period of storage and transport.

PREPARATION OF THE CONVEYANCE FOR TRANSPORT OF ALIMENTARY GOODS

The means of transport and reefer containers have a reduced capacity of quickly modifying the temperatures of alimentary products. For this reason it is necessary that cargo is at the correct keeping temperature and that the means of transport/container is pre-refrigerated so as to bring it at the identical temperature of goods.

The transport apparatus is designed to keep the product at the set temperature. The means of transport do not have a cooling capacity sufficient to reduce the temperature of cargo to the required level in a short time, therefore alimentary products must be at the correct temperature when they are loaded.

When perishableness of foodstuffs is high, it is necessary to maintain, also during transport, the thermo-hygrometrical conditions specific to each single product, so as to avoid decay of the qualitative characteristics.

The products loaded on the means of transport must already be refrigerated at the correct temperature when being loaded. If the temperature of food, when loaded, is higher than the desired one, the lowering of temperature during transport takes place very slowly, so possibly spoiling the qualitative characteristics of the product.

Always in this connection, it is advisable that the conveyance, before beginning loading operations, is refrigerated at the correct temperature and that loading is carried out as quickly as possible, if it be the case in conditioned surroundings.

The type of stacking in the loading area must allow to maintain uniform conditions of temperature and humidity. In this regard it is useful to remind that, in case of frozen or deep-frozen products, the rmic changes are the main cause of aggregation of ice crystals and subsequent sublimation of same with sweat and new forming of crystals on the walls of protective packing of the product.

This brings as a consequence the dehydration of the superficial part of foodstuffs, changes in colour and greater loss of liquids during defrosting.

Once loading is completed, the refrigerating system of the conveyance must be immediately switched on and must remain in working order also during stops.

As for transport of fruit on controlled temperature ships, particular care must be taken in respect of preparation of foodstuffs.

The packing of fruit and vegetables, usually, is carried out through crates, small cases, cartons, bins, trays or baskets following internationally standardized procedures. Once this phase is completed products must be kept in refrigerator cells where the process of withdrawal of field heat and metabolic heat generated by vegetables may begin.

Loading and stowing operations must be carried out by expert personnel following a stacking scheme adequate for the product, the length of voyage, the nature of packing.

Particular care must be taken by the shipper of foodstuffs as to instructions which must be given to the carrier for a correct execution of the transport.. In this connection, precise and detailed indications must always be given regarding characteristics of foodstuffs and, in particular, regarding the preservation temperature of goods, requiring that all information is written on the transport document so as to be easily readable by all the transport operators who, obviously, must take due note of such information to safeguard cargo.

In connection with execution of the transport it is recommended that personnel employed is trained with professional characteristics apt to understand the ample range of risks to which

foodstuffs may be exposed during transit and rendering them able to intervene, if necessary, so as to evaluate adequacy of stowage on board the vehicle, carry out the frequent checks during transport (checking temperatures, good working order of the refrigerating plant etc.) and correctly intervene in case of breakdown or accident to minimise damages (e.g. knowledge of the whereabouts of cold stores nearest to the place of occurrence).

Pre-refrigeration of the means of transport

Pre-refrigeration of the carrying conveyance is not codified by precise rules as there are many variables which must be taken into account and they are not all predeterminable: external temperature, cooling capacity of the unit and insulation of same (K values).

It is fundamental that goods are already at the temperature required for preservation at the time of loading save a few exceptions which we shall deal with further on.

If the temperature of cargo is already the correct one it will be useful but not strictly necessary to pre-refrigerate the means of transport.

In some countries there exists a recommended procedure for the loading of frozen products which provides for functioning of the refrigerating unit for about one hour at the desired temperature.

In the case of transport carried out by ships, reefer containers, refrigerator trucks or wagons there is a series of pre-transport checks, followed by interventions if necessary, which may be summarized as follows:

- metallic structure and weldings
- check of the wooden, rubber, plastic, resin parts etc.
- check of the door gaskets
- check of the refrigerating plant and of the electronic/control parts
- washing and sterilization of the loading area
- supplying of fuel, oil, cryogenic gas, cooling liquids, pipes for feeding of cold-producing liquids and/or gaseous fluids
- check of the electric and electric supply appliances

Subsequently particular care must be taken as for “loading area pre-refrigeration”, meaning by this operation the preparation of conveyance refrigerating it up to the desired temperature, that is the temperature at which the foodstuff will have to be kept during all the voyage.

This operation will allow to prevent increase of temperature of products, also avoiding the conditions of difference in temperature which would cause condensation of steam within the loading area.

Likewise, loading of foodstuffs must be carried out, if possible, in optimal conditions so as not to “stress” the product submitting same too high temperatures for long periods of time. These conditions are obtained avoiding that loading operations are effected during the hottest hours of the day and carrying them out in refrigerated premises or, if this is not possible, reducing to the minimum the duration of loading and carrying out such operation during the first hours of the morning, when outside temperatures are considerably lower.

Insulation of the means of transport

The transport apparatus which must be employed for perishable foodstuffs must be well insulated to delay flow of warmth through its walls. The insulating quality can be measured and the unit of measurement commonly used is the K coefficient. in order to obtain an ATP certificate

for international carriages of frozen perishable foodstuffs, the K coefficient for the apparatus must be 0.4 w/m2 per C or less: the lower the value the better the thermic insulation.

Plastic and especially polyurethane are the most common materials used as thermic insulators.

In the case of means of transport for road carriages the thickness of insulating material is usually about 70-80 mm for lateral walls and about 100 mm for the roof and the floor. Following betterments in the insulating technology of polyuretan, nowadays some producers employ lateral walls 60 mm thick.

Plastic has a low K value, it is light, watertight and is not subjected to the action of corroding agents.

Recent building technologies for road vehicles prescribe employment of sandwich panels, that is to say walls built with several interposed layers of materials such as laminated plastic, fibreglass, stainless steel and aluminium. Sandwich panels have a low K factor notwithstanding that the thickness of the walls is reduced in comparison with conventional technologies.

The outside coating must reflect the radiation of heat by employing reflective paints which reduce the heat load, so as to obtain a better result.

For reefer containers usually smoothed metal is employed for the external walls (stainless steel or aluminium).

The door gaskets must always be kept in good conditions and in good order, because if there are infiltrations due to wear and tear or to damages to same it is obvious that insulating materials, even if of very good quality, cannot guarantee the tightness required to maintain the set temperature.

All insulating materials deteriorate with time and therefore need checks and periodical inspections to keep the necessary conformity classes.

Stowage and lashing of goods

Lashing of goods inside the loading area must be performed skilfully so as to avoid shifting of cargo which would cause:

- crushing of packing with subsequent damage to content
- obstruction of the air flow pipes, with negative consequences on safe preservation of cargo

It is therefore necessary that the whole of packages forms an unique body with the structure of the means of transport.

If in between the packages, or between same and the walls, there are empty spaces, it is necessary to arrange structures to absorb, space, etc. so creating conditions avoiding shifting of packages, without contemporarily creating preferential air draughts.

Synthetically stowage must be carried out in such a way as to allow a better preservation of products being carried and the contrivances are different for loads with and without development of heat.

In the case of carriage of goods without development of heat (e.g. frozen or deep-frozen products) the packages will have to create a mass as compact as possible so as to be integrally swept by the cold air.

In case of carriage of goods with development of heat (e.g. fresh fruit and vegetables) it is necessary to maintain free circulation of air everywhere in the loading area and throughout the cargo.

In all cases goods must be loaded already at the preservation temperature or anyway as near the same as possible, except particular cases which will be dealt with product by product.

Besides thermic conditioning and hygrometric conditioning (that is through scheduled changes of air), also modification and control of the atmosphere surrounding the cargo may be carried out (Controlled Atmosphere).

The method of controlled atmosphere is applied fundamentally in containerized transport of vegetables in general and consists in the variation of the chemical composition of air acting from the outside on the percentages of oxygen, carbon dioxide and nitrogen.

Refrigerated vehicles allow to carry out transport of products with marked characteristics of perishableness, also for long voyages, but provided that the vehicle is in perfect working order and that packing of goods and stowage of same are carried out skilfully.

In order to allow the thermic conditioning plant to operate efficiently, it is necessary that stowage of goods is carried out in such a way that air can penetrate in all points of the cargo and that therefore same has a stowage "permeable" to passage of air. When inside cargo there are differences in temperature and relative humidity we are sometimes inclined to think that trouble is due to insufficient power of the conditioning plant. In fact the cause of this often resides in defective circulation of air owing to wrong placing of goods inside the loading area.

The following are contrivances of a general nature relevant to transport of perishable foodstuffs:

- cargo must be introduced in the conveyance at the prescribed preservation temperature or anyway with a very reduced thermic differential.
- distribution of cargo must be uniform.
- Transport must take place without opening doors/scuttles of the loading areas.

It is important to consider that cargo, correctly stowed, affords its contribution to the global economy of transport, that is to say it must be considered integral part of the refrigeration process. This is why it is necessary to give it adequate characteristics of surface and resistance to passage of air so as to ensure the regular carrying out of necessary thermal interchanges.

In this connection three types of cargo should be considered:

- *Cargo with development of heat*

  This type comprises fresh perishable products such as fruit and vegetables which develop a metabolic activity with production of heat and gas. The primary aim of preservation at a set temperature is to slow down (without causing irreparable damages) the metabolism of products. The purpose of circulation of air is to remove heat where it is produced and to render uniform as far as possible the temperature of cargo.

  As we are dealing with fresh products also the relative humidity must be checked, so as to obtain the right equilibrium between dehydration and prevention of fermentation phenomena.

  The stowage of cargo must permit a good circulation of air; this may be obtained acting on packing by applying linings along the edges, or spacing them out by purposely built regulators placed between packages upon loading.

  In this way a permeability of cargo to passage of air is obtained, which must be verified both along vertical and horizontal planes.

  It is therefore necessary that the structure of cargo provides for outflow routes for air, represented by passages made spacing out packagings.

  As for control of the gas products of metabolism, this is given by the air changes which must be carried out inside the loading areas as per instructions provided by shippers.

  In particular the most common sources of heat which may be present inside the loading area are listed here below:

  - heat conducted through insulation from external hot air;
  - heat absorbed from sun rays or from the road;
  - infiltration of heat from external hot air through small holes and cracks;
  - heat from the evaporation fan and from the engine;
  - heat from internal electric lights, if any;
  - heat introduced through open doors (very important in local distribution);
  - residual heat coming from air present in the loading area, and residual heat in insulating materials and in the internal cladding;

- alimentary products with a temperature higher than the requested one;
- metabolic heat.

– *Cargo without development of heat*
In consists in frozen or deep-frozen products , making up cargo which on the whole is more stable, hom ogeneous as for tem perature and with well defined needs as for therm al interchanges.
During trans port o nly tem perature will have to be maintained by com pensating therm ic dissipation. The more compact the cargo structure, the lower the thermic dissipation.
Particular att ention m ust be paid to free cir culation of air which must envelop the largest possible external surface of cargo.
Adequate passages for circulation of air must then be left all around cargo, avoiding tho ugh forming a direct communication between output and suction.

– *Cargo consisting in fresh meat*
In the particular case of transport by truck of fresh meat (part s of carc asses, carc asses, quarters, hams etc.) carried hangi ng, t he uniform distributio n of c irculation of air for such cargo is very difficult.
Inconveniences caused by possible short-circuits in the circulation of air will be therefore tentatively a voided by pa ssages for th e distribution of flow set up on the ceiling of the loading zo ne and b y stow ing g oods so as to allow the flow of air to envelop the highest possible number of packages and the greatest possible surface of each.

Examples of stowage

The three more frequently used models of stowage may be summarized as follows:

– *Lengthwise channels model of stowage*
In this m odel of stowage air is convey ed from pipes to the rear zone, enters the lengthwise channels and, after having cooled the cargo, reaches the front wall where it is sucked.
It is i mportant that sufficie nt space for air to circulate is left b etween the re ar wall and the last transver sal row. Carg o is therefore fixed in that point with a structure per meable to air , for example pallets placed vertically if doors have no internal bulges.
Great attention must be paid to the effect that cargo does not occlude output nor return of air. This is achieved by placing a series of vertical lists which have b een previously fixed to the wall.
Lengthwise channels stowage is appropriate for crates with a woo den or cardboard cover. It is not feasible when cargo is palletized.

– *“Funnel” or “chimney” model of stowage*
The m odel is im plemented when cargo is palle tized or is m ade up of d ifferent t ypes of packagings, as in the case of carriage of several shipments of different products.
Packagings are stacked in a colu mn, at the cen tre of which a vertical channel f or passage of air is left.
An i mpermeable w adding must be ins erted betw een the rear w all and the l ast transve rsal stack, becaus e air would find here an e asier way to flow out and would avoid the channels placed within the cargo. The return flow starts from the rear.

– *Uniform permeability model of stowage*
The model was contrived by the Railway Experimental Institute and was tested in many experimental carriages also in the ambit of the CNR "Containers" Project.
It implements a considerable and uniform permeability to circulation air, together with a good compactness of cargo, to the advantage of the safety of goods being carried.
In this model of stowage the effective distance in between packagings may be reduced to about 10 mm and, as against a thermic efficiency calculated at 95%, it brings about a decrease of available volume of the cargo unit from 4% to 8% according to the dimensions of packing.
For the execution of this model of stowage packagings are stacked leaving a space around the four vertical walls, so that conditioned air filters through cargo, descends to the floor, from which it is conveyed towards the suction opening.
Canalization is achieved by applying thin lists on the vertical corners of packagings.
The model of stowage described above results the most effective and safe one for carriage of fruit and vegetables when packages are not palletized.

LOSS PREVENTION: RECOMMENDATIONS FOR SHIPPER AND CARRIER

Insurers, on the basis of experience acquired in the field handling claims, have drawn up a series of recommendations meant for the shipper (consignor/freight forwarder/carrier) and/or the carrier.

The shipper

It is useful to remind the loader of the importance of five points which constitute, all together, the main recommendations for preparation of goods for transport, that is:

1. program with the carrier date and time of loading so as to allow him to get organized in time;
2. adequately pre-refrigerate goods (refrigerated alimentary products) before they are placed inside the refrigerator vehicle;
3. verify adequacy of conveyance and pre-refrigeration of same;.
4. provide for goods to be adequately stowed so as not to hinder the circulation of the air within the cell; refrigerator conveyances have inside them easy graphic evidence (warning lines and signals) which must be observed to permit constant circulation of air;
5. provide carrier with all necessary instructions for carriage and preservation goods and in particular indicate on transport documents the temperature to be kept during carriage; in particular the thermometric scale employed must be made explicit: Celsius or Fahrenheit.

The carrier

The carrier is responsible for keeping of the cargo. This liability extends also to damages due to variations in temperature (art. 1693 of the Civil Code).

The following recommendations are therefore provided.

Transport document

- Always verify the transport document, also to get to know the exact temperature to be kept during transit.
- Indicate who carries out stowage and who unloads goods (writing it down on the transport document).
- Take immediate exceptions on goods at time of loading, indicating on the transport document if packing is in bad condition, if goods have not been pre-refrigerated or are wet, soft or in evident damaged condition.
- Check the thermometric scale indicated on the transport document (Celsius/Fahrenheit).

Beware!

If the temperature of goods is higher than the one indicated on the transport document (refrigerated goods not adequately pre-refrigerated or frozen/deep-frozen goods in bad condition): refuse to carry out loading of same.

Preparation of the conveyance for transport

- The “refrigerator cell” of the truck must always be perfectly clean and odourless..
- The refrigeration plant must be started before loading the goods for an appropriate test and to pre-refrigerate the ambient.
- Program with shipper the date and time of loading.
- Do not open the doors of the refrigerator cell before beginning loading of goods.
- Turn off the refrigerating plant during loading.
- Check the goods which is being loaded (verify that it corresponds to transport documents).
- Always measure the temperatures inside the refrigerator cell, before, during and after loading.
- If there are no indications on the waybill, remember to set the temperature provided for by law according to the typology of goods.

Checks during transport

- Remember to defrost the plant about half an hour after it is switched on and, if doors are opened often, repeat such operation every 4/6 hours..
- After each defrosting check the correct erogation of “cold”.
- In case there is no thermometric recorder/alarm in the driving cabin, stop every two hours, in case of refrigerated transport, and every four hours, if frozen, to read the temperature indicated on the thermometer placed outside the refrigerating group and to verify on the panel if all parameters are correct; in case automatic defrosting is not available, effect several manual defrostings.
- If cargo consists in greens/vegetables/fresh fruit and the temperature is at least five degrees higher than the one on the thermostat, lower the thermostat by three degrees or even turn off the unit, open the cargo airing doors and also the box doors (depending on the external temperature) to let the heat out. If instead temperature is too low in comparison with the set one, turn off the unit and, if it be the case, always depending on the outside temperature, open the doors.
- In case the cargo consists in fresh meat hung on hooks, the same principles apply as the preceding point, except opening the doors to avoid the formation of sweat on the surface of meat (in this case the outside temperature and degree of humidity in comparison with the ambience where meat is kept should be evaluated beforehand)
- For all other refrigerated products, if temperature is too low or too high, it is always advisable to temporarily turn off the unit. The continuity of checks is fundamental to prevent and/or diminish damages in case of refrigerated products. Usually in this case carriages have a short duration.
- In case of frozen/deep-frozen products, if temperature is dangerously five degrees or more higher than the one of the thermostat, the latter must be lowered to the minimum and – if after a few hours there is no improvement – the unit must be turned off without ever opening the doors.

Measures to take in case of breakdown of the vehicle or of the refrigerating plant

Once a breakdown which could presumably lead to damage to goods is detected, it is appropriate to take the following initiatives if the destination warehouse is not nearby:

- contact one’s own firm and provide information about the damage;
- apply to a repair shop specialized in refrigerating plants to carry out the necessary repairs, considering the advisability of harbouring goods in the nearest cold store and/or of transhipping same onto another refrigerator vehicle.

Insurers have prepared for this purpose a list of the stationary refrigerator structures present in Italy where to harbour goods in case of damages, not immediately repairable, to the refrigerating plant of the truck.

The listed cold stores must be contacted from time to time, in case of need, so that they may verify their availability at the moment, both in terms of space and in connection with typology of goods.

A list of some repair shops specialized in refrigerating plants, present on the national territory, has also been prepared.

To ensure a good working order of the refrigerating plant it is vital to carry out a periodic maintenance of same and of the truck on which it is fitted, and it is necessary to check:

- refrigerating plant engine
- electrical system
- box
- refrigeration

It is also essential to carry it out in order to obtain from the insurer the requested refund as road carrier's liability policies provide for the obligation to furnish the invoices relating to the half-yearly overhauls of the refrigerating plant, as well as the invoices relevant to repairs of the breakdown which has caused the damage.

The ANIA site (www.ania.it) shows the complete and up-to-date set of recommendations regarding the risks of transport of perishable goods by motor vehicles also comprising the list of repair shops and cold stores.

Part 4

Insurance covers

INSURANCE COVERS

Elements for evaluation

The elements for evaluation of a transport risk are usually several and, in the case of transport of goods subject to thermo-climatic alterations, such elements inevitably increase.

The risk being dynamic, the various typologies of policies which may be offered, available time and other factors often complicate the work of those who must evaluate the problems related to transport.

Moreover not always in the evaluation of a risk all variables may be determined and evaluated beforehand and this uncertainty leads to making estimates and approximations which must take into account the available data and the experience acquired with time.

A schematization of the components of the risk is in many cases vital in order to find the appropriate links and to efficiently ponder the weight of each factor of the risk.

The risks of transport of goods may be schematically grouped into four categories:

- risks relevant to the voyage
- risks related to the means of transport
- risks related to the packaging/stowage
- risks relevant to the nature of goods

This schematization, which applies to all types of transport, in case of carriage of perishable goods must lead to consider distinctive and peculiar elements.

Risks relating to the voyage

It is evident that the length of the voyage to be carried out is proportional to the risk. In the case of transport of perishable goods such evaluation, however, is complicated by a series of factors:

- During a short-range transport goods are not usually subject to decay as the times of carriage are brief. On the other hand such typology of transport mainly relates to the distribution phase and therefore often problems arise due to the frequent opening of the means of transport with consequent variation in temperature inside it. Modalities and time needed to carry out unloading operations must be therefore taken into account in this case.
- During long-range transports there is an increase in the probability that there may be an interruption in the functioning of the machinery which must maintain the set temperature. On the other hand these are usually full loads of considerable mass. Such mass allows to maintain for long periods a constant temperature thanks to the insulation of the means of transport. In this connection it is estimated that not less than 8 hours of interruption in the delivery of cold is the time necessary for damage to take place during land transport of perishable goods, while this limit increases to 24 hours for sea transport considering the employment of reefer containers with a much greater mass and better insulated. In these cases, therefore, it should be borne in mind that there is the possibility to detect the possible malfunctioning of the refrigerating machinery and consequently the possibility of carrying out the necessary repairs in good time or harbouring goods in an adequate cold store.
- The characteristics of the regions and the level of economic development of the countries through which the voyage takes place are important with regard to the possibility of organizing within brief a possible recovery intervention following malfunctioning of the

refrigerating machinery. The network of specialized repair shops and the possible presence of cold stores along the route should therefore be verified.

– The temperature outside the means of transport is another element to be considered. There derives that the season and the climate in general greatly influence the risk and must be duly evaluated.

Risks relating to the means of transport

The means of transport usually employed are: truck, railway, ship and aircraft. Each means of transport has distinctive characteristics in connection with maintaining the cold chain. Let us examine the characteristics of each:

– *Truck with refrigerator cell*
About the technical characteristics of refrigerator cells, insulation, locks of the loading scuttles, refrigerating machineries please refer to Part 2 (page 48 and following pages).
As for the elements for evaluation of the risk it is clear that each building characteristic mentioned above is of great importance.
As a consequence insurance covers on goods carried under controlled temperature provide for the necessity to carry out periodic examinations of the efficiency of all parts involved.
Maintenance of the appliances is very important and, usually, users verify the efficiency of the machinery more frequently than requested by insurers (6 months).
However often problems arise in this connection as checks may be carried out in carrier's internal workshops so that there are no invoices, necessary to prove that maintenance has been effected. Being aware of such procedures can certainly be useful in the phase of policy underwriting.
From the point of view of evaluation of risk it should be borne in mind that the mass being carried strongly affects the keeping of temperature in case of stoppage of the delivery of cold. The greater the mass the slower the increase in temperature in the cell. As a consequence, with the same refrigerating machinery, a partial load will be more prone to decay than a full load.
Transhipments of perishable goods from one refrigerating cell to the other are particularly delicate operations owing to the difficulty in guaranteeing continuity of the "cold chain".
In the case of transfer of goods from and to storage warehouses the modality of carrying out operations in uniform temperature ambience should be evaluated (in this connection specialized warehouses effect transfer linking directly the truck openings to the warehouse doors by appropriate vestibules).
Employing different means of transport for the same carriage complicates the evaluation of risk and determines further problems relating to transhipments.
In transhipment of reefer containers between truck, ship and aircraft problems arise with regard to handling of the appliances apt to maintain the fixed temperature (an electric plug malfunctioning is often the trifling cause of considerable damages).

– *Semitrailer with reefer container*
In this case further elements to be evaluated add themselves to all the elements of risk previously described for transport by truck with refrigerating cell:
  a) plugging of the refrigerating machinery of the container to the power supply of the truck;
  b) origin of container, which may have carried out previous carriages with different means of transport (e.g. by sea).

It is useful in these cases to evaluate whether it is necessary to arrange for a survey when accepting goods.

– *Refrigerator wagon*
In Italy this type of transport is not adequately exploited.
The problems related to controlled temperature transport are similar to those explained above regarding containers. It must be further taken into consideration that carriages by rail are usually only one leg of a voyage carried out by different means of transport and this must be adequately evaluated.

– *Ship*
Transports by sea on ships equipped with refrigerator cells (Reefer) are totally specific and the relevant problems relate to the type of goods being carried.
Much more frequent are transports by sea of goods in reefer containers.
The same elements of evaluation of risk highlighted for trucks apply to these carriages.
Further problems are the long periods of transport and the impossibility to harbour/recover goods in case of malfunctioning of the refrigeration machinery.
Damages in these cases involve the entire cargo of container and this must be duly considered in evaluating the risk.
A further element to evaluate in this kind of transport is that containers are usually stacked one on top of the other.
There are frequent cases of structural damages to the cell caused by container loading and unloading operations.
In this connection it must be borne in mind that insurance covers for transport of perishable goods are usually closely linked to the possible breakdown or accidental stoppage of the refrigerating machinery. The typology of damages due to structural damage to the cell needs, in case it should be covered, endorsement of specific extended rules comprising this kind of damages.

– *Aircraft*
This means of transport is not usually employed for great volumes of goods under controlled temperature.
Instead, goods in liquid nitrogen containers are often carried by air exactly because the period of transport is usually brief, so reducing this component of the risk.
All what has been indicated above for rail and sea carriages regarding preliminary and subsequent voyages, relevant transhipment and stowage, also applies to transport by aircraft.

Risks relating to packing/stowage

Packing of goods under controlled temperature has a function linked not only to fractioning of cargo so as to facilitate its handling and to protection from mechanical shocks due to transport, but also to reducing to the minimum thermic variations during loading and unloading. For this reason goods are usually packed with insulating materials. Non-employment of such packagings brings about a special evaluation of the risk during loading/unloading and possible transhipment.

Stowage, in the case of perishable goods, must take into account, besides the necessity to optimize the loading capacity of the conveyance, also the necessity to keep an uniform and constant temperature inside the cell.

The system of distribution of cold inside the cell is of great importance because if there is no free circulation of air around items which must be refrigerated it is not possible to guarantee an uniform temperature within the cell.

It is therefore necessary to evaluate positioning of goods inside the cell so as to avoid that they may block the air output openings.

The danger of the opening s supplying cold air being blocked by sweat must not be neglected. The modern systems of refrigeration provide for automatic systems periodically eliminating sweat.

The presence of a chronothermostat and the check at fixed intervals of the temperature inside the container is fundamental to timely detect possible malfunctionings and in this connection insurance covers provide for a periodic check of temperatures and examination of data.

A particular mention must be made to liquid nitrogen appliances, once used also for containers, today they are limited to particular needs linked to the necessity for some goods to keep very low temperatures, which cannot be reached with normal engine machineries.

The main problem of such systems is that, once the nitrogen charge put in at the beginning of the voyage is used up, there is not usually the possibility to recharge on case of delay in delivery. Modern appliances, any way, have an autonomy of several days, which is normally more that sufficient to limit the effects of a possible delay in delivery.

Risks relating to the nature of goods

The nature of goods is an essential element in the evaluation of a risk of transport under controlled temperature as it the perishable nature of goods itself which determines specific modalities and problems.

Perishable goods have perishableness characteristics which are different from one to the other and the related problems are therefore vary varied.

Mostly frozen goods must be insured, and in this case the evaluation of risk is sufficiently uniform and independent from the nature of the goods, except if the required temperature must be predetermined from time to time and fixed by the shipper.

It is anyway a duty of the shipper to clearly indicate the temperature to be kept, informing the carrier about this and writing down the due instructions on the document of transport.

There are then goods which need to be carried at temperatures comprised in a precisely determined range, for instance flowers, fruit and fresh vegetables. In this case knowing the organoleptic characteristics of goods, the times and modalities of alteration of goods is fundamental in the evaluation of the risk.

There are then goods which must be carried at extremely low temperatures, which require specific appliances and containers, working on liquid nitrogen.

For a correct evaluation of the risk it becomes therefore essential to be in possession of adequate tools to deepen the knowledge of the organoleptic characteristics of goods. In this respect it is useful to avail oneself of an up-to-date merchandise encyclopaedia or access to internet, where it is possible to acquire useful information from specific sites.

Underwriting a risk on goods carried under controlled temperature

Variations in temperature during a transport of perishable goods is only one of the many components to evaluate when underwriting the risk and the very short time available to insurers generally leads to making rough estimates.

When evaluating a voyage policy many elements of risk would be ascertainable in a precise and thorough way, but usually this type of cover is requested at the time of loading or little before. This makes it necessary to rely on experience acquired in similar cases.

In time policies some aspects may be more thoroughly investigated (e.g. the nature of goods, packing etc.), while on the other hand other elements are assessable with difficulty (e.g. abiding by certain provisions in case of carriage entrusted to a carrier).

Knowledge of the matter and experience helps to limit as far as possible the range of variables to be verified so as to have a clearer view of the costs and risks of the insurance cover, the regulations in force and the possible loss prevention interventions to be carried out.

The approach is then different depending on whether the policy contractor is the owner of the goods, the carrier or the freight forwarder.

- In the first case as against a thorough analysis of the nature of goods, voyages, packing and means of transport, often it is impossible to verify that the provisions to fulfil during transport have been observed, as carriage is entrusted to third parties.
- When the policy contractor is the carrier, judgements prevail relating to the laws which limit carrier's liability. Such laws do not consider the nature of the goods being carried, but existence of liability on the part of the carrier must be thoroughly evaluated in the case of transport of perishable goods.
- In the case of policies taken out by freight forwarders, the firms producing goods, the means of transport and the destinations are very varied. The variables to take into account are therefore very many and it is necessary to draw up policies which adapt to the various cases as for regulations and costs.

Insurance covers, in case of transport of perishable goods, provide for specific clauses.

The policy rulings are usually structured so as to regulate most cases, but the underwriter must adequately integrate the standard clauses in the case he should insure risks with peculiar characteristics.

A good knowledge of the texts which are usually employed, both by the Italian insurance market and by international markets, is therefore essential.

In this connection here below are summarized the main characteristics of the covers more often provided by the Italian market (Enclosures 1 and 2) and the texts of the clauses usually employed in international trade ("Institute" clauses – Enclosure 3).

Enclosure 1 – main characteristics of the covers more often provided by the Italian market (insurance on goods)

Usually insurance on goods to be carried under controlled temperature is provided by a specific additional clause as an extension to the basic policy on goods.

Generally damages deriving from variations in temperature are payable if:

a) caused by : breakdown or accidental breakage of the refrigerating equipment resulting in stoppage or malfunctioning of the equipment itself for a minimum period of 24 consecutive hours during sea transport or 8 hours during air or road carriage;

or

b) resulting from:
   i) fire, lightning, explosion;
   ii) road, rail or sea accident involving the means of transport;
   iii) theft or armed robbery provided such risks are covered by the policy.

Among the exclusions usually present are damages deriving from:

a) incorrect setting of the thermostat;
b) non-prerefrigeration of the truck or container, when necessary;
c) non-ventilation or poor ventilation;
d) non-prerefrigeration of goods.

Insurance against damages deriving from variations in temperature is usually limited, in case of stopping or lying of the goods covered by the policy, to a period of a few days in every location.

For transport carried out by the policy Contractor with vehicles he owns or runs, as a rule the following insurance warranties are afforded, provided that

a) the vehicle is equipped with a machinery fit to produce and maintain the temperature required for preservation of the goods being carried;
b) the Contractor, during the six months preceding underwriting of the insurance, has had a specialized workshop checking and maintaining the above-mentioned machinery and that such check and maintenance are repeated, subsequently, every 6 months;
c) the Contractor, or whoever in his place, monitors the temperature of the cells with the thermometers provided , writing it down if the vehicle is not equipped with a suitable temperature recording instrument, both during transport and during possible stops, at intervals of no more than:
   - 8 hours for deep-frozen or frozen products
   - 4 hours for refrigerated or fresh products.

In addition to the usual obligations in case of damages, the Contractor – or whoever in his place – in case of a potentially detrimental breakdown or accidental breakage during transport carried out with vehicles he owns or runs must apply to the nearest specialized workshop to have the breakdown or failure ascertained and, if it be the case, have the necessary repairs carried out.

If the time necessary for repairs and the remaining length of the voyage are such that it is reasonably foreseen that damage may occur or worsen – insurance cover remaining anyway in force during this period – the Contractor, or whoever in his place, must:

- temporarily give shelter to the goods in the nearest refrigerated warehouse

or

- ask for the intervention of a rescue refrigerated truck by which the remaining part of the voyage may be carried out.

The Contractor, or whoever in his place, must show the Survey Agent or Surveyor – appointed to intervene as per policy provisions – the recording of the detected temperatures.

Usually it is required that the Contractor - in order to put forward a claim, in connection with transport carried out by vehicles he owns or runs - must produce

- the invoices issued by specialized workshops indicating in detail the work carried out and the parts which have been replaced during the last two checks on the refrigerating machinery;
- the invoice relating to the repair works carried out after the breakdown or accidental failure;
- the sanitary/phytopathologic certificate of origin of goods (when provided for).

Finally, deductibles may be possibly provided for in connection with payment of damages deriving from variations in temperature.

Enclosure 2 – main characteristics of the covers more often provided by the Italian market (carrier's liability insurance)

Usually carrier's liability insurance for damages to goods to be carried under controlled temperature is afforded by a specific clause in addition to the basic policy which, as a rule, does not include cover of goods to be carried by refrigerated trucks or by isothermic trucks or by trucks not equipped with refrigerating machineries.

1) Perishable goods carried by refrigerated trucks

As a rule liability for loss or damage to perishable goods resulting from variations in temperature is covered provided that such variations are due to:

a) breakdown or accidental failure of the refrigerating machinery resulting in stoppage or malfunctioning of the machinery itself;
b) events occurring during transport which cause damages leaving clear traces, ascertainable by the Survey Agent or Surveyor, on the truck or on the refrigerated cells such that functonality regarding preservation of goods is impaired, wholly or partly;
c) theft or stealing of goods always provided that such events are included in the basic cover.

Cover is afforded on the basis of certain fundamental conditions:

a) that the truck is equipped with machinery fit to produce and maintain the temperature required for preservation of the goods being carried;
b) that the Insured, during the six months before underwriting the policy, has had the above-mentioned machinery checked and maintained by a specialized workshop and that such check and maintenance are renewed, subsequently, every 6 months;
c) that the Insured, or whoever in his place, monitors the temperature of the cells with the thermometers provided, writing it down if the vehicle is not equipped with a suitable temperature recording instrument, both during transport and during possible stops, at intervals of no more than:
   - 8 hours for deep-frozen or frozen products
   - 4 hours for refrigerated or fresh products.

Among the Exclusions usually present are also damages deriving from:

a) incorrect setting of the thermostat;
b) non-prerefrigeration of the truck, when necessary;
c) non-ventilation or poor ventilation, when same is attributable to incorrect stowage carried out by and under the responsibility of the Shipper;
d) non-prerefrigeration of goods.

As a rule cover begins with loading of the goods on board the truck and expires with unloading from same; it remains in force during possible stops of goods – always on board the vehicle – before, during and after the course of voyage, provided that such stops fall within the scope of the ordinary course of transit; it expires anyway 3 days after arrival of the vehicle at final destination provided that the refrigerating machinery is kept regularly working.

Included in t he cover afforded is almost alway s the possible liabilit y of t he Insured for l oss or damages occurring while goods are being loaded, unloaded or transhipped.

In addition to the usual obligations in c ase of ac cident, the Insure d - or whoever in his place – in case of a potentially detrimental break down or accidental failure during transport carried out by vehicles he owns or runs must

a) apply to the nearest specialized workshop to carry out repairs of the breakdown or failure;
b) have the goods tem porarily sheltered in the near est cold store, i n case the ti me needed f or repairs and the rem aining length of voyage ar e such that occurrence or ag gravation of damages may be reasonably foreseen, cover remaining in force during such period,

or, as an alternative to the above

ask for the intervention of a rescu e r efrigerated truck by which the re maining part of voy age may be carried out;

c) show the Sur vey Agent or the Survey or – who intervened as per policy pro visions – the recording of the temperatures ascertained.

The Insured is also asked to produce:

a) the invoices issued by spe cialized workshops indicating i n detail the work carried out and the parts which have been replaced durin g the last two c hecks on the refrigeratin g machinery;
b) the invoice relating to the repair works carried out after the breakdown or accidental failure;
c) the sanitary/phytopathologic certificate of origin of goods (when provided for).

Finally, deductibles may be possibly provided for in connection with payment of damages deriving from variations in temperature (except those occurring as a consequence of road accidents).

2) Perishable goods carried by isothermic trucks not equipped with refrigerating machinery

Liability for loss or damage to perishable goods de riving from variations in temperature is usually covered also in case of:

a) the truck running off the road and not being able to get back onto it with its own means;
b) fire, explosion of the vehicle;
c) overturning, crash and collision of the vehicle;
d) fire, collision, crash or submersion of the ferryboat;
e) the vehicle falling into water or onto ground during roll on or roll off from the ferryboat;
f) theft or stealing of goods provided that such occurrences are included in the basic cover.

Enclosure 3 - texts of the clauses usually employed in international commerce ("Institute" clauses")

1/1/86

INSTITUTE FROZEN FOOD CLAUSES (A) - Excluding Frozen Meat

RISKS COVERED

1 This insurance covers, except as provided in Clauses 4, 5, 6 and 7 below,

1.1 all risks of loss of or damage to the subject-matter insured, other than loss or damage resulting from any variation in temperature howsoever caused. — Risks Clause

1.2 loss of or damage to the subject-matter insured resulting from any variation in temperature attributable to

1.2.1 breakdown of refrigerating machinery resulting in its stoppage for a period of not less than 24 consecutive hours

1.2.2 fire or explosion

1.2.3 vessel or craft being stranded grounded sunk or capsized

1.2.4 overturning or derailment of land conveyance

1.2.5 collision or contact of vessel craft or conveyance with any external object other than water

1.2.6 discharge of cargo at a port of distress.

2 This insurance covers general average and salvage charges, adjusted or determined according to the contract of affreightment and/or the governing law and practice, incurred to avoid or in connection with the avoidance of loss from any cause except those excluded in Clauses 4, 5, 6 and 7 or elsewhere in this insurance. — General Average Clause

3 This insurance is extended to indemnify the Assured against such proportion of liability under the contract of affreightment "Both to Blame Collision" Clause as is in respect of a loss recoverable hereunder. In the event of any claim by shipowners under the said Clause the Assured agree to notify the Underwriters who shall have the right, at their own cost and expense, to defend the Assured against such claim. — "Both to Blame Collision" Clause

EXCLUSION

4 In no case shall this insurance cover — General Exclusion Clause

4.1 loss damage or expense attributable to wilful misconduct of the Assured

4.2 ordinary leakage, ordinary loss in weight or volume, or ordinary wear and tear of the subject-matter insured.

4.3 loss damage or expense caused by insufficiency or unsuitability of packing or preparation of the subject-matter insured (for the purpose of this Clause 4.3 " packing " shall be deemed to include stowage in a container or liftvan but only when such stowage is carried out prior to attachment of this insurance or by the Assured or their servants)

4.4 loss damage or expense caused by inherent vice or nature of the subject-matter insured (except loss damage or expense resulting from variation in temperature specifically covered under Clause 1.2 above)

4.5 loss damage or expense proximately caused by delay, even though the delay be caused by a risk insured against (except expenses payable under Clause 2 above)

4.6 loss damage or expense arising from insolvency or financial default of the owners managers charterers or operators of the vessel

4.7 loss damage or expense arising from the use of any weapon of war employing atomic or nuclear fission and/or fusion or other like reaction or radioactive force or matter.

4.8 loss damage or expense arising from any failure of the Assured or their servants to take all reasonable precautions to ensure that the subject-matter insured is kept in refrigerated or, where appropriate, properly insulated and cooled space

4.9 any loss damage or expense otherwise recoverable hereunder unless prompt notice thereof is given to the Underwriters and, in any event, not later than 30 days after the termination of this insurance.

5 5.1 In no case shall this insurance cover loss damage or expense arising from — Unseaworthiness and Unfitness Exclusion Clause

unseaworthiness of vessel or craft,

unfitness of vessel craft conveyance container or liftvan for the safe carriage of the subject-matter insured,

where the Assured or their servants are privy to such unseaworthiness or unfitness, at the time the subject-matter insured is loaded therein.

5.2 The Underwriters waive any breach of the implied warranties of seaworthiness of the ship and fitness of the ship to carry the subject-matter insured to destination, unless the Assured or their servants are privy to such unseaworthiness or unfitness.

6 In no case shall this insurance cover loss damage or expenses caused by — War Exclusion Clause

6.1 war civil war revolution rebellion insurrection, or civil strife arising therefrom, or any hostile act by or against a belligerent power

6.2 capture seizure arrest restraint or detainment (piracy excepted), and the consequences thereof or any attempt thereat

6.3 derelict mines torpedoes bombs or other derelict weapons of war.

7 In no case shall this insurance cover loss damage or expense — Strikes Exclusion Clause

7.1 caused by strikers, locked-out workmen, or persons taking part in labour disturbances, riots or civil commotions

7.2 resulting from strikes, lock-outs, labour disturbances, riots or civil commotions

7.3 caused by any terrorist or any person acting from a political motive.

DURATION

8 8.1 This insurance attaches from the time the goods are loaded into the conveyance at freezing works or cold store at the place named herein for the commencement of the transit, continues during the ordinary course of transit and terminates either — Transit Clause

8.1.1 on delivery to the cold store or place of storage at the destination named herein,

8.1.2 on delivery to any another cold store or place of storage, whether prior to or at the destination named herein, which the Assured elect to use either

8.1.2.1 for storage other than in the ordinary course of transit or

8.1.2.2 for allocation or distribution

or

8.1.3 on the expiry of 5 days after discharge overside of the goods hereby insured from the oversea vessel at the final port of discharge,

whichever shall first occur.

8.2 If, after discharge overside from the oversea vessel at the final port of discharge, but prior to termination of this insurance, the goods are to be forwarded to a destination other than that to which they are insured hereunder, this insurance, whilst remaining subject to termination as provided for above, shall not extend beyond the commencement of transit to such other destination.

8.3 This insurance shall remain in force (subject to termination as provided for above and to the provisions of Clause 9 below) during delay beyond the control of the Assured, any deviation, forced discharge, reshipment or transhipment and during any variation of the adventure arising from the exercise of a liberty granted to shipowners or charterers under the contract of affreightment.

9 If owing to circumstances beyond the control of the Assured either the contract of carriage is terminated at a port or place other than the destination named therein or the transit is otherwise terminated before delivery of the goods as provided for in Clause 8 above, then this insurance shall also terminated *unless prompt notice is given to the Underwriters and continuation of cover is requested when the insurance shall remain in force, subject to an additional premium if required by the Underwriters,* either — Termination of Contract of Carriage Clause

9.1 until the goods are sold and delivered at such port or place, or, unless otherwise specially agreed, until the expiry of 30 days after arrival of the goods hereby insured at such port or place, whichever shall first occur,

or

9.2 if the goods are forwarded within the said period of 30 days (or any agreed extension thereof) to the destination named herein or to any other destination, until terminated in accordance with the provisions of Clause 8 above.

10 Where, after attachment of this insurance, the destination is changed by the Assured, *held covered at a premium and on conditions to be arranged subject to prompt notice being given to the Underwriters.* — Change of Voyage Clause

CLAIMS

11 11.1 In order to recover under this insurance the Assured must have an insurable interest in the subject-matter insured at the time of the loss. — Insurable Interest Clause

11.2 Subject to 11.1 above, the Assured shall be entitled to recover for insured loss occurring during the period covered by this insurance, notwithstanding that the loss occurred before the contract of insurance was concluded, unless the Assured were aware of the loss and the Underwriters were not.

12 Where, as a result of the operation of a risk covered by this insurance, the insured transit is terminated at a port or place other than that to which the subject-matter is covered under this insurance, the Underwriters will reimburse the Assured for any extra charges properly and reasonably incurred in unloading storing and forwarding the subject-matter to the destination to which it is insured hereunder. — Forwarding Charges Clause

This clause 12, which does not apply to general average or salvage charges, shall be subject to the exclusions contained in Clause 4, 5, 6 and 7 above, and shall not include charges arising from the fault negligence insolvency or financial default of the Assured or their servants.

13 No claim for Constructive Total Loss shall be recoverable hereunder unless the subject-matter insured is reasonably abandoned either on account of its actual total loss appearing to be unavoidable or because the cost of recovering, reconditioning and forwarding the subject-matter to the destination to which it is insured would exceed its value on arrival. — Constructive Total Loss Clause

14 14.1 If any Increased Value insurance is effected by the Assured on the cargo insured herein the agreed value of the cargo shall be deemed to be increased to the total amount insured under this insurance and all Increased Value insurances covering the loss, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured. — Increased Value Clause

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

14.2 **Where this insurance is on Increased Value the following clause shall apply:**

The agreed value of the cargo shall be deemed to be equal to the total amount insured under the primary insurance and all Increased Value insurances covering the loss and effected on the cargo by the Assured, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total mount insured.

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

BENEFIT OF INSURANCE

15 This insurance shall not inure to the benefit of the carrier or other bailee. — Not to Inure Clause

MINIMISING LOSSES

16 It is the duty of the Assured and their servants and agents in respect of loss recoverable hereunder — Duty of Assured Clause

16.1 to take such measures as may be reasonable for the purpose of averting or minimising such loss,

and

16.2 to ensure that all rights against carriers, bailees or other third parties are properly preserved and exercised

and the Underwriters will, in addition to any loss recoverable hereunder, reimburse the Assured for any charges properly and reasonably incurred in pursuance of these duties.

17 Measures taken by the Assured or the Underwriters with the object of saving, protecting or recovering the subject-matter insured shall not be considered as a waiver or acceptance of abandonment or otherwise prejudice the rights of either party. — Waiver Clause

AVOIDANCE OF DELAY

18 It is a condition of this insurance that the Assured shall act with reasonable despatch in all circumstances within their control. — Reasonable Despatch Clause

LAW AND PRACTICE

19 This insurance is subject to English law and practice. — English Law and Practice Clause

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NOTE: - It is necessary for the Assured when they become aware of an event which is "held covered" under this insurance to give prompt notice to the Underwriters and the right to such cover is dependent upon compliance with this obligation.

SPECIAL NOTE:- This insurance does not cover loss damage or expense caused by embargo, or by rejection prohibition or detention by the government of the country of import or their agencies or departments, but does not exclude loss of or damage to the subject-matter insured caused by risks insured hereunder and sustained prior to any such embargo rejection prohibition or detention.

1/1/86

INSTITUTE FROZEN FOOD CLAUSES (C) - Excluding Frozen Meat

RISKS COVERED

1 This insurance covers, except as provided in Clauses 4, 5, 6 and 7 below,

1.1 loss of or damage to the subject-matter insured attributable to — Risks Clause

1.1.1 fire or explosion

1.1.2 vessel or craft being stranded grounded sunk or capsized

1.1.3 overturning or derailment of land conveyance

1.1.4 collision or contact of vessel craft or conveyance with any external object other than water

1.1.5 discharge of cargo at a port of distress.

1.2 loss of or damage to the subject-matter insured caused by

1.2.1 General average sacrifice

1.2.2 Jettison

2 This insurance covers general average and salvage charges, adjusted or determined according to the contract of affreightment and/or the governing law and practice, incurred to avoid or in connection with the avoidance of loss from any cause except those excluded in Clauses 4, 5, 6 and 7 or elsewhere in this insurance. — General Average Clause

3 This insurance is extended to indemnify the Assured against such proportion of liability under the contract of affreightment "Both to Blame Collision" Clause as is in respect of a loss recoverable hereunder. In the event of any claim by shipowners under the said Clause the Assured agree to notify the Underwriters who shall have the right, at their own cost and expense, to defend the Assured against such claim. — "Both to Blame Collision" Clause

EXCLUSION

4 In no case shall this insurance cover — General Exclusion Clause

4.1 loss damage or expense attributable to wilful misconduct of the Assured

4.2 ordinary leakage, ordinary loss in weight or volume, or ordinary wear and tear of the subject-matter insured.

4.3 loss damage or expense caused by insufficiency or unsuitability of packing or preparation of the subject-matter insured (for the purpose of this Clause 4.3 " packing " shall be deemed to include stowage in a container or liftvan but only when such stowage is carried out prior to attachment of this insurance or by the Assured or their servants)

4.4 loss damage or expense caused by inherent vice or nature of the subject-matter insured (except loss damage or expense resulting from variation in temperature specifically covered under Clause 1.2 above)

4.5 loss damage or expense proximately caused by delay, even though the delay be caused by a risk insured against (except expenses payable under Clause 2 above)

4.6 loss damage or expense arising from insolvency or financial default of the owners managers charterers or operators of the vessel

4.7 deliberate damage to or deliberate destruction of the subject-matter insuredd or any part thereof by the wrongful act of any person or persons

4.8 loss damage or expense arising from the use of any weapon of war employing atomic or nuclear fission and/or fusion or other like reaction or radioactive force or matter.

4.9 loss damage or expense arising from any failure of the Assured or their servants to take all reasonable precautions to ensure that the subject-matter insured is kept in refrigerated or, where appropriate, properly insulated and cooled space

4.9 any loss damage or expense otherwise recoverable hereunder unless prompt notice thereof is given to the Underwriters and, in any event, not later than 30 days after the termination of this insurance.

5 5.1 In no case shall this insurance cover loss damage or expense arising from — Unseaworthiness and Unfitness Exclusion Clause

unseaworthiness of vessel or craft,

unfitness of vessel craft conveyance container or liftvan for the safe carriage of the subject-matter insured,

where the Assured or their servants are privy to such unseaworthiness or unfitness, at the time the subject-matter insured is loaded therein.

5.2 The Underwriters waive any breach of the implied warranties of seaworthiness of the ship and fitness of the ship to carry the subject-matter insured to destination, unless the Assured or their servants are privy to such unseaworthiness or unfitness.

6 In no case shall this insurance cover loss damage or expenses caused by

War Exclusion Clause

6.1 war civil war revolution rebellion insurrection, or civil strife arising therefrom, or any hostile act by or against a belligerent power

6.2 capture seizure arrest restraint or detainment (piracy excepted), and the consequences thereof or any attempt thereat

6.3 derelict mines torpedoes bombs or other derelict weapons of war.

7 In no case shall this insurance cover loss damage or expense

Strikes Exclusion Clause

7.1 caused by strikers, locked-out workmen, or persons taking part in labour disturbances, riots or civil commotions

7.2 resulting from strikes, lock-outs, labour disturbances, riots or civil commotions

7.3 caused by any terrorist or any person acting from a political motive.

DURATION

8 8.1 This insurance attaches from the time the goods are loaded into the conveyance at freezing works or cold store at the place named herein for the commencement of the transit, continues during the ordinary course of transit and terminates either

Transit Clause

8.1.1 on delivery to the cold store or place of storage at the destination named herein,

8.1.2 on delivery to any another cold store or place of storage, whether prior to or at the destination named herein, which the Assured elect to use either

8.1.2.1 for storage other than in the ordinary course of transit or

8.1.2.2 for allocation or distribution

Or

8.1.3 on the expiry of 5 days after discharge overside of the goods hereby insured from the oversea vessel at the final port of discharge,

whichever shall first occur.

8.2 If, after discharge overside from the oversea vessel at the final port of discharge, but prior to termination of this insurance, the goods are to be forwarded to a destination other than that to which they are insured hereunder, this insurance, whilst remaining subject to termination as provided for above, shall not extend beyond the commencement of transit to such other destination.

8.3 This insurance shall remain in force (subject to termination as provided for above and to the provisions of Clause 9 below) during delay beyond the control of the Assured, any deviation, forced discharge, reshipment or transhipment and during any variation of the adventure arising from the exercise of a liberty granted to shipowners or charterers under the contract of affreightment.

9 If owing to circumstances beyond the control of the Assured either the contract of carriage is terminated at a port or place other than the destination named therein or the transit is otherwise terminated before delivery of the goods as provided for in Clause 8 above, then this insurance shall also terminated *unless prompt notice is given to the Underwriters and continuation of cover is requested when the insurance shall remain in force, subject to an additional premium if required by the Underwriters,* either

Termination of Contract of Carriage Clause

9.1 until the goods are sold and delivered at such port or place, or, unless otherwise specially agreed, until the expiry of 30 days after arrival of the goods hereby insured at such port or place, whichever shall first occur,

Or

9.2 if the goods are forwarded within the said period of 30 days (or any agreed extension thereof) to the destination named herein or to any other destination, until terminated in accordance with the provisions of Clause 8 above.

10 Where, after attachment of this insurance, the destination is changed by the Assured, *held covered at a premium and on conditions to be arranged subject to prompt notice being given to the Underwriters.*

Change of Voyage Clause

CLAIMS

11 11.1 In order to recover under this insurance the Assured must have an insurable interest in the subject-matter insured at the time of the loss.

Insurable Interest Clause

11.2 Subject to 11.1 above, the Assured shall be entitled to recover for insured loss occurring during the period covered by this insurance, notwithstanding that the loss occurred before the contract of insurance was concluded, unless the Assured were aware of the loss and the Underwriters were not.

12 Where, as a result of the operation of a risk covered by this insurance, the insured transit is terminated at a port or place other than that to which the subject-matter is covered under this insurance, the Underwriters will reimburse the Assured for any extra charges properly and reasonably incurred in unloading storing and forwarding the subject-matter to the destination to which it is insured hereunder. Forwarding Charges Clause

This clause 12, which does not apply to general average or salvage charges, shall be subject to the exclusions contained in Clause 4, 5, 6 and 7 above, and shall not include charges arising from the fault negligence insolvency or financial default of the Assured or their servants.

13 No claim for Constructive Total Loss shall be recoverable hereunder unless the subject-matter insured is reasonably abandoned either on account of its actual total loss appearing to be unavoidable or because the cost of recovering, reconditioning and forwarding the subject-matter to the destination to which it is insured would exceed its value on arrival. Constructive Total Loss Clause

14 14.1 If any Increased Value insurance is effected by the Assured on the cargo insured herein the agreed value of the cargo shall be deemed to be increased to the total amount insured under this insurance and all Increased Value insurances covering the loss, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured. Increased Value Clause

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

14.2 Where this insurance is on Increased Value the following clause shall apply:

The agreed value of the cargo shall be deemed to be equal to the total amount insured under the primary insurance and all Increased Value insurances covering the loss and effected on the cargo by the Assured, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total mount insured.

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

BENEFIT OF INSURANCE

15 This insurance shall not inure to the benefit of the carrier or other bailee. Not to Inure Clause

MINIMISING LOSSES

16 It is the duty of the Assured and their servants and agents in respect of loss recoverable hereunder Duty of Assured Clause

16.1 to take such measures as may be reasonable for the purpose of averting or minimising such loss,

And

16.2 to ensure that all rights against carriers, bailees or other third parties are properly preserved and exercised

and the Underwriters will, in addition to any loss recoverable hereunder, reimburse the Assured for any charges properly and reasonably incurred in pursuance of these duties.

17 Measures taken by the Assured or the Underwriters with the object of saving, protecting or recovering the subject-matter insured shall not be considered as a waiver or acceptance of abandonment or otherwise prejudice the rights of either party. Waiever Clause

AVOIDANCE OF DELAY

18 It is a condition of this insurance that the Assured shall act with reasonable despatch in all circumstances within their control. Reasonable Despatch Clause

LAW AND PRACTICE

19 This insurance is subject to English law and practice. English Law and Practice Clause

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NOTE: - It is necessary for the Assured when they become aware of an event which is "held covered" under this insurance to give prompt notice to the Underwriters and the right to such cover is dependent upon compliance with this obligation.

SPECIAL NOTE:- This insurance does not cover loss damage or expense caused by embargo, or by rejection prohibition or detention by the government of the country of import or their agencies or departments, but does not exclude loss of or damage to the subject-matter insured caused by risks insured hereunder and sustained prior to any such embargo rejection prohibition or detention.

1/1/86

FROZEN FOOD EXTENSION CLAUSES - For use only with the Institute Frozen Food Clauses (A) 1/1/86)

Clause 1 and Clauses 4.4 and 4.5 of the attached Institute Frozen Food Clauses (A) 1/1/86 are deemed to be deleted and replaced by:

1 Subject always to the goods being in sound condition at the time of attachment, this insurance covers, except as provided in Clauses 4, 5, 6 and 7 below, loss of, deterioration of, or damage to the subject-matter insured which shall arise during the currency of this insurance.

4 4.4 loss damage or expense arising from bone taint, salmonella, infection prior to attachment of this insurance, fault in preparation dressing cooling freezing wrapping or packing

4.5 claims arising from loss of market

Nevertheless, in the absence of prior notice to the Underwriters and agreement of any additional premium required by them, this insurance excludes any claim for deterioration of or damage to the subject-matter insured where the period between the first passing of the goods into a Freezing Chamber and attachment of this insurance exceeds 60 days.

1/1/86

INSTITUTE STRIKES CLAUSES (FROZEN FOOD) - Excluding Frozen Meat

RISKS COVERED

1 This insurance covers, except as provided in Clause 3 and 4 below, loss of or damage to the subject-matter insured caused by — Risks Clause

1.1 strikers, locked-out workmen, or persons taking part in labour disturbances, riots or civil commotions

1.2 any terrorist or any person acting from a political motive.

2 This insurance covers general average and salvage charges, adjusted or determined according to the contract of affreightment and/or the governing law and practice, incurred to avoid or in connection with the avoidance of loss from any cause except those excluded in Clauses 4, 5, 6 and 7 or elsewhere in this insurance. — General Average Clause

EXCLUSION

3 In no case shall this insurance cover — General Exclusion Clause

3.1 loss damage or expense attributable to wilful misconduct of the Assured

3.2 ordinary leakage, ordinary loss in weight or volume, or ordinary wear and tear of the subject-matter insured.

3.3 loss damage or expense caused by insufficiency or unsuitability of packing or preparation of the subject-matter insured (for the purpose of this Clause 3. 3 " packing " shall be deemed to include stowage in a container or liftvan but only when such stowage is carried out prior to attachment of this insurance or by the Assured or their servants)

3.4 loss damage or expense caused by inherent vice or nature of the subject-matter insured (except loss damage or expense resulting from variation in temperature specifically covered under Clause 1.2 above)

3.5 loss damage or expense proximately caused by delay, even though the delay be caused by a risk insured against (except expenses payable under Clause 2 above)

3.6 loss damage or expense arising from insolvency or financial default of the owners managers charterers or operators of the vessel

3.7 loss damage or expense arising from the absence shortage or withholding of equipment, power, fuel, coolant, refrigerant or labour of any description whatsoever resulting from any strike, lockout, labour disturbance, riot or civil commotion

3.8 any claim based upon loss of or frustration of the voyage adventure

3.9 loss damage or expense arising from the use of any weapon of war employing atomic or nuclear fission and/or fusion or other like reaction or radioactive force or matter.

3.10 loss damage or expense caused by war civil war revolution rebellion insurrection, or civil strife arising therefrom, or any hostile act by or against a belligerent power.

3.11 any loss damage or expense otherwise recoverable hereunder unless prompt notice thereof is given to the Underwriters and, in any event, not later than 30 days after the termination of this insurance.

4 4.1 In no case shall this insurance cover loss damage or expense arising from — Unseaworthiness and Unfitness Exclusion Clause

unseaworthiness of vessel or craft,

unfitness of vessel craft conveyance container or liftvan for the safe carriage of the subject-matter insured,

where the Assured or their servants are privy to such unseaworthiness or unfitness, at the time the subject-matter insured is loaded therein.

4.2 The Underwriters waive any breach of the implied warranties of seaworthiness of the ship and fitness of the ship to carry the subject- matter insured to destination, unless the Assured or their servants are privy to such unseaworthiness or unfitness.

DURATION

5 5.1 This insurance attaches from the time the goods leave the warehouse or place of storage at the place named herein for the commencement of the transit, continues during the ordinary course of transit and terminates either — Transit Clause

5.1.1 on delivery to the cold store or place of storage at the destination named herein,

5.1.2 on delivery to any another cold store or place of storage, whether prior to or at the destination named herein, which the Assured elect to use either

5.1.2.1 for storage other than in the ordinary course of transit or

5.1.2.2 for allocation or distribution

or

5.1.3 on the expiry of 5 days after discharge overside of the goods hereby insured from the oversea vessel at the final port of discharge,

whichever shall first occur.

5.2 If, after discharge over side from the oversea vessel at the final port of discharge, but prior to termination of this insurance, the goods are to be forwarded to a destination other than that to which they are insured hereunder, this insurance, whilst remaining subject to termination as provided for above, shall not extend beyond the commencement of transit to such other destination.

5.3 This insurance shall remain in force (subject to termination as provided for above and to the provisions of Clause 6 below) during delay beyond the control of the Assured, any deviation, forced discharge, reshipment or transhipment and during any variation of the adventure arising from the exercise of a liberty granted to shipowners or charterers under the contract of affreightment.

6 If owing to circumstances beyond the control of the Assured either the contract of carriage is terminated at a port or place other than the destination named therein or the transit is otherwise terminated before delivery of the goods as provided for in Clause 5 above, then this insurance shall also terminated *unless prompt notice is given to the Underwriters and continuation of cover is requested when the insurance shall remain in force, subject to an additional premium if required by the Underwriters,* either

Termination of Contract of Carriage Clause

6.1 until the goods are sold and delivered at such port or place, or, unless otherwise specially agreed, until the expiry of 30 days after arrival of the goods hereby insured at such port or place, whichever shall first occur,

Or

6.2 if the goods are forwarded within the said period of 30 days (or any agreed extension thereof) to the destination named herein or to any other destination, until terminated in accordance with the provisions of Clause 5 above.

7 Where, after attachment of this insurance, the destination is changed by the Assured, *held covered at a premium and on conditions to be arranged subject to prompt notice being given to the Underwriters.*

Change of Voyage Clause

CLAIMS

8 8.1 In order to recover under this insurance the Assured must have an insurable interest in the subject-matter insured at the time of the loss.

Insurable Interest Clause

8.2 Subject to 8.1 above, the Assured shall be entitled to recover for insured loss occurring during the period covered by this insurance, notwithstanding that the loss occurred before the contract of insurance was concluded, unless the Assured were aware of the loss and the Underwriters were not.

9 9.1 If any Increased Value insurance is effected by the Assured on the cargo insured herein the agreed value of the cargo shall be deemed to be increased to the total amount insured under this insurance and all Increased Value insurances covering the loss, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured.

Increased Value Clause

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

9.2 Where this insurance is on Increased Value the following clause shall apply:

The agreed value of the cargo shall be deemed to be equal to the total amount insured under the primary insurance and all Increased Value insurances covering the loss and effected on the cargo by the Assured, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total mount insured.

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

BENEFIT OF INSURANCE

10 This insurance shall not inure to the benefit of the carrier or other bailee.

Not to Inure Clause

MINIMISING LOSSES

11 It is the duty of the Assured and their servants and agents in respect of loss recoverable hereunder

Duty of Assured Clause

11.1 to take such measures as may be reasonable for the purpose of averting or minimising such loss,

And

11.2 to ensure that all rights against carriers, bailees or other third parties are properly preserved and exercised

and the Underwriters will, in addition to any loss recoverable hereunder, reimburse the Assured for any charges properly and reasonably incurred in pursuance of these duties.

12 Measures taken by the Assured or the Underwriters with the object of saving, protecting or recovering the subject-matter insured shall not be considered as a waiver or acceptance of abandonment or otherwise prejudice the rights of either party. Waiver Clause

AVOIDANCE OF DELAY

13 It is a condition of this insurance that the Assured shall act with reasonable despatch in all circumstances within their control. Reasonable Despatch Clause

LAW AND PRACTICE

14 This insurance is subject to English law and practice. English Law and Practice Clause

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NOTE: - It is necessary for the Assured when they become aware of an event which is "held covered" under this insurance to give prompt notice to the Underwriters and the right to such cover is dependent upon compliance with this obligation.

SPECIAL NOTE:- This insurance does not cover loss damage or expense caused by embargo, or by rejection prohibition or detention by the government of the country of import or their agencies or departments, but does not exclude loss of or damage to the subject-matter insured caused by risks insured hereunder and sustained prior to any such embargo rejection prohibition or detention.

1/1/86

INSTITUTE FROZEN MEAT CLAUSES (A) - (not suitable for chilled, cooled or fresh meat)

RISKS COVERED

1 This insurance covers all risks of loss of or damage to the subject-matter insured except as provided in Clauses 4, 5, 6 and 7 below,

2. This insurance covers general average and salvage charges, adjusted or determined according to the contract of affreightment and/or the governing law and practice, incurred to avoid or in connection with the avoidance of loss from any cause except those excluded in Clauses 4, 5, 6 and 7 or elsewhere in this insurance. Risks Clauses

3. This insurance is extended to indemnify the Assured against such proportion of liability under the contract of affreightment "Both to Blame Collision" Clause as is in respect of a loss recoverable hereunder. In the event of any claim by shipowners under the said Clause the Assured agree to notify the Underwriters who shall have the right, at their own cost and expense, to defend the Assured against such claim. General Average Clause "Both to Blame Collision" Clause

EXCLUSION

4 In no case shall this insurance cover

4.1 loss damage or expense attributable to wilful misconduct of the Assured

4.2 ordinary leakage, ordinary loss in weight or volume, or ordinary wear and tear of the subject-matter insured.

4.3 loss damage or expense caused by insufficiency or unsuitability of packing or preparation of the subject-matter insured (for the purpose of this Clause 4.3 "packing" shall be deemed to include stowage in a container or liftvan but only when such stowage is carried out prior to attachment of this insurance or by the Assured or their servants). General Exclusions Clause

4.4 loss damage or expense caused by inherent vice or nature of the subject-matter insured (except loss damage or expense resulting from variation in temperature whilst this insurance is in force)

4.5 loss damage or expense proximately caused by delay, even though the delay be caused by a risk insured against (except expenses payable under Clause 2 above)

4.6 loss damage or expense caused by insolvency or financial default of the owners managers charterers or operators of the vessel where, at the time of the subject-matter insured on board the vessel, the Assured are aware, or in the ordinary course of business should be aware, that such insolvency or financial default could prevent the normal prosecution of the voyage.

This exclusion shall not apply where this insurance has been assigned to the party claiming hereunder who has bought or agreed to buy the subject-matter insured in good faith under a binding contract.

4.7 loss damage or expense arising from the use of any weapon of war employing atomic or nuclear fission and/or fusion or other like reaction or radioactive force or matter.

4.8 loss damage or expense on shore caused directly or indirectly by earthquake, volcanic eruption and/or fire resulting therefrom

4.9 loss damage or expense arising from any failure of the Assured or their servants to take all reasonable precautions to ensure that the subject-matter insured in kept in refrigerated or, where appropriate, properly insulated and cooled space.

5 5.1 In no case shall this insurance cover loss damage or expense arising from

5.1.1 unseaworthiness of vessel or craft or unfitness of vessel or craft for the safe carriage of the subject-matter insured, where the Assured are privy to such unseaworthiness or unfitness, at the time the subject-matter insured is loaded therein.

5.1.2 unfitness of container liftvan or land conveyance for the safe carriage of the subject-matter insured where loading therein is carried out prior to attachment of this

insurance or by the Assured or their servants.

Unseaworthiness and unfitness Exclusion Clause

5.2 Where this insurance has been assigned to the party claiming hereunder who has bought or agreed to buy the subject-matter insured in good faith under a binding contract, exclusion 5.1.1 above shall not apply.

5.3 The Underwriters waive any breach of the implied warranties of seaworthiness of the ship and fitness of the ship to carry the subject-matter insured to destination.

6 In no case shall this insurance cover loss damage or expense caused by

6.1 war civil war revolution rebellion insurrection, or civil strife arising therefrom, or any hostile act by or against a belligerent power

6.2 capture seizure arrest restrain or detainment (piracy excepted), and the consequences thereof or any attempt thereat

6.3 derelict mines torpedoes bombs or other derelict weapon of war.

War Exclusion Clause

7 In no case shall this insurance cover loss damage or expense

7.1 caused by strikes, locked-out workmen, or persons taking part in labour disturbances, riots or civil commotions

7.2 resulting from strikes, lock-outs, labour disturbances, riots or civil commotions

7.3 caused by any terrorist or any person acting from a political motive.

DURATION

Strikes Exclusion Clause

8 8.1 This insurance attaches from the time

8.1.1 the goods pass into the cooling and/or freezing chambers of the works at the placed named herein, provided that the period in such chambers prior to shipment on board the oversea vessel shall not exceed 60 days unless prompt notice be given to the Underwriters and an additional premium paid for each further period of 30 days or party thereof.

DELETE SECTIONS NOT APPLICABLE

Transit Clause

8.1.2 the goods are loaded into the conveyance at the freezing works or cold store at the place named herein for the commencement of the transit.

8.1.3 of loading of the goods unto the oversea vessel.

8.2 This insurance continues during the ordinary course of transit to and whilst in

8.2.1 cold store at the destination named herein

or

8.2.2 any other cold store which the Assured elect to use following discharge of the goods from the oversea vessel at the port of discharge either

8.2.2.1 for storage other than in the ordinary course of transit or

8.2.2.2 for allocation or distribution.

8.3 This insurance terminates

8.3.1 *for transit to a destination in the Continent of Europe (including Eire and the United Kingdom), U.S.A. or Canada* on the expiry of 30 days

8.3.2 *for transit to a destination elsewhere* on the expiry of 5 days after final discharge of the goods from the oversea vessel at the port or discharge.

8.4 Any disposal of the goods other than by storage as in 8.2.1 or 8.2.2 above (except with the prior consent of the Underwriters) or any removal from cold store before the expiry of the relevant period in 8.3.1 or 8.3.2 above shall terminate the insurance on such goods.

8.5 If, after discharge overside from the oversea vessel at the final port of discharge, but prior to termination of this insurance, the goods are to be forwarded to add estination other than that to which they are insured hereunder, this insurance, whilst remaining subject to termination as provided for above, shall not extend beyond the commencement of transit to such other destination.

8.6 This insurance shall remain in force (subject to termination as provided for above and to the provisions of Clause 9 below) during delay beyond the control of the Assured, any deviation, forced discharge, reshipment or transhipment and during any variation of the adventure arising from the exercise of a liberty granted to shipowners or charterers under

the contract of affreighment.

9 If owing to circumstances beyond the control of the Assured either the contract of carriage is terminated at a port or place other than the destination named therein or the transit is otherwise terminated before delivery of the goods as provided for in Clause 8 above, then this insurance shall also terminated *unless prompt notice is given to the Underwriters and continuation of cover is requested when the insurance shall remain in force, subject to an additional premium if required by the Underwriters, either*

Termination of Contract of Carriage Clause

9.1 until the goods are sold and delivered at such port or place, or, unless otherwise specially agreed, until the expiry of 30 days after arrival of the goods hereby insured at such port or place, whichever shall first occur,

or

9.2 if the goods are forwarded within the said period of 30 days (or any agreed extension thereof) to the destination named herein or to any other destination, until terminated in accordance with the provisions of Clause 8 above.

10 Where, after attachment of this insurance, the destination is changed by the Assured, *held covered at a premium and on conditions to be arranged subject to prompt notice being given to the Underwriters.*

CLAIMS

11 11.1 In order to recover under this insurance the Assured must have an insurable interest in the subject-matter insured at the time of the loss.

Change of Voyage Clause

11.2 Subject to 11.1 above, the Assured shall be entitled to recover for insured loss occurring during the period covered by this insurance, notwithstanding that the loss occurred before the contract of insurance was concluded, unless the Assured were aware of the loss and the Underwriters were not.

Insurable Interest Clause

11.3 Prompt notice of any deterioration loss or damage shall be given to Underwriters upon first discovery and any claim for depreciation or damage is conditional upon Underwriters having been given an opportunity to inspect such depreciation or damage before termination of the insurance.

12 Where, as a result of the operation of a risk covered by this insurance, the insured transit is terminated at a port or place other than that to which the subject-matter is covered under this insurance, the Underwriters will reimburse the Assured for any extra charges properly and reasonably incurred in unloading storing and forwarding the subject-matter to the destination to which it is insured hereunder.

Notice of Claim Clause

This clause 12, which does not apply to general average or salvage charges, shall be subject to the exclusions contained in Clause 4, 5, 6 and 7 above, and shall not include charges arising from the fault negligence insolvency or financial default of the Assured or their servants.

Forwarding Charges Clause

13 No claim for Constructive Total Loss shall be recoverable hereunder unless the subject-matter insured is reasonably abandoned either on account of its actual total loss appearing to be unavoidable or because the cost of recovering, reconditioning and forwarding the subject-matter to the destination to which it is insured would exceed its value on arrival.

14 Should the subject-matter insured or any part thereof not be shipped any claim in respect thereto shall be adjusted on the basis of its insured values less, where included, freight, duty and all charges not incurred.

Constructive Total Loss Clause

15 15.1 If any increased value insurance is effected by the Assured on the cargo insured herein the agreed value of the cargo shall be deemed to be increased to the total amount insured under this insurance and all Increased Value insurances covering the loss, and liability under this insurance shall be in such proportion as the sum insured

Adjustment Clause

herein bears to such total amount insured.
In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

Increased Value Clause

15.2 **Where this insurance is on Increased Value the following clause shall apply:**
The agreed value of the cargo shall be deemed to be equal to the total amount insured under the primary insurance and all Increased Value insurances covering the loss and effected on the cargo by the Assured, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured.
In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

BENEFIT OF INSURANCE

16 This insurance shall not inure to the benefit of the carrier or other bailee.

Not to Inure Clause

MINIMISING LOSSES

17 It is the duty of the Assured and their servants and agents in respect of loss recoverable hereunder

17.1 to take such measures as may be reasonable for the purpose of averting or minimising such loss,
and

17.2 to ensure that all rights against carriers, bailees or other third parties are properly preserved and exercised

and the Underwriters will, in addition to any loss recoverable hereunder, reimburse the Assured for any charges properly and reasonably incurred in pursuance of these duties.

Duty of Assured Clause

18 Measures taken by the Assured or the Underwriters with the object of saving, protecting or recovering the subject-matter insured shall not be considered as a waiver or acceptance of abandonment or otherwise prejudice the rights of either party.

AVOIDANCE OF DELAY

19 It is a condition of this insurance that the Assured shall act with reasonable despatch in all circumstances within their control.

Waiver Clause

LAW AND PRACTICE

20 This insurance is subject to English law and practice.

Reasonable Despatch Clause

NOTE:- It is necessary for the Assured when they become aware of an event which is "held covered" under this insurance to give prompt notice to the Underwriters and the right to such cover is dependent upon compliance with this obligation.

English Law and practice Clause

SPECIAL NOTE:- This insurance does not cover loss damage or expense caused by embargo, or by rejection prohibition or detention by the government of the country of import or their agencies or departments, but does not exclude loss of or damage to the subject-matter insured caused by risks insured hereunder and sustained prior to any such embargo rejection prohibition or detention.

INSTITUTE FROZEN MEAT CLAUSES (A) - 24 Hours Breakdown - (not suitable for chilled. cooled or fresh meat)

RISKS COVERED

1 This insurance covers provided in Clauses 4, 5, 6 and 7 below, Risks Clause

1.1 all risks of loss of or damage to the subject-matter insured, other than loss or damage resulting from any variation in temperature howsoever caused.

1.2 loss of or damage to the subject-matter insured resulting from any variation in temperature attributable to

1.2.1 breakdown of refrigerating machinery resulting in its stoppage for a period of not less than 24 consecutive hours

1.2.2 fire or explosion

1.2.3 vessel or craft being stranded grounded sunk or capsized

1.2.4 overturning or derailment of land conveyance

1.2.5 collision or contact of vessel craft or conveyance with any external object other than water

1.2.6 discharge of cargo at a port of distress.

2. This insurance covers general average and salvage charges, adjusted or determined according to the contract of affreightment and/or the governing law and practice, incurred to avoid or in connection with the avoidance of loss from any cause except those excluded in Clauses 4, 5, 6 and 7 or elsewhere in this insurance. General Average Clause

3. This insurance is extended to indemnify the Assured against such proportion of liability under the contract of affreightment "Both to Blame Collision" Clause as is in respect of a loss recoverable hereunder. In the event of any claim by shipowners under the said Clause the Assured agree to notify the Underwriters who shall have the right, at their own cost and expense, to defend the Assured against such claim. "Both to Blame Collision" Clause

EXCLUSION

4 In no case shall this insurance cover General Exclusions Clause

4.1 loss damage or expense attributable to wilful misconduct of the Assured

4.2 ordinary leakage, ordinary loss in weight or volume, or ordinary wear and tear of the subject-matter insured.

4.3 loss damage or expense caused by insufficiency or unsuitability of packing or preparation of the subject-matter insured (for the purpose of this Clause 4.3 "packing" shall be deemed to include stowage in a container or liftvan but only when such stowage is carried out prior to attachment of this insurance or by the Assured or their servants).

4.4 loss damage or expense caused by inherent vice or nature of the subject-matter insured (except loss damage or expense resulting from variation in temperature specifically covered under Clause 1.2 above)

4.5 loss damage or expense proximately caused by delay, even though the delay be caused by a risk insured against (except expenses payable under Clause 2 above)

4.6 loss damage or expense caused by insolvency or financial default of the owners managers charterers or operators of the vessel where, at the time of loading of the subject-matter insured on board the vessel, the Assured are aware, or in the ordinary course of business should be aware, that such insolvency or financial default could prevent the normal prosecution of the voyage

This exclusion shall not apply where this insurance has been assigned to the party claiming hereunder who has bought or agreed to buy the subject-matter insured in good faith under a binding contract

4.7 loss damage or expense arising from the use of any weapon of war employing atomic or nuclear fission and/or fusion or other like reaction or radioactive force or matter.

4.8 loss damage or expense on shore caused directly or indirectly by earthquake, volcanic eruption and/or fire resulting therefrom

4.9 loss damage or expense arising from any failure of the Assured or their servants to take all reasonable precautions to ensure that the subject-matter insured is kept in refrigerated or, where appropriate, properly insulated and cooled space.

5 5.1 In no case shall this insurance cover loss damage or expense arising from

5.1.1 unseaworthiness of vessel or craft or u nfitness of ves sel or craf t for t he s afe c arriage of the subject-matter insured, where t he As sured are privy to s uch un seaworthiness or unfitnes s, at the time the subject-matter insured is loaded therein.

Unseaworthiness and unfitness Exclusion Clause

5.1.2 unfitness of container liftvan o r land conveyance for the safe carriage of the s ubject-matter insured, wher e l oading th erein is carried ou t pri or to at tachment of this ins urance or b y th e Assured or their servants.

5.2 W here this ins urance h as been as signed to the party claiming hereund er who has bou ght or agreed to buy the subject-matter insured in good faith under a binding contract, exclusion 5.1.1 above shall not apply.

5.3 The Underwriters waive an y breach of the implied warranties of seaworthiness of the ship and fitness of the ship to carry the subject-matter insured to destination.

War Exclusion Clause

6 In no case shall this insurance cover loss damage or expense caused by

6.1 war civil war revolution rebellion insurrection, or civil strife arising therefrom, or any hostile act by or against a belligerent power

6.2 capture seizure arrest restraint or detainment (piracy excepted), and the consequences thereof or any attempt thereat

6.3 derelict mines torpedoes bombs or other derelict weapons of war.

Strikes Exclusion Clause

7 In no case shall this insurance cover loss damage or expense

7.1 caused by strikes, locked-out workmen, or persons taking part in labour disturbances, riots or civil commotions

7.2 resulting from strikes, lock-outs, labour disturbances, riots or civil commotions

7.3 caused by any terrorist or any person acting from a political motive.

Transit Clause

DURATION

8 8.1 This insurance attaches from the time

8.1.1 the goods pass into the cooling and/or freezing chambers of the works at the place named herein, provided that the period in such chambers prior to shipment on board the oversea vessel shall not exceed 60 days unless prompt notice be given to the Underwriters and an additional premium paid for each further period of 30 days or part thereof. ( ) (DELETE) SECTIONS (NOT) APPLICABLE

8.1.2 the goods are loaded into the conveyance at freezing works or cold store at the place named herein for the commencement of the transit.

8.1.3 of loading of the goods into the oversea vessel.

8.2 This insurance continues during the ordinary course of transit to and whilst in

8.2.1 cold store at the destination named herein

or

8.2.2 any other cold s tore which the Assured elect to use following discharge of the goods from the oversea vessel at the port of discharge either

8.2.2.1 for storage other than in the ordinary course of transit or

8.2.2.2 for allocation or distribution.

8.3 This insurance terminates

8.3.1 *for transit to a destination in the Continent of Europe (including Eire and the United Kingdom), U.S.A. or Canada* on expiry of 30 days

8.3.2 *for transit to a destination elsewhere* on the expiry of 5 days after final discharge of the goods from the oversea vessel at the port of discharge.

8.4 Any disposal of the goods other than b y storage as in 8.2.1 or 8.2.2 above (except with the prior consent of the Underwriters) or any removal f rom cold store before the exp iry of the relevan t period in 8.3.1 or 8.3.2 above shall terminate the insurance on such goods.

8.5 If, af ter disch arge overside fro m the oversea v essel at the f inal port of disch arge, but prior to termination of this insurance, th e goods are to be forwarded to a destination other than th at to which the y are insured hereun der, th is insura nce, whilst rem aining subj ect to term ination a s provided for above, shall not extend b eyond th e commen cement of transit to such oth er destination.

8.6 This insurance shall remain in force (subject to termination as provided for above and to the provisions of Clause 9 below) during delay bey ond th e con trol of the Assured, an y d eviation,

forced discharge, reshipment or transhipment and during any variation of the adventure arising from the exercise of a liberty granted to shipowners or charterers under the contract of affreightment.

Termination of Contract of Carriage Clause

9 If owing to circumstances beyond the control of the Assured either the contract of carriage is terminated at a port or place other than the destination named therein or the transit is otherwise terminated before delivery of the goods as provided for in Clause 8 above, then this insurance shall also terminated *unless prompt notice is given to the Underwriters and continuation of cover is requested when the insurance shall remain in force, subject to an additional premium if required by the Underwriters,* either

9.1 until the goods are sold and delivered at such port or place, or, unless otherwise specially agreed, until the expiry of 30 days after arrival of the goods hereby insured at such port or place, whichever shall first occur,

or

Change of Voyage Clause

9.2 if the goods are forwarded within the said period of 30 days (or any agreed extension thereof) to the destination named herein or to any other destination, until terminated in accordance with the provisions of Clause 8 above.

Insurable Interest Clause

10 Where, after attachment of this insurance, the destination is changed by the Assured, *held covered at a premium and on conditions to be arranged subject to prompt notice being given to the Underwriters.*

CLAIMS

11 11.1 In order to recover under this insurance the Assured must have an insurable interest in the subject-matter insured at the time of the loss.

11.2 Subject to 11.1 above, the Assured shall be entitled to recover for insured loss occurring during the period covered by this insurance, notwithstanding that the loss occurred before the contract of insurance was concluded, unless the Assured were aware of the loss and the Underwriters were not.

Forwarding Charges Clause

11.3 Prompt notice of any deterioration loss or damage shall be given to Underwriters upon first discovery and any claim for depreciation or damage is conditional upon Underwriters having been given an opportunity to inspect such depreciation or damage before termination of the insurance.

12 Where, as a result of the operation of a risk covered by this insurance, the insured transit is terminated at a port or place other than that to which the subject-matter is covered under this insurance, the Underwriters will reimburse the Assured for any extra charges properly and reasonably incurred in unloading storing and forwarding the subject-matter to the destination to which it is insured hereunder.

Constructive Total Loss Clause

This clause 12, which does not apply to general average or salvage charges, shall be subject to the exclusions contained in Clause 4, 5, 6 and 7 above, and shall not include charges arising from the fault negligence insolvency or financial default of the Assured or their servants.

13 No claim for Constructive Total Loss shall be recoverable hereunder unless the subject-matter insured is reasonably abandoned either on account of its actual total loss appearing to be unavoidable or because the cost of recovering, reconditioning and forwarding the subject-matter to the destination to which it is insured would exceed its value on arrival.

Adjustment Clause

14. Should the subject-matter insured or any part thereof not be shipped any claim in respect thereto shall be adjusted on the basis of its insured value less, where included, freight, duty and all charges not incurred.

Increased Value Clause

15. 15.1 If any Increased Value insurance is effected by the Assured on the cargo insured herein the agreed value of the cargo shall be deemed to be increased to the total amount insured under this insurance and all Increased Value insurances covering the loss, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured.

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

15.2 **Where this insurance is on Increased Value the following clause shall apply:**

The agreed value of the cargo shall be deemed to be equal to the total amount insured under the

primary insurance and all Increased Value insurances covering the loss and effected on the cargo by the Assured, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured. Not to Inure Clause

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances. Duty of Assured Clause

BENEFIT OF INSURANCE

16. This insurance shall not inure to the benefit of the carrier or other bailee.

MINIMISING LOSSES

17. It is the duty of the Assured and their servants and agents in respect of loss recoverable hereunder

17.1 to take such measures as may be reasonable for the purpose of averting or minimising such loss,

and

17.2 to ensure that all rights against carriers, bailees or other third parties are properly preserved and exercised Waiver Clause

and the Underwriters will, in addition to any loss recoverable hereunder, reimburse the Assured for any charges properly and reasonably incurred in pursuance of these duties.

18. Measures taken by the Assured or the Underwriters with the object of saving, protecting or recovering the subject-matter insured shall not be considered as a waiver or acceptance of abandonment or otherwise prejudice the rights of either party. Reasonable Despatch Clause

AVOIDANCE OF DELAY

19. It is a condition of this insurance that the Assured shall act with reasonable despatch in all circumstances within their control. English Law and practice Clause

LAW AND PRACTICE

20. This insurance is subject to English law and practice.

NOTE:- It is necessary for the Assured when they become aware of an event which is "held covered" under this insurance to give prompt notice to the Underwriters and the right to such cover is dependent upon compliance with this obligation.

SPECIAL NOTE:- This insurance does not cover loss damage or expense caused by embargo, or by rejection prohibition or detention by the government of the country of import or their agencies or departments, but does not exclude loss of or damage to the subject-matter insured caused by risks insured hereunder and sustained prior to any such embargo rejection prohibition or detention.

1/1/86

INSTITUTE FROZEN MEAT CLAUSES (C) and 24 Hours Breakdown - (not suitable for chilled, cooled or fresh meat)

RISKS COVERED

1 This insurance covers, except as provided in Clauses 4, 5, 6 and 7 below, Risks Clause

1.1 loss of or damage to the subject-matter insured attributable to

1.1.1 fire or explosion

1.1.2 vessel or craft being stranded grounded sunk or capsized

1.1.3 overturning or derailment of land conveyance

1.1.4 collision or contact of vessel craft or conveyance with any external object other than water

1.1.5 discharge of cargo at a port of distress

1.1.6 breakdown of refrigerating machinery resulting in its stoppage for a period of not less than 24 consecutive hours

1.2 loss of or damage to the subject-matter insured caused by

1.2.1 general average sacrifice

1.2.2 jettison.

2 This insurance covers general average and salvage charges, adjusted or determined according to the contract of affreightment and/or the governing law and practice, incurred to avoid or in connection with the avoidance of loss from any cause except those excluded in Clauses 4, 5, 6 and 7 or elsewhere in this insurance. General Average Clause

3 This insurance is extended to indemnify the Assured against such proportion of liability under the contract of affreightment "Both to Blame Collision" Clause as is in respect of a loss recoverable hereunder. In the event of any claim by shipowners under the said Clause the Assured agree to notify the Underwriters who shall have the right, at their own cost and expense, to defend the Assured against such claim. "Both to Blame Collision" Clause

EXCLUSIONS

4 In no case shall this insurance cover General Exclusion Clause

4.1 loss damage or expense attributable to wilful misconduct of the Assured

4.2 ordinary leakage, ordinary loss in weight or volume, or ordinary wear and tear of the subject-matter insured

4.3 loss damage or expense caused by insufficiency or unsuitability of packing or preparation of the subject-matter insured (for the purpose of this Clause 4.3 " packing " shall be deemed to include stowage in a container or liftvan but only when such stowage is carried out prior to attachment of this insurance or by the Assured or their servants)

4.4 loss damage or expense caused by inherent vice or nature of the subject-matter insured (except loss damage or expense resulting from variation in temperature specifically covered under Clause 1.1.6 above)

4.5 loss damage or expense proximately caused by delay, even though the delay be caused by a risk insured against (except expenses payable under Clause 2 above)

4.6 loss damage or expense cause by insolvency or financial default of the owners managers charterers or operators of the vessel where, at the time of loading of the subject-matter insured on board the vessel, the Assured are aware, or in the ordinary course of business should be aware, that such insolvency or financial default could prevent the normal prosecution of the voyage.

This exclusion shall not apply where this insurance has been assigned to the party claiming hereunder who has bought or agreed to buy the subject-matter insured in good faith under a binding contract

4.7 deliberate damage to or deliberate destruction of the subject-matter insured or any part thereof by the wrongful act of any person or persons

4.8 loss damage or expense arising from the use of any weapon of war employing atomic or nuclear fission and/or fusion or other like reaction or radioactive force or matter

4.9 loss damage or expense on shore caused directly or indirectly by earthquake, volcanic eruption and/or fire resulting therefrom

4.10 loss damage or expense arising from any failure of the Assured or their servants to take all reasonable precautions to ensure that the subject-matter insured is kept in refrigerated or, where appropriate, properly insulated and cooled space.

5 5.1 In no case shall this insurance cover loss damage or expense arising from Unseaworthiness

5.1.1 unseaworthiness of vessel or craft or unfitness of vessel or craft for the safe carriage of the subject-matter insured, where the Assured are privy to such unseaworthiness or unfitness, at the time the subject-matter insured is loaded therein

and Unfitness Exclusion Clause

5. 1.2 unfitness of container liftvan or land conveyance for the safe carriage of the subject-matter insured, where loading therein is carried out prior to attachment of this insurance or by the Assured or their servants.

5.2 Where this insurance has been assigned to the party claiming hereunder who has bought or agreed to buy the subject-matter insured in good faith a binding contract, exclusion 5.1.1 above shall not apply.

5.3 The Underwriters waive any breach of the implied warranties of seaworthiness of the ship and fitness of the ship to carry the subject-matter insured to destination.

6 In no case shall this insurance cover loss damage or expense caused by

War Exclusion Clause

6.1 war civil war revolution rebellion insurrection, or civil strife arising therefrom, or any hostile act by or against a belligerent power

6.2 capture seizure arrest restraint or detainment (piracy excepted), and the consequences thereof or any attempt thereat

6.3 derelict mines torpedoes bombs or other derelict weapons of war.

7 In no case shall this insurance cover loss damage or expense

Strikes Exclusion Clause

7.1 caused by strikers, locked-out workmen, or persons taking part in labour disturbances, riots or civil commotions

7.2 resulting from strikes, lock-outs, labour disturbances, riots or civil commotions

7.3 caused by any terrorist or any person acting from a political motive.

DURATION

8 8.1 This insurance attaches from the time

Transit Clause

8.1.1 the goods pass into the cooling and/or freezing chambers of the works at the place named herein, provided that the period in such chambers prior to shipment on board the oversea vessel shall not exceed 60 days unless prompt notice be given to the Underwriters and an additional premium paid for each further period of 30 days or part thereof.

DELETE SECTIONS NOT APPLICABLE

8.1.2 the goods are loaded into the conveyance at the freezing works or cold store at the place named herein for the commencement of the transit.

8.1.3 of loading of the goods into the oversea vessel.

8.2 This insurance continues during the ordinary course of transit to and whilst in

8. 2.1 cold store at the destination named herein

or

8.2.2 any other cold store which the Assured elect to use following discharge of the goods from the oversea vessel

at the port of discharge either

8.2.2.1 for storage other than in the ordinary course of transit or

8.2.2.2 for allocation or distribution.

8.3 This insurance terminates

8.3.1 *for transit to a destination in the Continent of Europe (including Eire and the United Kingdom), U.S.A. or*

Canada on the expiry of 30 days

8.3.2 *for transit to a destination elsewhere* on the expiry of 5 days

after final discharge of the goods from the oversea vessel at the port of discharge.

8.4 Any disposal of the goods other than by storage as in 8. 2.1 or 8. 2.2 above (expect with the prior consent of the Underwriters) or any removal from cold store before the expiry of the relevant period in 8.3.1 or 8.3.2 above shall terminate the insurance of such goods.

8.5 If, after discharge over side from the oversea vessel at the final port of discharge, but prior to termination of this insurance, the goods are to be forwarded to a destination other than that to which they are insured hereunder, this insurance, whilst remaining subject to termination as provided for above, shall not extend beyond the commencement of transit to such other destination.

8.6 This insurance shall remain in force (subject to termination as provided for above and to the provisions of Clause 9 below) during delay beyond the control of the Assured, any deviation, forced discharge, reshipment or transhipment and during any variation of the adventure arising from the exercise of a liberty granted to shipowners or charterers under the contract of affreightment.

9 If owing to circumstances beyond the control of the Assured either the contract of carriage is terminated at a port or place other than the destination named therein or the transit is otherwise terminated before delivery of the goods as provided for in Clause 8 above, then this insurance shall also terminated *unless prompt notice is given to the Underwriters and continuation of cover is requested when the insurance shall remain in force, subject to an additional premium if required by the Underwriters,* either

Termination of Contract of Carriage Clause

9.1 until the goods are sold and delivered at such port or place, or, unless otherwise specially agreed, until the expiry of 30 days after arrival of the goods hereby insured at such port or place, whichever shall first occur,

or

9.2 if the goods are forwarded within the said period of 30 days (or any agreed extension thereof) to the destination named herein or to any other destination, until terminated in accordance with the provisions of Clause 8 above.

10 Where, after attachment of this insurance, the destination is changed by the Assured, *held covered at a premium and on conditions to be arranged subject to prompt notice being given to the Underwriters.*

Change of Voyage Clause

CLAIMS

11 11.1 In order to recover under this insurance the Assured must have an insurable interest in the subject-matter insured at the time of the loss.

Insurable Interest Clause

11.2 Subject to 11.1 above, the Assured shall be entitled to recover for insured loss occurring during the period covered by this insurance, notwithstanding that the loss occurred before the contract of insurance was concluded, unless the Assured were aware of the loss and the Underwriters were not.

11.3 Prompt notice of any deterioration loss or damage shall be given to Underwriters upon first discovery and any claim for depreciation or damage is conditional upon Underwriters having been given an opportunity to inspect such depreciation or damage before termination of the insurance.

Notice of Claim Clause

12 Where, as a result of the operation of a risk covered by this insurance, the insured transit is terminated at a port or place other than that to which the subject-matter is covered under this insurance, the Underwriters will reimburse the Assured for any extra charges properly and reasonably incurred in unloading storing and forwarding the subject-matter to the destination to which it is insured hereunder.

Forwarding Charges Clause

This clause 12, which does not apply to general average or salvage charges, shall be subject to the exclusions contained in Clause 4, 5, 6 and 7 above, and shall not include charges arising from the fault negligence insolvency or financial default of the Assured or their servants.

13 No claim for Constructive Total Loss shall be recoverable hereunder unless the subject-matter insured is reasonably abandoned either on account of its actual total loss appearing to be unavoidable or because the cost of recovering, reconditioning and forwarding the subject-matter to the destination to which it is insured would exceed its value on arrival.

Constructive Total Loss Clause

14 Should the subject-matter insured or any part thereof not be shipped any claim in respect thereto shall be adjusted on the basis of its insured value less, where included, freight, duty and all charges not incurred.

Adjustment Clause

15 15.1 If any Increased Value insurance is effected by the Assured on the cargo insured herein the agreed value of the cargo shall be deemed to be increased to the total amount insured under this insurance and all Increased Value insurances covering the loss, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured.

Increased Value Clause

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

15.2 **Where this insurance is on Increased Value the following clause shall apply:**

The agreed value of the cargo shall be deemed to be equal to the total amount insured under the primary insurance and all Increased Value insurances covering the loss and effected on the cargo by the Assured, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured.

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

BENEFIT OF INSURANCE

16 This insurance shall not inure to the benefit of the carrier or other bailee.

Not to Inure Clause

MINIMISING LOSSES

17 It is the duty of the Assured and their servants and agents in respect of loss recoverable hereunder

Duty of Assured Clause

17.1 To take such measures as may be reasonable for the purpose of averting or minimising such loss, and

17.2 To ensure that all rights against carriers, bailees or other third parties are properly preserved and exercised and the Underwriters will, in addition to any loss recoverable hereunder, reimburse the Assured for any charges properly and reasonably incurred in pursuance of these duties.

18 Measures taken by the Assured or the Underwriters with the object of saving, protecting or recovering the subject-matter insured shall not be considered as a waiver or acceptance of abandonment or otherwise prejudice the rights of either party.

AVOIDANCE OF DELAY

19 It is a condition of this insurance that the Assured shall act with reasonable despatch in all circumstances within their control. Reasonable

Despatch Clause

LAW AND PRACTICE

20 This insurance is subject to English law and practice. English Law and Practi

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NOTE: - It is necessary for the Assured when they become aware of an event which is "held covered" under this insurance to give prompt notice to the Underwriters and the right to such cover is dependent upon compliance with this obligation.

SPECIAL NOTE:- This insurance does not cover loss damage or expense caused by embargo, or by rejection prohibition or detention by the government of the country of import or their agencies or departments, but does not exclude loss of or damage to the subject-matter insured caused by risks insured hereunder and sustained prior to any such embargo rejection prohibition or detention.

1/1/86

INSTITUTE STRIKES CLAUSES (FROZEN MEAT) - (not suitable for chilled, cooled or fresh meat)

RISKS COVERED

1. This insurance covers, except as provided in Clause 3 and 4 below, loss of or damage to the subject-matter insured caused by — Risks Clause

1.1 strikes, locked-out workmen, or persons taking part in labour disturbances, riots or civil commotions

1.2 any terrorist or any person acting from a political motive.

2. This insurance covers general average and salvage charges, adjusted or determined according to the contract of affreightment and/or the governing law and practice, incurred to avoid or in connection with the avoidance of loss from a risk covered under these clauses. — General Average Clause

EXCLUSIONS

3. In no case shall this insurance cover — General Exclusions Clause

3.1 loss damage or expense attributable to wilful misconduct of the Assured

3.2 ordinary leakage, ordinary loss in weight or volume, or ordinary wear and tear of the subject-matter insured

3.3 loss damage or expense caused by insufficiency or unsuitability of packing or preparation of the subject-matter insured (for the purpose of this Clause 3.3 "packing" shall be deemed to include stowage in a container or liftvan but only when such stowage is carried out prior to attachment of this insurance or by the Assured or their servants)

3.4 loss damage or expense caused by inherent vice or nature of the subject-matter insured

3.5 loss damage or expense proximately caused by delay, even though the delay be caused by a risk insured against (except expenses payable under Clause 2 above)

3.6 loss damage or expense arising from insolvency or financial default of the owners managers charterers or operators of the vessel where, at the time of loading of the subject-matter insured on board the vessel, the Assured are aware, or in the ordinary course of business should be aware, that such insolvency or financial default could prevent the normal prosecution of the voyage

This exclusion shall not apply where this insurance has been assigned to the party claiming hereunder who has bought or agreed to buy the subject-matter insured in good faith under a binding contract

3.7 loss damage or expense arising from the absence shortage or withholding of equipment, power, fuel, coolant, refrigerant or labour of any description whatsoever resulting from any strike, lockout, labour disturbance, riot or civil commotion

3.8 any claim based upon loss of or frustration of the voyage adventure

3.9 loss damage or expense arising from the use of any weapon of war employing atomic or nuclear fission and/or fusion or other like reaction or radioactive force or matter

3.10 loss damage or expense caused by war civil war revolution rebellion insurrection, or civil strife arising therefrom, or any hostile act by or against a belligerent power.

3.11 any loss damage or expense on shore caused directly or indirectly by earthquake, volcanic eruption and/or fire resulting therefrom.

4. 4.1 In no case shall this insurance cover loss damage or expense arising from

4.1.1 unseaworthiness of vessel or craft, or unfitness of vessel craft for the safe carriage — Unseaworthi-

of the subject-matter insured, where the Assured are privy to such unseaworthiness or unfitness, at the time the subject-matter insured is loaded therein

ness and Unfitness Clause

4.1.2 unfitness of container lift van or land conveyance for the safe carriage of the subject-matter insured, where loading therein is carried our prior to attachment of this insurance or by the Assured or their servants.

4.2 Where this insurance has been assigned to the party claiming hereunder who has bought or agreed to buy the subject-matter insured in good faith under a binding contract, exclusion 4.1.1 above shall not apply.

4.3 The Underwriters waive any breach of the implied warranties of seaworthiness of the ship and fitness of the ship to carry the subject-matter insured to destination.

DURATION

5. 5.1 This insurance attaches from the time

Transit Clause

5.1.1 the goods pass into the cooling and/or freezing chambers of the works at the place named herein, provided that the period in such chambers prior to shipment on board the oversea vessel shall not exceed 60 days unless prompt notice be given to the Underwriters and an additional premium paid for each further period of 30 days or party thereof.

DELETE SECTIONS NOT APPLICABLE

5.1.2 the goods are loaded into the conveyance at the freezing works or cold store at the place named herein for the commencement of the transit.

5.1.3 of loading of the goods into the oversea vessel.

5.2 This insurance continues during the ordinary course of transit to and whilst in

5.2.1 cold store at the destination named herein

or

5.2.2 any other cold store which the Assured elect to use following discharge of the goods from the oversea vessel at the port of discharge either

5.2.2.1 for storage other than in the ordinary course of transit or

5.2.2.2 for allocation or distribution.

5.3 This insurance terminates

5.3.1 *for transit to a destination in the Continent of Europe (including Eire and the United Kingdom), U.S.A. or Canada* on the expiry of 30 days

5.3.2 *for transit to a destination elsewhere* on the expiry of 5 days

after final discharge of the goods from the oversea vessel at the port of discharge.

5.4 Any disposal of the goods other than by storage as in 5.2.1 or 5.2.2 above (except with the prior consent of the Underwriters) or any removal from cold store before the expiry of the relevant period in 5.3.1 or 5.3.2 above shall terminate the insurance on such goods.

5.5 If, after discharge overside from the oversea vessel at the final port of discharge, but prior to termination of this insurance, the goods are to be forwarded to a destination other than that to which they are insured hereunder, this insurance, whilst remaining subject to termination as provided for above, shall not extend beyond the commencement of transit to such other destination.

5.6 This insurance shall remain in force (subject to termination as provided for above and to the provisions of Clause 6 below) during delay beyond the control of the Assured, any deviation, forced discharge, reshipment or transhipment and during any variation of the adventure arising from the exercise of a liberty granted to shipowners or charterers under the contract of affreightment.

6. If owing to circumstances beyond the control of the Assured either the contract of carriage is terminated at a port or place other than the destination named therein or the transit is otherwise terminated before delivery of the goods as provided for in Clause 5 above, then this insurance shall also terminated *unless prompt notice is given to the Underwriters and continuation of cover is requested when the insurance shall remain in*

Termination of Contract of Carriage Clause

force, subject to an additional premium if required by the Underwriters, either

6.1 until the goods are sold and delivery at such port or place, or, unless otherwise specially agreed, until the expiry of 30 days after arrival of the goods hereby insured at such port or place, whichever shall first occur,

or

6.2 if the goods are forwarded within the said period of 30 days (or any agreed extension thereof) to the destination named herein or to any other destination, until terminated in accordance with the provisions of Clause 5 above.

Change of Voyage Clause

7. Where, after attachment of this insurance, the destination is changed by the Assured, *held covered at a premium and on conditions to be arranged subject to prompt notice being given to the Underwriters.*

CLAIMS

Insurable Interest Clause

8.1 8.1 In order to recover under this insurance the Assured must have an insurable interest in the subject-matter insured at the time of the loss.

8.2 Subject to 8.1 above, the Assured shall be entitled to recover for insured loss occurring during the period covered by this insurance, notwithstanding that the loss occurred before the contract of insurance was concluded, unless the Assured were aware of the loss and the Underwriters were not.

Notice of Claim Clause

8.3 Prompt notice of any deterioration loss or damage shall be given to Underwriters upon first discovery and any claim for depreciation or damage is conditional upon Underwriters having been given an opportunity to inspect such depreciation or damage before termination of the insurance.

Adjustment Clause

9. Should the subject-matter insured or any part thereof not be shipped any claim in respect thereto shall be adjusted on the basis of its insured value less, where included, freight, duty and all charges not incurred.

Increased Value Clause

10. 10.1 If any Increased Value insurance is effected by the Assured on the cargo insured herein the agreed value of the cargo shall be deemed to be increased to the total amount insured under this insurance and all Increased Value insurances covering the loss, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured.

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

10.2 **Where this insurance is on Increased Value the following clause shall apply**:

The agreed value of the cargo shall be deemed to be equal to the total amount insured under the primary insurance, and all Increased Value insurances covering the loss and effected on the cargo by the Assured, and liability under this insurance shall be in such proportion as the sum insured herein bears to such total amount insured.

In the event of claim the Assured shall provide the Underwriters with evidence of the amounts insured under all other insurances.

BENEFIT OF INSURANCE

Not to Inure Clause

11. This insurance shall not inure to the benefit of the carrier or other bailee.

MINIMISING LOSSES

Duty of Assured Clause

12. It is the duty of the Assured and their servants and agents in respect of loss recoverable hereunder

12.1 to take such measures as may be reasonable for the purpose of averting or minimising such loss,

and

12.2 to ensure that all rights against carriers, bailees or other third parties are properly

preserved and exercised

and the Underwriters will, in addition to any loss recoverable hereunder, reimburse the Assured for any charges properly and reasonably incurred in pursuance of these duties.

Waiver Clause

13. Measures taken by the Assured or the Underwriters with the object of saving, protecting or recovering the subject-matter insured shall not to considered as a waiver or acceptance of abandonment or otherwise prejudice the rights of either party.

AVOIDANCE OF DELAY

Reasonable Despatch Clause

14. It is a condition of this insurance that the Assured shall act with reasonable despatch in all circumstances within their control.

LAW AND PRACTICE

English Law and Practice Clause

15. This insurance is subject to English law and practice.

NOTE:- It is necessary for the Assured when they become aware of an event which is "held covered" under this insurance to give prompt notice to the Underwriters and the right to such cover is dependent upon compliance with this obligation.

SPECIAL NOTE:- This insurance does not cover loss damage or expense caused by embargo, or by rejection prohibition or detention by the government of the country of import or their agencies or departments, but does not exclude loss of or damage to the subject-matter insured caused by risks insured hereunder and sustained prior to any such embargo rejection prohibition or detention.

1/1/86

IMTA FROZEN MEAT EXTENSION CLAUSES – (For use only with the Institute Frozen Meat Clauses (A) 1/1/86)

Clause 1 and Clauses 4.4 and 4.5 of the attached Institute Frozen Meat Clauses (A) 1/1/86 are deemed to be deleted and replaced by:

1 Subject always to the goods being in sound condition at the time of attachment, this insurance covers, except as provided in Clauses 4, 5, 6 and 7 below, loss of, deterioration of, or damage to the subject-matter insured which shall arise during the currency of this insurance.

4 4.4 loss damage or expense arising from bone taint, salmonella, infection prior to attachment of this insurance, fault in preparation dressing cooling freezing wrapping or packing

4.5 claims arising from loss of market.

Nevertheless, in the absence of prior notice to the Underwriters and agreement of any additional premium required by them, this insurance excludes any claim for deterioration of or damage to the subject-matter insured where the period in freezing works and in any cold store, before loading into the conveyance for commencement of the transit, exceeds 60 days.

PROCEDURES TO FOLLOW IN CASE OF DAMAGE

Duty to advise the loss

The main obligations resting on the insured at the time of occurrence of damage are three:

1. Advise the loss.
2. Take all reasonable steps to avoid or diminish the consequences.
3. Safeguard the recovery action against parties liable for the loss.

As for the duty to advise the rules may be found in art. 1913 of the Civil Code, while as for the consequences of the failure to advise the insurer reference must be made to art. 1915 of the Civil Code.

The insured must advise the loss to the insurer or to the intermediary authorized to finalize the contract within 3 days staring from the date when the loss has occurred or the insured has come to know about it. Advising, though, is not necessary if the insurer or the agent authorized to finalize the contract intervene within the above time limit to salvage goods or ascertain the loss.

In fact policies make great use of this right, requiring an immediate notice to insurer or to the agent to whom the policy is assigned: immediate notice is justified by the importance that timely intervention of the surveyor or of the survey agent may have, both to single out possible liabilities of third parties and to ascertain the nature of the loss.

Precisely pinpointing this last aspect is of great importance also in view of the possibility of agreeing on forms of loss prevention. The navigation code, while holding valid the principles laid down in art. 1913 of the Civil Code, bestows on the insured the duty to advise even when the ship has been declared unseaworthy, although the goods have suffered no damages due to the occurrence: also in this case the reason for the rule is easily explainable.

Goods on board an unseaworthy ship, even if not damaged, are in a situation of great danger and it is therefore necessary to inform insurers, so as to agree on the possible steps to take to avoid the risk of damage to goods.

Actions undertaken to avoid or mitigate the loss

Particularly important, then, is the duty to undertake every reasonable action to avoid or mitigate the loss; in practice, the insured must behave as if he were not insured. The code mentions in this connection the duty to salvage; however this type of salvage must be definitely distinguished from “salvage” in its proper meaning.

Art. 534 of the Navigation Code precises the civil rule, extending the duty to salvage to the captain of the ship and to the servants and representatives of the insured. It is deemed that the extension of the duty to salvage to the captain may apply in case of hull insurance, as the right of the owner of goods may not be prejudiced by the unreasonable behaviour of the captain.

This is made clear also by Art. 524 of the Navigation Code, which extends the insurance cover on goods to malice of the captain. As for the limits within which expenses are refundable the difference existing between the rule laid down by the Civil Code and the one of the Navigation Code must be always kept in mind.

In fact while according to the Civil Code such expenses are refundable as long as they are reasonable, even if adding them to the material damage they amount to more than the insured

value, according to the navigation code it is possible to agree that expenses made to avoid or mitigate the loss are payable as long as they are not higher than the insured value when added to the material damage: art. 10 of the General Conditions of the Italian Policy for the insurance of goods in transit – 1998 ANIA Edition, of pure reference - confirms (as already stated) the provisions of the Civil Code.

It is clear that anyway such expenses are refundable only if they have been incurred in connection with a risk insured: if for instance the occurrence giving rise to damages relates to a war risk (not covered by the policy), expenses made to avoid or limitate damages cannot be paid to the insured.

The greatest problems arise when verifying possible settlement of such expenses on limited insurance covers: in these cases the best legal theories deem that such expenses are refundable only if incurred in order to avoid a risk insured. However objections to this point of view have been made saying that a small leak in a ship, if neglected, may lead to a total loss: also without considering that, as already stated, it is a precise duty of the insured to behave as if he were not insured.

Safeguarding the recovery action against liable third parties

Finally it is the duty of the insured to safeguard the recovery action against third parties liable for the loss, proceeding to express all due reserves at the time of delivery and safeguarding time-bar limits.

In particular this last aspect is of great importance if it is taken into account that (as already indicated) when dealing with transport there are somewhat short time-bars: as for land transport by truck the time-bar is one year when carriage takes place on a national basis, eighteen months when it is carried out on international basis, terms which may be interrupted by a registered claim letter.

As for international sea transport it can be said that in most cases, that is where the Hague-Visby Rules apply, the time-bar is one year (however, as already stated, extensible), and may be interrupted by bringing a legal action.

It is still debated who must interrupt such terms when damage has not yet been paid by insurers: jurisprudence has been very favourable to insureds under this aspect, considering insurers able to safeguard time-bar limits since the moment in which they are aware of damages, that is to say since they have received notice of the loss. It is a thesis which is very hard on insurers, if it is considered that the notice of loss is very often extremely vague. Moreover the insurer is empowered to act only once he has settled the claim. Perhaps the most reasonable solution is to consider that it is a duty of the insured to safeguard time-bar limits, discharging him from such onus if the insurer, though able to settle the claim, arbitrarily delays payment.

Sue and Labour Clause

Considering the first fundamental duty of the Insured in case of damage, it is appropriate to deal with the content of the *Sue and Labour Clause*:

> "It is the duty of the Assured to act at all time as though he were not insured and to take such measures for the preservation of the insured property as a prudent uninsured person would take..."

The meaning of this clause is therefore to place on the Insured the obligation to take those particular measures in case of damage with the same interest of him who does not benefit from the protection afforded by the Insurer.
On the basis of the Sue and Labour Clause the undertaking of the Insurer is supplementary to the contract of insurance, in the sense that the Insured may obtain from the Insurer payment of the expenses made in accordance with the clause over and above the indemnity due for the damages: practically for expenses incurred to avoid or mitigate the loss there is an indemnity which may be greater than the sum insured. Expenses not inconsiderately incurred are paid by the Insurer in proportion to what the sum insured is as against the insurable value (this concept was expressed by the Marine Insurance Act, MIA, the fundamental English law for marine insurance, and included in the policies employed by our market). Damages relating to general average and contribution are not anyway included in the clause, nor those expenses incurred to avoid or mitigate damages which are not covered.

Rules to follow in case of loss or damage to the goods being carried

Policy on goods

Provisions of the policy conditions with a view to a simpler and quicker settlement of damages relating to this insurance cover remaining unalte red, we list an d rem ind here below the main contractual rules which must be followed in case of loss.

Activities to be carried out immediately
Proof of damage and holding third responsible parties liable

In case of loss or damage

1. Apply due remarks on the goods delive ry documents and send, within the terms and in the forms provided for by the transport documents, a claim in writing to the carrier.
   The rem arks will have to describe in detail th e damage and/or the shortage and m ust be countersigned by the driver to be considered valid. For damages which are not visible upo n delivery of goods a regist ered letter with proof of r eceipt will have to be se nt to the first carrier, holding the latter liable and detailing the list and the value of goods da maged or lost. Such claim must be sent right away and, as a ru le, no later than 8 days for transport within Italy and 7 days for international transport subject to CMR.

2. Immediately advise the Insurer with whom the contract has been taken out. Notice given by telephone, telefax, telegram or e-mail must contain, besides the description of damage and a rough estimate of same, also the exact location where goods are lying.

3. The Insurer will appoint a surveyor, whose name will be made known also to the Claimant. In some cases the Claimant may directly appoint a surveyor.

So as not to jeopardize the insurance cover, the state of the goods must not be modified before the intervention of the surveyor.

4. Survey ascertainments must take place, whenever possible, jointly with all interested parties (Seller and/or Buyer of goods, Carriers, Insurers and Freight Forwarder) and therefore the Claimant must send a formal invitation to joint ascertainments.

5. Do everything possible to avoid or mitigate the loss, taking all steps necessary to salvage goods, the expenses of which will be borne by the Insurer.
   The Insurer has the right to take whatever action aimed at such purpose, without any prejudice to the respective rights and without his intervention influencing the legal situation of the goods.

6. Refrain from transacting and/or cashing payments from third liable parties without the prior written agreement of the Insurer, so as not to prejudice totally or partially possible subsequent recovery actions.

Claim filing activities.
Documents to provide

With the aim to facilitate a quick settlement of claims it is recommended that the documents which are provided, if they are not originals, are legible, complete, gathered quickly and sent to the Insurer by swift means.

The indications about the documents which should be provided are generic and not binding and may be supplemented by further requests depending on the actual necessities.

Standard documents

In order to ask for payment, the documents which must be provided for all claims are:

1) Transport Documents / Bill of Lading / Waybill
2) Invoice of sale of goods
3) Survey report if it has been arranged
4) Statement to the Authorities, in case of theft, armed robbery or fire
5) Report of the Authorities which intervened, when theft of goods occurred together with stealing of the vehicle employed for transport and the latter has been found.

Documents for particular events or situations

1) If the Claimant is not the party entitled to claim: assignment of rights and credits deriving from the contract of sale, insurance and transport, issued by the party entitled to claim.
2) Groupage shipments
   a. Packing list when the content of packages is not detailed on the invoice or on the transport documents.
   b. Cargo manifest
3) Identification of carrier's liability
   c. Invoices for freight
   d. Letter of protest to the carrier if damages were not visible at the time of delivery of goods to final consignee.
   e. CH100 in original or analogous document for rail carriages.
   f. Copy of the circulation card of the motor vehicle.

4) Transport of refrigerated goods on one's own vehicles: copy of the invoices proving that maintenance of the refrigerating machinery has been carried out regularly in case of refrigerated transport.

Carrier's liability policy

In the case the Insured is a carrier a carrier's liability policy is recommended.

Provisions of the policy conditions with a view to a simpler and quicker settlement of damages relating to this insurance cover remaining unaltered, we list and remind here below the main contractual rules which must be followed in case of loss.

Activities to be carried out immediately
Proof of damage and holding liable responsible parties

In case of loss or damage:

1. At the time of loading, check that goods correspond to those indicated on the transport documents, are adequate for transport and do not show visible damages or unconditionings. In case the carrier should detect an unconformity, damage or unconditioning he must place a remark on transport documents when accepting goods, having the Shipper countersigning it.

2. At the time of delivery of cargo, if remarks are placed on delivery documents of goods, verify the correctness of such declarations possibly not countersigning same or indicating his own objections. In any case refrain from voluntarily accepting liability.

3. Remarks must detail damages and/or shortages and must be countersigned by the driver to be considered valid.

4. For damages which are not visible upon delivery of goods the party suffering damages must send a registered letter with proof of receipt to the first carrier, holding the latter liable and detailing the list and the value of goods damaged or lost. This claim must be sent swiftly and, as a rule, within and not later than 8 days for transport within Italy and 7 days for international transport subject to CMR.

5. Immediately advise the Insurer with whom the contract has been taken out. Notice given by telephone, telefax, telegram or e-mail must contain, besides the description of damage and a rough estimate of same, also the exact location where goods are lying.

6. The Insurer will appoint a surveyor, whose name will be made known to the Claimant. In some cases the Claimant may directly appoint a surveyor.

    a. So as not to jeopardize the insurance cover, the state of the goods must not be modified before the intervention of the surveyor.

    b. Whenever possible, survey ascertainments must take place jointly with all interested parties (Seller and/or Buyer of goods, Carriers, Insurers and Freight Forwarder) and preferably the carrier will arrange with the claimant or with the appointed surveyor a formal meeting to ascertain damages.

    c. Take every step necessary to avoid or mitigate the loss, providing for salvage of the goods, the expenses of which will be borne by the insurer. The Insurer has the right to

take whatever action aimed at that p urpose, without any prejudice to the respective rights and without its intervention influencing the legal situation of the goods.

d. Refrain fro m transacting and/or cashing pa yments fro m the carrier without the prio r written agreement of the Insurer, so as not to prejudice totally or partially possibl e subsequent recovery actions.

Claim filing activities
Documents to be provided

With the ai m to facilitate a quick settlement of clai ms it is reco mmended that the documents which are provided, if they are not originals, are legible, complete, gathered quickly and sent to the Insurer by swift means.

The indications about the documents which should be provided are generic and not binding and may be supplemented by further requests depending on the actual necessities.

Standard documents

In order to request payment, documents which must be provided for all claims are:

1) Transport documents / Bill of Lading / Waybill bearing remarks
2) Debit note
3) Invoice of sale of goods
4) Freight invoices (if the policy is on the amount of freight invoiced)
5) Survey report if it has been arranged
6) Possible correspondence exchanged with the Consignor/consignee or other carriers
7) Statement to the Authorities in case of theft or other offence resulting in damages to goods
8) Report by the Authorities which have intervened , when theft of t he goods occ urred together with stealing of the vehicle employed for transport and the latter has been found.

Documents for particular events or situations

1) If the Clai mant is not the party entitled to clai m: assignment of ri ghts and credits deriving from the contract of sale, insurance and transport, issued by the party entitled to claim.
2) If a recovery action from a Carrier is undergone
   a. Debit note by the party entitled to claim in favour of Claimant
   b. Proof of payment by Claimant
3) If a recovery action from a Company is undergone
   a. Discharge and subrogation receipt
   b. Request for payment
4) Groupage shipments
   a. Packing list in case the content of packages is not detailed on the invoice or on transport documents.
   b. Cargo manifest
5) Identification of carrier’s liability
   a. Letter of protest to the carrier if damag es were not visible upon delivery of g oods to final consignee.
   b. Original CH100 claim form or equivalent document for transport by rail
   c. Copy of the circulation card of the motor vehicle.
6) Transport of refrigerated goods by one’s own vehicles: copy of the invoices proving the periodical maintenance of the refrigerating machinery in case of refrigerated goods.

SURVEY ASCERTAINMENTS

Surveyor's fulfilments

In this chapter purely technical aspects relating to surveyor's duties are taken into consideration.

In the specific case the surveyor should have a good technical knowledge of perishable alimentary products and of the systems employed for their preservation, of the means of transport and of the alterations which preserved foodstuffs may undergo in case the standard requisites are not maintained in any one segment of the chain which goes from production in a broad sense up to delivery to the final consumer.

It would be advisable to also possess a fairly good knowledge of the sources of supply of raw materials, of the transformation and production modalities, packaging methods included, of the typologies and rules regarding packing and of all what relates to the physical distribution of products, including storage.

Obviously as a background it is essential to know the new hygienic/sanitary regulations which are of greater and greater importance and influence not only the production and distribution aspects of products but also the final evaluations of the amount of damages.

Damages to preserved alimentary goods may take place in any moment along the distribution chain, on which our attention will be focused and it is a duty of the surveyor, having the above requisites, to ascertain which are the nature and the cause of the alterations found.

As for physical and temporal collocation of damages which may take place, excluding therefore any possible form of loss prevention, which will be discussed in a different chapter, the surveyor may find himself before two possibilities:

- occurrences happening during storage in warehouses where goods may lie covered any way by insurance falling within the scope of transport/marine insurance; this may happen before or after the actual carriage or during same, owing to temporary stops, transhipments, possible urgencies.
- occurrences happening in the course of transport for transfer of goods from the production or storage location to final consignee.

In our analysis we shall only deal with goods carried under controlled temperature in ship holds, in container and by truck, as these are now the most frequent cases and they are the weakest link in the distribution chain not only owing to their complexity and because the means of transport, for various reasons, cannot be always kept under control, but also because of negligence or unpreparedness by them who perform the actual transport.

It should be noted that railway wagons may be nowadays totally likened to reefer containers.

Let us now pass on to deal with the fulfilments of the surveyor involved in damages to alimentary products under controlled temperature, whatever the conveyance employed:

a) once received the appointment to intervene, immediately contact those entrusted with the shipment to locate goods and summarily reconstruct the facts, ascertaining whether interested cargo is still on board the means of transport;

b) in the affirmative, intervene as quickly as possible trying however not to hinder actions possibly already taken by interested parties to safeguard goods, for instance transhipment or immediated estuffing so as to place goods in cold stores; the importance of a timely intervention by the surveyor is clear because it permits to take the necessary measures to protect the goods and to "photograph" the situation, verifying the distribution of temperatures in the cargo as originally stowed and also the distribution / diffusion / severity

of alterations; this is of course fundamental to try to understand the possible causes of the occurrence;

c) if instead the goods are no more on board the conveyance, the first thing to be done is to ensure that they are duly harboured in premises with an adequate temperature for their best recovery and keeping and then to endeavour to trace and inspect the means of transport, if possible;

d) the inspection of the means of transport must allow to ascertain its operative conditions at the time of occurrence and in the meantime permit to reconstruct the whole course of transit, at least beginning from loading/stowage, thanks to an inspection, if possible, of the recordings of the temperatures tracked by the on board appliances; for the technical inspection of the conveyance the surveyor may need the help of fiduciary technicians expert in refrigerating machineries to which he may resort in case of need; obviously not always is it possible to inspect firstly the means of transport, then the goods, it depends on the various cases and on the various possibilities that arise/are evaluated from time to time;

e) Once the conditions of the means of transport have been ascertained and therefore with an idea which should be already sufficiently clear about what has happened, which is not always possible above all if the surveyor is dealing with a reefer container, the latter proceeds to inspect the goods, both to evaluate its organoleptic, and therefore commercial, degradation and to collect other clues, if necessary, to determine the causes of damage; obviously the examination of goods must be always carried out on samples which must statistically represent the entire shipment and its state at the time and possibly jointly with other parties interested in the transport and in the goods themselves; it will have to be evaluated from time to time which types of ascertainments must be carried out depending on the quality of the product, the temperatures which have been reached, on the severity therefore of the alterations in values and length of time; according to the outcomes of the ascertainments, possibly also instrumental, to which goods have been subject, it may be understood which are the possible developments of a degenerative nature, and therefore also of a sanitary nature, which the goods may undergo.

As a background the surveyor should be immediately informed about the conditions under which transport is carried out, so as not to omit any details when collecting information and data from the actual carriers insured and furthermore it would be advisable that he may receive/collect as soon as possible also the usual paperwork:

- transport document (bill of lading; CMR; delivery receipt or bulletin or waybill)
- sales invoice with incoterms
- loading or stowage plan
- sanitary documents
- possible remarks regarding the condition of goods when loaded
- circulation card if dealing with a truck.

Again immediately after appointment and first request for documents which should ideally be received before intervention, the surveyor must instruct the insured or whoever is entitled to do so to send to the party who materially held goods at the time of occurrence or any way to who was responsible for transport a due letter of protest within the time limits provided for by ruling laws, inviting him to joint ascertainments and holding him liable for all the consequences of the loss.

In practice therefore it is up to the surveyor to verify the condition of goods and to evaluate their damaged state and therefore the technical-commercial damage and furthermore to verify and ascertain the cause of damage itself and to provide for the first steps necessary to safeguard the future rights of the insurers who have appointed him.

In the context of his ascertainments the surveyor must evaluate the adequacy of the means of transport employed, of the packing and stowage of goods, reconstruct the timings of transport on its whole, verify that declarations made to him are consistent with the available documents, besides obviously making sure that damage is indeed due to problems of temperature during transport and not to other factors or defects of manufacture or preservation which took place before loading the means of transport.

In conclusion, the surveyor who must inspect a cargo of perishable alimentary products which has been carried or must be carried must always have the same reference parameters whatever means of transport is employed. The surveyor, given for granted that packing is adequate, must also verify that:

- vehicles and/or storage premises employed for transport/storage are clean, kept in good state, without any form of contamination and with no formation of sweat and moulds on the surfaces;
- if loading areas are employed for various goods in alternative with foodstuffs they must allow an adequate cleaning and hinder accumulation of dirt and contact with other materials;
- the various loading areas are designed so that temperature and the other physical parameters important for preservation of the product may always be kept under control.

Inspection of damaged perishable goods according to the means of transport

Transport by reefer container

Practically all sea transports take place by container, so that inside them we may find all kinds of goods under controlled temperature, from fresh to frozen.

As we have already set out in the second chapter containers are equipped with their own machinery which cools and distributes air in the loading area from which it is separated by an insulated bulkhead, as insulated are the doors and all the other surfaces of the container itself.

If at the time of intervention the container is still full then all data indicated on the display of the refrigerating unit must be checked, that is: set-point, temperature of the input and output air, possible alarms verifying, on the plate applied to the unit, what the symbol of the evidenced alarm refers to.

It is also advisable to read, on the label serving this purpose, the date and locality of the last PTI and, opening the little door placed near the display or the "Partlow", to extract the PTI card and check it.

If by chance the unit still has the "Partlow" disc positioned in its place, check it verifying first when the recording began and then reconstructing the course of voyage following backwards the trend of the chart.

Unfortunately as it is well known such charts are rarely found in the container and when they are present they usually refer only to the period following discharge – storage in the terminal.

Shipping companies have more and more the tendency not to hand over such charts as well as the computerized recordings of values and events and therefore it is necessary to make shift only with the help of verifying the technical conditions of the container and of its unit at the time of ascertainments and of the objective conditions of goods.

Before opening the container doors it is necessary to check the perfect tightness of same, the conditions of the external insulating coating, of the gaskets, the positioning of openings for the change of air, the level of cold-producing gas through its indicator, the state of draining.

Once these first ascertainments have been carried out, the doors may be opened to proceed to the due recordings of temperatures.

There are generally two typical cases of goods well below 0° C and goods kept at a temperature of 0° C or more.

In the first case upon opening of the doors, if everything is in order, a cloud apparently coming out of the loading area will appear: this is due to the mixing of internal cold air with hotter and more humid external air with consequent condensation of humidity of the latter because of the sudden cooling.

This is already a sign of the internal temperature.

Another important issue to verify, before any other ascertainment, is vertical stowage and stowage by the doors, with particular regard to the structure of the inside of the doors themselves, that is to say if they have grooves, reliefs or if they are completely smooth.

We remind at first that frozen products are carried in containers almost always packed in non-palletized cartons, on the contrary of refrigerated ones, mostly vegetables, which instead are palletized to facilitate as much as possible the circulation of cold air and the elimination of metabolic heat.

Also fresh alimentary products, such as cheese, processed pork meat etc., which are any way more rarely carried in containers, are usually palletized so as to be more easily handled.

In the case of frozen goods the modern techniques provide for a compact stowage, with cartons even very near the side walls without deeming any more essential an irregular or "honeycomb" stowage.

In fact it is fundamental that the cargo of cartons is enveloped along all its length by a layer of cold air moving from the side where the refrigerating unit is, usually from below, passing through the floor grooves, arriving at the doors where it is deviated upwards passing between cargo and the doors themselves and, brushing the top surface of the mass, going back to the unit side sucked by the system, returning to the expansion chamber where it is newly cooled.

It is therefore clear that air must be free to circulate around the mass of cartons also near the doors and on the top of the container; laterally no problems arise if all the above takes place regularly, because a thermic equilibrium sets in, involving all the environment.

Stowage must then allow the circulation of air without cartons crossing the floor planks and/or the red line of maximum vertical stowage.

However in case the doors have the above-mentioned reliefs/grooves on their internal surface a possible leaning of cartons against them does not generate any problem as air flows the same.

As for the distance between the ceiling and the mass of cargo, it must be equal at least to the height of the grating grooves.

Obviously the surveyor must also verify the state of the cartons, that is check if they have retained their shape or if they have broken below because of the increase in temperature, with softening of product, absorption of humidity.

If the lower cartons have broken, cargo can be overturned towards the doors and lowered in height.

Formations of ice and possible leakages are of course immediately ascertained as extension and positioning, considering that they may be useful to understand the origin of damages.

Once these first ascertainments have been effected the temperatures of the product in the first cartons are measured, at three different heights, near the doors, that is to say in the zone which is farthest from the intake of cold air and therefore is the less favoured.

If possible, in case the container is not destuffed immediately, the temperature values of other cartons resting more to the inside should be taken.

Anyway the ideal would be to follow the entire operations of destuffing of the container taking the temperatures of goods at regular intervals so as to have a clear idea of the distribution of values, as compared with the height of cargo and the distance from the doors or from the unit.

The contemporary opening of cartons in which temperature is recorded with ensuing verification of the condition of goods is always fundamental to pinpoint the cause of damage.

Furthermore during destuffing the state of cartons may be verified, that is if they are humid, glued one to the other because of superficial freezing, how possible leakages between cartons are distributed, in which zone they have lost their shape and finally if there are leakages on the floor, where and in which state, that is whether frozen or not.

Unfortunately it is more and more frequent to be advised when the container has already been destuffed and goods are in cold store, with the cartons palletized by consignee.

This precludes the above ascertainments and therefore deprives the surveyor of those essential elements which may help him to understand what has actually happened in the container.

The facts must therefore be reconstructed with those who were present at the destuffing of the container, asking for information as to the above aspects, hoping that temperatures have been measured at the beginning and/or during destuffing.

Another negative aspect is that almost always stowage of cartons in the cold store of consignees or of third parties does not reflect the one originally existing in the container.

The conveyance may be still in the unloading location and here, if warehouses are fitted with adequate electric sockets, the refrigerating unit may be turned on and all necessary functioning tests may be carried out.

If instead the container is no more available it is essential that who is competent to do so asks the ocean carrier that same is put at disposal of surveyors for the necessary tests of the working order of its refrigerating unit.

In any case, wherever the inspection takes place, the unit must be made to operate before at the temperature requested for the voyage and then at 0° C verifying all the parameters and functions as already stated: practically an actual PTI is effected.

Obviously this ascertainment should be carried out as soon as possible after destuffing to limit the risks of possible outside interventions on the unit.

The surveyor must also instruct the interested party or who should do so on his behalf to ask for a copy of the recordings of the temperatures during the voyage from the time of stuffing up to discharge, temperatures which are recorded on the "Partlow" if present or which may be drawn from the computerized system of the unit.

The analysis of the temperature recordings is fundamental both because it clearly allows to verify whether during the voyage there have been defects in maintaining the regular values and because it permits to verify the duration of the problem (thermic increase or excessive cooling in case for example of vegetable products) and the values reached.

Moreover this verification may afford a further help to surveyor in understanding which kind of occurrence has taken place and which was the cause of the problem.

Finally it may happen that goods are carried by isothermal "ConAir" containers, that is to say those which though being insulated are not equipped with an autonomous refrigerating unit but must be plugged into the cold-producing system of the ship or fitted with a so-called "rucksack" (or "clip-on) which is simply a mobile unit.

In these cases, besides the usual verifications on goods and on the distribution of temperatures and alterations, it is necessary to proceed to on board inspection of the air distribution system in the zone where the container was stowed, as there are always columns which feed at least four containers simultaneously.

If the conveyance has travelled with a "rucksack" its conditions must be ascertained always through the usual functioning tests.

It is clear that if the "Con Air" container has travelled on board plugged into the ship's sockets (and therefore not with the "rucksack") the investigation will have to be centred on reconstructing the stowage of the containers in the same column in which the one we are interested in was stacked and on the analysis of the temperature recording charts; this is somewhat complicated but luckily this type of container is being less and less employed.

In conclusion, in case of "ConAir" containers it is necessary to also verify the good working order of the system of opening/closing of the intakes for the changing of air.

These are two holes on the front part of the container, one above the other, to which the sleeves of the on board system or of the "Clip-on" are connected.

The holes have a closing system with a pin supported by a spring which when it is turned one way uncouples and permits the opening of the hole by detaching a disc which closed it.

It has happened that the system did not work or even that it was not opened when positioning goods in stow (on intake or output) without the crew noticing anything, not even from the on-line recordings of temperature in the engine-room.

Transport by refrigerated vehicles

Besides the goods mentioned in the case of containers, inside trucks often refrigerated fresh meat, hung to hooks, is carried, that is to say carcasses, half-carcasses, breasts etc.

For good ascertainments also in cases of transport by truck it would be necessary to be able to be present at unloading of cargo, whichever this is, verifying temperatures and the objective conditions of goods in the various stowing positions.

In practice the ascertainments on cargo are the same ones valid for containers.

As for ascertainments on the refrigerating unit of the truck, if intervention is effected when goods are still on board then all functions are checked and especially whether the temperature indicated by the thermometer outside the unit is comparable to the one of the goods, always remembering that in the case of trucks intake of air always takes place from the top.

The units that nowadays are fitted on trucks are usually "Thermoking" or "Carrier" and their functioning and the hydraulic control systems are subject to continuous evolution, from this there derives the importance of specific knowledge of the surveyor intervening.

Also these units may be equipped with a computerized recorder or writing disc of temperatures when we are dealing with international transports, while in other cases usually there is no recording.

In the first case, provided that it is possible to obtain the recording or on the spot thanks to the driver or subsequently, it should be possible to reconstruct what has happened during transport.

If instead the temperature recordings are not available then all the information becomes fundamental which can be obtained from the driver as to timings of the voyage, how occurrences took place upon loading and during the voyage and all the outcomes of the technical ascertainments on the unit and finally the distribution of temperatures and the type of degeneration of goods ascertained during destuffing.

To verify the functioning of the refrigerating unit the same applies as for containers making it work setting the desired temperature up to when it is reached and maintained.

Contemporarily inside the loading area the correct intake and circulation of cold air must be verified, possibly when the area is still full.

In conclusion, whatever the means of transport, it is essential to carry out all technical and documentary ascertainments which may consent to verify not only the causes and the extent of damages, but also the duration of the events and the correspondence between what he has reconstructed and the policy terms, which generally the surveyor should know so as to collect documents accordingly.

As stated above generally the refrigerating units nowadays almost universally fitted on trucks are of the type working by expansion of cold-producing gas to cool air which is conveyed directly in the loading area while other systems, which are anyway mentioned in the second chapter for information purposes, only represent a very low percentage.

Finally the insurer should verify also the general conditions of the maintenance state of the conveyances, evaluating the adequacy of the means itself as for protection from thermic exchanges

by measuring the thickness of the walls, taking note of the date of building (containers) and, in case of trucks, examining the "ATP" certificate.

If there should be doubts as to insulation of the walls then the surveyor will have to ask for a technical proof in order to evaluate the "K" factor.

Transport by refrigerated holds

Nowadays ships with traditional holds have so decreased in number that this type of transport is limited to fresh fruit and frozen fish, in particular tuna in bulk.

It is not the case to take into consideration tankers for oils or other heated products nor fishing boats as cases are very few.

Fresh fruit, especially bananas, kiwis, pears, apples, citrus fruits, is carried in normal refrigerated holds at variable temperatures according to the product (pls rfr to appendix).

All fruit nowadays is carried adequately packed in sophisticated packagings, often enriched by substances which help to preserve the product and are designed on purpose to allow the flow of cold air, sweat and gas exchanges with the environment, stacking in usual pallets easy to handle.

The surveyor must as soon as possible get on board the ship and introduce himself to the captain asking permission to go into the holds to carry out, jointly with surveyors representing the carrier, the due verifications on condition of the goods and of the refrigerating plant.

It is advisable in such a phase to acquire the stowage plan and the first pieces of information on the system of cooling of the holds besides the bill of lading, even before beginning the technical ascertainments.

At this point, once obtained the captain's permission to proceed, it may happen that the hold involved in the problem is still closed or that it is already open and being discharged or, again, already cleared.

In the first case it is a good rule to get immediately into the engine-room to verify, with the air cooling system still operating, the physical parameters at that moment, that is temperatures in the various positions of the detectors (air and pulp of fruit), humidity, carbon dioxide and ambient ethylene if necessary and significant, system functions such as possible defrostings, manual or automatic changes in air, temperature setting.

Always with closed hold it is then possible to get into the zone of the air-coolers to verify the working order of fans, the correctness of detectors, measure the temperatures in the pulp of fruit that may be reached, have a first-hand idea of the adequacy of the circulation of fresh air and of the stowage.

Upon opening of the hold it is necessary to quickly examine the temperatures of the pulp of fruit contained on top in the pallets placed at the four corners of the square of the hatch and then go on in the hold or on the quay measuring as pallets are progressively available taking care to measure temperatures at three different heights when pallets are identical choosing them in the various positions of stowage to understand the distribution of values, a technique which may help to pinpoint the cause of damage.

Obviously this type of ascertainment is carried out with the same method even if discharging has begun, partly on board and partly on the quay or otherwise only on the quay if discharging operations have been completed.

With empty holds it is necessary to verify the condition of the gratings which have holes in them to permit the flow of air.

Generally the holds of these ships are fed in couples by the same distributor of cold air, that is to say that in a couple of interdecks cold air is conveyed generally from aft or from fore in the lower part of the interdeck below, is sucked in the upper room through the dividing gratings and then returns to the cooling system sucked through the grid of the air cooler of the upper deck where detectors are placed to verify the temperature value of the return air.

It is therefore possible, always with the full collaboration of the crew, to verify the production of cold air, independently from the system employed, and its distribution / circulation in the stow, besides the reliability of the various detectors availing oneself of adequate thermometers.

Of corse, if anomalies in the production of cold are detected, the investigation in the engine-room must be made more thoroughly to pinpoint the cause of the phenomenon after having obtained from the crew all data relating to the typology and functioning of the cooling system on the whole.

It is clear that at this level it could be necessary to ask for the intervention of a technician expert in refrigeration or of a surveyor skilled in the specific field; obviously this is a choice to be made from time to time depending on the specific knowledge of the surveyor who has already been appointed and on the complexity of the case.

Anyway these investigations, if backed also by the typed or handwritten indications on the logbook of the values of temperature and of other parameters like ethylene, humidity, changes of air during voyage, may evidence a defect in the ship's refrigeration system, both as to production of cold air at the right temperature and its distribution/circulation in the hold.

A breakdown in the cold air production plant is less and less frequent, owing to the fact that systems are certainly very simple and seldom cause problems.

There may instead be problems after production, that is to say in the distribution of air at the correct temperature in the various holds.

There derives the importance of the gathering of documents by the surveyor regarding construction plans of the refrigerating plant and of all the recordings of voyage relating to the preservation of goods, always provided that the captain collaborates, which happens less and less frequently.

Generally common practice tells that unfortunately on board permission to get into the holds is rarely granted and moreover the documents which are made available are less and less.

It is therefore necessary to verify from time to time in the quickest possible way the real conditions of goods and the extent of a possible damage potentially caused by the sea carrier so as to allow whom concerned to take the appropriate steps towards the carrier before the ship sails from the port of discharge.

On board besides investigations carried out as above, it is useful that the surveyor verifies the stowage of pallets whenever possible because even a small empty space is sufficient to give rise to a preferential flow of cold air so leaving a zone, usually of limited extension, without an adequate refrigeration and circulation of air and this, in the case of fresh fruit, may create problems if the accumulation of metabolic heat and of gas products is taken into account.

Also an excessive height of pallets may give rise to bad circulation of the cold air.

As for frozen fish, it is usually carried in bulk.

The operative method of the surveyor is anyway the same in connection with ascertainments to be effected on board and in the hold.

In the particular case only temperatures and distribution of cold air are of interest.

The single fish, usually of great dimensions (especially tuna), must never adhere one to the other as this may mean that increases of temperature have taken place followed by lowering of temperature, which is a quite likely occurrence in the case of frozen tuna in brine (technique which is less and less employed).

Annex 1

Operative cards

Transport in integrally refrigerated container

1) RECONSTRUCTION OF THE VOYAGE

a) name of the carrier/its P&I/name of the owner of the container if different from the carrier
b) marks and number of the container; ISO mark; year of building
c) characteristics of stow and delivery conditions as per B/L
d) locality and date of stuffing
e) documents at departure: invoice for goods with sales conditions; possible documents of origin and/or sanitary and/or analysis documents; bill of lading
f) possible remarks on B/L or letter of indemnity by the shipper
g) who has materially carried out the stuffing or on behalf of whom
h) container pre-refrigerated before stuffing
i) duration of stuffing; time when stuffing was completed and doors were closed with number of the seal
j) possible paperwork relating to the conditions also of temperature of goods when loaded
k) instructions given by the shipper as to transport temperature and positioning of the air intakes; verification of data on B/L
l) data provided by possible chronothermorecorder placed in the loading area by the shipper; whether indicated on the B/l or not
m) date of departure of the full container from the loading site to the terminal where it will be embarked; means of transport employed if equipped of its own generator for the functioning of the refrigerating unit of the container; thermostat already set by the shipper or not; date of delivery of the container to the terminal and calculation of the days/hours needed for transport
n) documents relating to the receipt by the terminal
o) possible place and date when the refrigerating unit was turned on if it had not already been switched on and made to work on departure from the place of stuffing; thermostat set by whom? Possible chart of temperature recordings placed by whom, where and when?
p) date and place of boarding the ship with possible remarks by the carrier upon receipt from the terminal and taking on board
q) stowage position on board
r) reconstruction of the entire course of voyage with place and date of possible transhipments
s) date and place of discharge with possible remarks by the receiving terminal
t) duration and facts possibly occurring during stay in the discharge terminal
u) date and outcomes of the veterinary verification at the border
v) date of withdrawal by the freight forwarder and date and place of delivery for destuffing
w) land transport carried out by vehicle equipped with autonomous generator?
x) Date of opening of the doors for destuffing and of detection of damages

2) DATA RELATING TO THE TIMING OF THE ASCERTAINMENT OF DAMAGES

a) date, time and place in which damage was discovered
b) date and time of notice of damage to the company insuring goods
c) date and time of the request for intervention of a surveyor
d) date and time of the intervention of the surveyor to begin ascertainments
e) state and conditions of the container upon intervention
f) possible previous steps taken by who held the container

3) REFRIGERATING PLANT AND STATE OF THE LOADING AREA

a) presence of “Partlow” graphic disc in its seat; check of the “PTI” sheet reading and taking note of the labels applied on the refrigerating unit
b) external general conditions of the container, year in which it was built , maintenance state, inspection of insulation and of the door closing system
c) make, model and year of building of the refrigerating unit; general conditions of maintenance
d) plugged or not at the time of intervention with thermostat set at::
e) possibly date and time when it was switched off
f) refrigerating unit working: setting of the thermostat, temperature values indicated at the various stages of operation acting on the “mode” key of the “display”; possible alarms lit and verification of their meaning on the plate applied to the unit; verification of the level of cold-producing gas; regularity of the discharge of defrosting water through its pipe
g) operating tests of the unit carried out when container is still full or partially full or when it is empty
h) state of the possible external air intakes and their setting
i) analysis of the possible “Partlow” disc or of the computerized recording of temperatures
j) opening of the loading area doors after verification of the seal
k) first general impression upon opening the doors
l) measurement of temperatures of goods at three heights
m) verification of the stowage conditions of packages
n) conditions of the floor and of the ceiling

4) ASCERTAINING CONDITIONS OF GOODS

a) temperature of goods; distribution during discharge with particular attention to the stowage positions
b) temperature requested on the transport document
c) evaluation of the adequacy of packing; conditions of packing and then of goods contained therein
d) typology of damage; description of organoleptic alterations
e) stowage of packages in respect of the points of intake and return of cold air
f) presence of ice in the loading area

5) QUANTIFICATION OF DAMAGES

a) outcomes of possible chemical and/or microbiological analyses or anything else which may be useful to determine the type of damages and limit them
b) total loss and cause thereof, disposal costs and relevant documents
c) possible salvage value, even if partial, of goods
d) possible qualitative technical-commercial decay of the product with necessity to grant a mean depreciation expressed in percentage
e) evaluation of the possible selection costs or any other expenses directly deriving from damages

6) CAUSE OF DAMAGES

a) damage due to a cause preceding containerization: goods already spoilt, loaded at incorrect temperature, insufficient/inadequate packing
b) damage due to bad stowage
c) damage due to insulation/container tightness defects
d) damage due to wrong setting of the thermostat
e) damage due to prolonged and/or repeated voluntary stoppages of the refrigerating unit; number of hours of the stoppages
f) damage due to technical breakdown of the unit: typology, duration of the stoppage, spatial/temporal collocation of the occurrence
g) damage due to wrong calibration of the thermostat
h) excessive duration of the voyage and reasons therefor

Land transport (truck)

1) RECONSTRUCTION OF THE VOYAGE

a) Name of the carrier or second carrier/s – actual carrier
b) Identification of the vehicle and its documents
c) name and personal data of the driver
d) place, date and time of loading
e) departure documents: invoice for goods with sales conditions, possible origin and/or sanitary documents, transport document with terms of carriage
f) description by the driver of the loading modalities: beginning and end of loading; localization of goods upon loading; possible recordings of the temperature of goods upon loading; possible objections, difficulties raised by the shipper with regard to the means of transport; possible anomalies ascertained by the driver at the time of /during loading; who materially carried out loading and stowage of packages
g) The motor vehicle has been pre-refrigerated before loading? For how long? At what temperature?
h) Instructions provided by the shipper for transport
i) Time when loading was completed and doors were closed; safety system of closing of same (padlock, seal)
j) Time when the refrigerating unit was turned on and value at which the thermostat was set
k) Detailed course of voyage with description of the whereabouts and duration of possible stops, changes of the tractor, changes of the driver
l) Detail of the stops and whereabouts for customs and/or sanitary operations
m) Standard driving of the vehicle by the driver exhibiting chronotachograph; enquiry on the driving modalities of the vehicle with regular stops and verifications of the working order of the refrigerating unit with particular regard to temperatures indicated by thermometers placed outside the box and outside the unit itself
n) Date and time of arrival in the delivery place of goods with indication of the time at which the loading area doors were opened or anyway of the discovery of damages; this if up to the arrival at final destination the driver noticed no problems

2) DATA RELATING TO THE TIMING OF THE ASCERTAINMENT OF DAMAGES

a) date, time and place in which the driver or the consignee have discovered the damages
b) date and time of notice given to the insurance company of the actual carrier
c) date and time of request for the intervention of a surveyor
d) date and time of the intervention of the surveyor and beginning of ascertainments
e) request and drawing up by the driver of a detailed declaration about the sequence of facts from the moment of departure to the one of arrival at final destination
f) description of possible actions, with place and date, carried out by the driver to safeguard goods such as for example provisional repair of the unit, harbouring of goods in temporary cold store, transhipment etc.

3) REFRIGERATING PLANT AND STATE OF THE LOADING AREA

a) gathering all documents relating to the technical and building characteristics of the loading area and of the refrigerating unit; circulation card, sanitary permits, ATP, regular maintenance of the working order of the unit
b) external general conditions of the loading area, year when it was built, evaluation of the maintenance state, inspection of the insulation, evaluation of correspondence between ATP certification and characteristics of the temperature value requested for transport, conditions of the closing state of doors

c) make, model and year of building of the refrigerating unit; general conditions of maintenance
d) type of feeding
e) investigation on the timings of possible turning off before the survey ascertainments
f) setting of the thermostat
g) with goods still in the loading area, verification of the values indicated on the thermometers of the unit and of the box; same operation to be performed with an empty loading area
h) with the unit operating: verification of the values of pressure of cold-producing gas in connection with the various operative phases of the unit; defrosting cycles (manual or automatic) comprising the phase of discharge of water; correspondence of the recorded temperatures with the one which has been set
i) analysis of the possible recorder of temperatures, whether by graphic disc or computerized
j) opening doors of the loading area after verification of the seal
k) verification of the thickness of the insulation of the walls
l) first general impression at the time of opening the doors
m) measurement of the temperatures of goods at three heights once the doors are open
n) verification of the stowage conditions of packages
o) conditions of the floor and of the ceiling

4) ASCERTAINING THE CONDITION OF GOODS

a) temperature of the goods: distribution along the whole discharge with particular regard to the positions of stowage
b) temperature requested on the transport document
c) evaluation of the adequacy of packing; condition of the packagings and/or external condition of goods
d) typology of damages; description of the organoleptic alterations
e) positioning of the detectors in respect of the goods, stowage of goods in respect of the points of intake and return of the cold air
f) presence of sweat or ice in the loading area
g) external ambient temperature

5) QUANTIFICATION OF DAMAGES

a) outcomes of possible chemical and/or microbiological analyses or anything else which may be useful to determine the type of damages and limit them
b) total loss and cause thereof, disposal costs and relevant documents
c) possible salvage value, even if partial, of goods
d) possible qualitative technical-commercial decay of the product with necessity to grant a mean depreciation expressed in percentage
e) evaluation of the possible selection costs or any other expenses directly deriving from damages

6) CAUSE OF DAMAGES

a) damage due to a cause preceding containerization: goods already spoilt, loaded at incorrect temperature, insufficient/inadequate packing
b) damage due to bad stowage
c) damage due to insulation/container tightness defects
d) damage due to wrong setting of the thermostat
e) damage due to insufficient period of operation of the refrigerating unit; indicate number of hours of stoppage/voluntary turning off of the unit
f) damage due to technical breakdown of the unit: typology, duration of the stoppage, spatial/temporal collocation of the occurrence
g) damage due to wrong calibration of the thermostat
h) excessive duration of the voyage and reasons therefor

Transport in hold

1) RECONSTRUCTION OF THE VOYAGE/ASCERTAINMENTS ON BOARD

a) name of the ship and its characteristics; year when it was built; ship building plan
b) name of the owner and possible various charterers; with relevant P&Is
c) possible charter parties
d) date and place of the beginning of loading operations; temperatures and humidity in the loading port
e) modalities/delivery times of goods to load from quay
f) possible notes/remarks upon loading with relevant documents (Mate's receipt); temperatures of goods upon loading
g) description of the carrying out of loading operations with relevant documents (excerpt from the logbook)
h) date when loading operations were completed
i) documents relating to the state of facts when loading, cargo manifest and stowage plan
j) instructions given by the shipper to the captain in connection with the phase of possible pre-refrigeration of holds and with the conditions of keeping temperature and other physical and chemical parameters during transport (humidity, carbon dioxide, ethylene, changes of air)
k) documents relating to the pre-refrigeration operations and maintaining of the various parameters during loading acquiring the excerpt of the engine logbook
l) possible remarks on B/L or letter of indemnity by the shipper
m) who materially carried out loading and stowage and on whose behalf
n) date of departure of the ship from the port
o) detailed description of the sea voyage, indicating places and dates of possible ports of call and reason for same; possible problems of a technical or nautical nature encountered by the ship during the voyage (acquiring the excerpt of the logbook)
p) documents of departure: invoice for goods with sales conditions; possible origin and/or sanitary documents and/or analyses: B/L
q) date of arrival at the port of discharge and beginning of the discharge operations

2) ASCERTAINMENTS DURING DISCHARGE

a) date, time and place in which damage has been discovered
b) date and time of notice given to the company insuring goods
c) date and time of the request for intervention of a surveyor
d) date and time of intervention of the surveyor and beginning of ascertainments
e) state of the discharge operations at the beginning of ascertainments
f) interventions on board acquiring: excerpt of the logbook, excerpt of the engine logbook with temperature recordings, timings/modalities of the changes of air, measures of parameters such as humidity, carbon dioxide, ethylene
g) inspection of the engine room checking the air cooling system and its technical characteristics (type of cooling, number of compressors, methods of setting temperatures, description of the cold air distribution system in the single compartments of the hold); verification of the efficiency and calibration of the temperature recording detectors; verification of the values recorded by all the various detectors, the various thermometers included; verification of the temperature recording system; verification of the systems of control and recording of humidity, carbon dioxide, ethylene
h) inspection in the single air coolers of the number and good working order of the fans and efficiency of the reachable detectors
i) inspection and verification of the systems of air change
j) intevention in the hold as soon as possible to carry out thermometric measurements which must be carried out during the various phases of discharge and in different positions of stowage; contemporary verification of the conditions of goods and distribution in the hold of possible anomalies
k) typology of stowage and adequacy of same for a good distribution of cold air

l) conditions of cargo compartments when holds are empty; maintenance, insulation state, conditions of gratings, of air pipes, of the systems of thermal measurement and of the various parameters, of the distribution and return of air
m) description of the discharge operations; acquiring the statement of facts and of return of the ship
n) date and time of the end of discharge
o) acquiring protests sent to the carrier by the party entitled to do so

3) ASCERTAINMENT OF THE CONDITION OF GOODS

a) temperature of the goods: distribution during the whole discharge with particular regard to the positions of stowage
b) temperature requested on the transport document
c) possible measurements of the other parameters in the single packages: carbon dioxide, ethylene
d) presence in the hold and/or on packages of ethylene absorbers; state of same
e) condition of packing, adequacy thereof
f) objective condition of goods; typology of organoleptic alterations
g) relation between stowage position and distribution of damages
h) presence of sweat or ice in the loading area and/or on packages

4) QUANTIFICATION OF DAMAGES

a) outcomes of the possible chemical or microbiological analyses or anything else which may be useful to determine typology of damages and to limit the extent of same
b) total loss and cause thereof, disposal costs and relevant documents
c) possible salvage value, even if partial, of goods
d) possible qualitative technical-commercial decay of product with ensuing necessity to grant a mean depreciation expressed in percentage
e) evaluation of the possible selection costs or any other expenses deriving directly from damages

5) CAUSE OF DAMAGE

a) damage due to causes preceding discharge: goods already spoilt, loaded at incorrect temperature, insufficient/inadequate packing
b) damage due to bad stowage
c) damage due to wrong instructions by the shipper
d) damage due to non-compliance by the crew with the instructions of the shipper as to the phase of pre-refrigeration of the cargo compartments
e) damage due to wrong conduction of temperatures on board owing to non-compliance with the instructions of the shipper in the phase of quick refrigeration and/or of maintaining (wrong setting of the thermostat, wrong indication by badly calibrated detector/s, voluntary turning off of the cooling system)
f) damage due to non-compliance with the keeping of other parameters such as for example insufficient/wrong changes of air, too high percentage of carbon dioxide
g) damage due to technical breakdown of the system of production and/or distribution of cold air; description of the breakdown and duration of the stoppage, spatial-temporal collocation of the occurrence
h) excessive duration of the voyage and reasons therefor

Annex 2

Documents to be provided to insurers in case of damage

Documents	Sea transport			Road transport					Carriage by rail	Air transport
	Damages in the port	Transport		Owner with vehicles		Carrier liability policy	Owner/Carrier			
		By container	*In bulk*	*own*	*Of third parties*		*Partial theft, non-delivery, shortages*	*Total theft, armed robbery*		
Insurance certificate	●	●	●	●	●	·	●	●	●	●
Bill of Lading (1)	●	●	●	·	·	·	·	·	·	●
Master Air Waybill	·	·	·	·	·	·	·	·	·	●
Waybill (1)	·	·	·		●	●	●	●	●	●
CMR waybill (1)	·	·	·	●	●	●	·	·	·	·
Transport document (1)	·	·	·	●	●	●	●	●	·	·
Packing list (2)	●	●	●	●	●	●	●	●	●	●
Cargo manifest (3)	·	·	·	·			●	●		·
Survey report (4)	●	●	●	●	●	●	●	●	●	●
Letter of protest to carriers (8)	●	●	●		●	●	●	●	●	●
Delivery receipts with remarks	●	●	●	·	·	·	·	·	·	·
Short-landing certificate	●	●	●	·	·	·	·	·	·	·
Letter of protest to warehouse	●	●	●	·			·	·	·	·
FS verbal process mod.ch100	·	·	·	·	·	·	·	·	●	·
Statement to Authorities (5)	·	·	·				●	●		
Report of vehicle found	·	·	·	·	·	·		●		·
Decree of nonsuit	·	·	·	·	·		●	●	·	·
Correspondence exchanged	●	●	●	●	●	●	●	●	●	●
Sales invoice (6)	●	●	●	●	●	●	●	●	●	●
Credit note (3)	●	●	●	●	●	●	●	●	●	●
Invoice for freight (6)	●	●	●		●	●	●	●	●	●
Debit note to the carrier		·	·		●	●	●	●		·
Assignment of rights deriving from the transport contract (7)	●	●	●	●	●	●	●	●	●	●

(1) If goods have been partially delivered or delivered in a damaged condition the copy signed by consignees must be provided, bearing due remarks

(2) If on the invoice the content of the single packages is not detailed

(3) Only in cases of loss of possession when in the statement to Authorities the list of missing goods is not indicated

(4) For appointment of the Surveyor apply to the Company Head Office to obtain confirmation of the name in the list

(5) The facts and the data relating to the shipment must be indicated in detail

(6) It must contain the indication of the terms of sale and the weight of goods

(7) It is necessary when transport has been carried out and claimant is not the consignee of goods

(8) It is essential for cases in which damage is not visible upon delivery to the final consignee (valid only if made within the time limits provided by law)

N.B.: **a) for combined transport the documents requested are those indicated in the various legs of voyage**

b) the documents indicated above refer to generic cases and may therefore be supplemented by specific requests

c) in case of general average immediately advise the Company Head Office to agree on actions and on documents to ask for

Part 5

Regulations scheme

REGULATIONS ON TRANSPORT AND SAFETY OF ALIMENTARY GOODS

Introduction

Alimentary legislation in Europe has undergone in the last years an impressive renewal, which continues to date, and which has led to the rationalization of the rules governing all the phases of foodstuffs manufacturing.

Cornerstone of this process is (EC) Regulation 852/2004, which replaced the 93/43/EC Directive, incorporated in the Italian law by the Law by Decree 155/97. This Decree focused the rules which food companies are called upon to abide by in order to "guarantee the fitness for human consumption of an alimentary product taking into account its intended use" (art. 2, a).

Fitness of the product for consumption is based on three fundamental principles:

1. identification and evaluation of the risks connected with every phase of production, from the growing of plants or the rearing of animals to the consumption of the end product;
2. determining the critical points at which checks should be carried out to avoid danger;
3. enacting a monitoring system for such critical points.

The basis of the entire ruling is the systematic introduction of the duty of business self-control, with the aim of preventing alimentary risks, also attained through a closer collaboration with the control authorities.

The obligation resting on the companies producing foodstuffs to devise, carry out and maintain permanent procedures based upon the principles of the HACCP system is confirmed by the most recent rules governing hygiene of alimentary products, (EC) Regulation 852/2004 (art. 5).

Companies operating in the alimentary field must also guarantee that all the phases of production, processing and distribution of foodstuffs undergoing their control satisfy the hygiene requirements set down in the regulation itself (art. 3 of (EC) Reg. 852/2004). The obligation of self-control does not depend on the nature, public or private, of the company (the hygienic safety of a hospital canteen must be the same one provided by a restaurant or an ice-cream shop or a private club), nor does it depend on the aim to profit of such company.

The great novelty introduced by this last law in comparison with the preceding one is extending these obligations also to primary production, in consideration of the fact that this is the producing sector in which the most important sanitary emergencies have lately occurred (e.g. mad cow, dioxine, aphlatoxin etc.).

Therefore also the definition of "factory", as given in art. 2 c) of the Regulation, is extended to every unit of an alimentary concern, along all the producing line.

A very important legal aspect is the one of the "person in charge of the alimentary company: the owner of the alimentary company or the person in charge specifically empowered". In practice such character is embodied by the "legal representative" of the company, or by a "nominee" of his, who must have ample decision-making power entrusted to him by the owner, apart from, obviously, being in possession of adequate professional skills. The proxy represents an important fact for the delegated party, to whom all civil and criminal liabilities for a negative occurrence end up. Therefore the proxy must be written with the approval of the party receiving it, who so becomes the legal referent for everything concerning alimentary safety in the company.

In addition to Regulation 852/2004, other rules have been issued, Regulations 853/2004, 854/2004 and 882/2004, making up the so-called "hygiene package".

(EC) Regulation 853/2004 disciplines production of foodstuffs of animal origin, also fixing specific rules in respect of products such as meat, live bivalves molluscs, fishing products, raw milk, eggs.

This Regulation also establishes that companies must be acknowledged by sanitary Authorities, and registered along the lines set forth by (EC) Regulation 852/2004.

Regulations 854/2004 and 882/2004 deal with organization of controls on alimentary products. In particular, Regulation 854/2004 deals with the same products disciplined by Regulation 853/2004, while Regulation 882/2004 applies to controls on all alimentary products, comprising vegetal ones, as well as fodder.

Regulation 882/2004 repealed the 89/397/EEC Directive, incorporated in Italian legislation by Law by Decree 123/93.

Controls also apply to conformity with Community rules of alimentary products imported from non-EU countries, which in Italy is checked by Health Ministry inspective bodies at the time of entry in the national territory and therefore in the European Union. The obligation to conform with Community rules also extends to plants producing foodstuffs.

With the aim of verifying conformity with European Union requirements of imported products, the rules provide for drawing up lists both of non-EU countries (or parts of same) and of plants lying in non-EU countries which may carry out export towards Community territory.

Application of these new rules is gradual, and provides for some exceptions. In particular, (EC) Regulation 2076/2005 fixes a transitional period of four years, up to 31st December 2009, to wholly enact Regulations 853/2004 and 854/2004, packaging and alimentary chain information excluded. (EC) Regulation 2074/2005, instead, contains the departures to rules regarding hygiene as to production of foodstuffs having traditional characteristics.

Legislation for the sector

At the level of legislation for the sector the introduction of the new Regulations regarding alimentary hygiene has led to repeal of several so-called "vertical" rules, i.e. specific to single alimentary products, regarding foodstuffs of animal origin (meat, milk, eggs, fishing products), as well as controls on alimentary products. Directive 2004/41/EC is the law which repeals several rules regarding animal foodstuffs (owing to the large number of repealed rules it has been nicknamed "Killer Directive"), referring to the European Regulations for the list of the rules which are no more in force.

The above-mentioned Directive has been recently incorporated in the Italian legislation by the Law by Decree 193/2007. This law repeals the implementation decrees of the European Directives specific for animal foodstuffs which are no more valid (pls refer to Table 1 for a summary of repealed rules).

Rules governing controls on foodstuffs

Decree 193/2007 has also repealed other Italian laws incorporating Community Directives relating to official controls on foodstuffs. The following are therefore no more in force:

- art. 2 of Law 283/1962 which provided for compulsory sanitary authorization for alimentary companies;
- Law by Decree 123/93, relating to official controls on foodstuffs (excepting art. 4 which relates to particulary types of foodstuffs and manners of control and art. 2 sub-section 3 indicating the authorized laboratories);

- Law by Decree 155/1997 (obligation of self-control by HACCP method);
- Law by Decree 156/1997 (additional measures regarding official controls on foodstuffs).

Furthermore, Law by Decree 193/2007 defines the character of the operator in alimentary field with the aim of ascertaining liabilities in respect of violations of rules governing production, processing transport and distribution of foodstuffs, including primary production, as well as for non-application of self-control based on HACCP system, and fixes the sanctions deriving from violations of such rules, which following introduction of the hygiene package still survived for the aspects relating to sanctions (Law by Decree 155/97, art. 8).

Table 1 – Directives repealed by Directive 2004/41/EC and relevant Italian Decrees of incorporation repealed by Law by Decree 193/2007

Community directives repealed by Directive 2004/41/CE	**Decrees of incorporation in the Italian legislation repealed by Law by Decree 193/2007**
Dir. 64/433/EC (as amended by Dir. 91/497/EC and 91/498/EC) relating to production and sale of fresh meat	Law by Decree 286/94
Dir. 71/118/EC (as amended by Dir. 92/116/EC) relating to production and sale of yardbirds meat	Presidential Ruling by Decree 495/97
Dir. 89/437/EC relating to production and sale of egg products	Law by Decree 65/93
Dir. 91/492/EC relating to production and sale of live bivalves	Law by Decree 530/92 (art. 20 has not been repealed)
Dir. 91/493/EC relating to production and sale of fishing products	Law by Decree 531/92
Dir. 91/494/EC relating to import of poultry from non-EU countries	Presidential Ruling by Decree 558/92
Dir. 91/495/EC relating to production and sale of rabbit and raised game meat	Presidential Ruling by Decree 559/92
Dir. 77/99/EC (as amended by Dir. 92/5/EC) relating to production and sale of meat by-products and some products of animal origin	Law by Decree 537/92
Dir. 92/45/EC relating to production and sale of game meat	Presidential Ruling by Decree 607/96
Dir. 92/46/EC relating to production and sale of milk and milk by-products	Presidential Ruling by Decree 54/97 (artt. 19 and 26 and Encl. C, Chapter. I, A), points 4 and 7 have not been repealed)
Dir. 94/65/EC relating to production and sale of minced meat and meat preparations	Presidential Ruling by Decree 309/98

EC Regulation 178/2002: the problem of traceability

The globaliz ation of m arkets and the consider able com plexity of the production processes imposes a r egulation of al l aspects bot h as for or ganization of exchang es and production methods of alimentary products.

The Europea n Union has recently laid down in the docum ent by which the European Alimentary Authority has been set up (EC Regul ation 178/2002), the common principles which are at the basis of alimentary legislation and has defined the term inology of same, focusing o n the application methods and the aims of the ruling in respect of foodstuffs.

The EU deems in fact that alimentary legislation must ensure:

1. high level of health safeguarding;
2. correct working of the market of alimentary products;
3. clear definitions to enhance the agreement as to definition of foodstuff;
4. high q uality and independ ent scientific control at the basis of t he analy sis of the risk relating to foodstuffs;
5. respect of t he rights of the consumer a nd guarantee of the availability of accurat e information;
6. traceability of alimentary products;
7. full responsibility of the market operators as for safety of alimentary products;
8. compliance with international agreements regarding trade;
9. clear develo pment of ali mentary legislati on and free ac cess to inform ation in this connection.

The EC Regulation 178/2002 which was enac ted in Januar y 2005 im poses as a further obligation the traceability of alimentary products, which each firm is due to guarantee, through the enactment of an adequate traceability system. In particular art. 18 of such regulation defines traceability a s the possibility to reconstruct and fo llow the cours e of a fo odstuff, of an ani mal fodder, of an anim al intended for alimentary pro duction or of a substance intended or apt to b e employed as an ingredient of a foodstuf f or of a fodd er throughout the producti on, transformation and distribution phases. The ai m is to make sure that every thing entering the chain follows a documented course, from raw materials to consumption by the final consumer.

The authority at a national and comm unity level, through the issuing of proper regulations, tries to enable both the consumer and the ad ministrations themselves to identif y the origin of pr oducts. The concept of traceability (art. 18, EC regulati on 178/2002) that there derives is founded on the necessity to trace back al l the raw materials employed by the producer, s o as to be able to individuate parties possibl y liable for undesired presences in foodstuffs. Recent laws i mpose to accompany each product, whether of a vegetable or animal origin, with certif icates bearin g the place of production and the main product characteristics.

Up to now onl y some products were tr aceable, such as meat, fish and eggs, that is those most dangerous for consumer health, where in the p ast case s of sa nitary em ergence have oc curred, inducing the legislator to i ntervene. The presen t rules extend as fr om January 2005 the obligation of traceability to all agricultural products, allowing to individuate any product in each of the phases of the production cycle.

The traceability consists in em ploying “fingerprints”, that is the d ocuments col lected fro m t he various oper ators invol ved in the pr oduction proc ess, to isolate a producti on chain in case of emergencies (contamination) and allow the producer and the control organisms which must vigilate on citizens’ alimentary safety to deal with and control possible situations of danger thro ugh the knowledge of the various producti on processes (flow of raw materials: documents of origin and destination). Traceability i s therefore a neutral tool which does n ot confer a p articular qual ity t o alimentary pr oducts. Im portant, instead, is the conce pt that derives therefro m, that is to say the assumption of liability on the part of every com ponent of the production chain in safegu arding

wholesomeness of the product. Traceability enacts in a more extensive way the concept of preventive control already stated by Law by Decree 155/1997.

The differences between the laws of the various countries may constitute an obstacle to the free circulation of products like fruit and vegetables. In fact, Italian law as to maximum residues allowable in foodstuffs is generally more cautionary in comparison with the one of other countries, as for example USA. Nonetheless a sufficient efficiency has not been attained in prevention and control of compliance with limits set by law. In Italy presently almost 400 active substances are allowed, for more than half of which the maximum limits allowable are different from those proposed by the EU. This situation is the same also for the other Community countries. Moreover within the single States legislation conflicts may arise between the central authority and the local authorities. Often these differences do not have a precise explanation, especially if the restrictions are periodically changed or involve similar crops. Furthermore the documents needed to evaluate the effects and the employment methods of a phytosanitary substance are in all cases the ones provided by the producer.

Information sources

Cannella C. La tracciabilità: cos'è e come viene presentata al consumatore. *6th Neotron international symposium – Food safety in the supply chain*. Modena 24 febbraio 2005.

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European Community Commission. Proposal for a regulation of the European Parliament and of the Council laying down the general principals and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food. Brussels, 2000.

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Regulation references

Directive 93/43/EEC
Law by Decree 155/1997 and subsequent amendments
Law 526/1999

THE BROADENING OF THE EUROPEAN UNION AND ALIMENTARY SAFETY

The route which leads a Country to join the European Union begins with a request to adhere addressed to the Council, which appoints the Commission to evaluate the capability of the applying Country to meet the requirements for entry. If the Commission's advice is favourable, the Council unanimously issues a contractual mandate. Then the entry negotiations between the candidate Country and the member States begin.

The first phase of the process (pre-entry) aims to prepare the Country standing as candidate for entry in the Union, through measures such as association agreements, partnerships, participating in European programmes, agencies and commissions, co-financing.

In a later phase (screening) the European legislation, or Community acquis, is then illustrated to the candidate Country, which discusses the various chapters of the legislation.

The entry route is constantly monitored by the European Commission, which informs thereof the European Council and Parliament, and during this period progress reports are issued, so as to verify the advancing of the candidate Country. In such way the candidate Country receives help in preparing for entry. Before its joining the Union, the Commission draws up a comprehensive report regarding its monitoring, on the basis of which corrective actions are taken in its role of custodian of the Treaties, among which financial instruments, infraction proceedings, guarantees.

Once negotiations are over, a draft entry treaty is drawn up, agreed between the Council and the candidate Country. Such draft is then submitted to the Commission for an advice, and to the Parliament for consent. After the signature, the treaty is submitted to the member States and to the candidate Country for ratification, which marks the actual entry of the new member in the European Union.

In the latest years twelve Countries have joined the Union in this way. Entry in 2004: Cyprus, Czech Republic, Esthonia, Latvia, Lithuania, Poland, Hungary, Malta, Slovakia and Slovenia and entry in 2007: Bulgaria and Rumania.

From the point of view of alimentary rules, the negotiations for the entry of these countries have implied bringing the new member States in line with European rules, applying the principle of Community acquis, i.e. the application of the European legislation. Broadening cannot in fact determine lower standards in alimentary safety, or turn out in greater risks for the consumer.

Anyway, transition periods have been agreed in respect of the veterinary sector (which comprises rules relating to health and well-being of animals, identification and registration of same, controls on internal market, controls at outer frontiers and public safety requirements of plants processing foodstuffs of animal origin) and the phytosanitary sector (rules concerning hygiene of vegetables, seeds, pesticides, parasites, multiplication materials).

Widening has in fact moved the borders of the European Union eastward and southward, so bringing about the necessity to provide for new control locations, furnished with premises, equipment and qualified personnel. These locations at the borders of Countries recently entered in the European Union will have to be approved by a juridical decision through the permanent Committee for alimentary chain and animal health, made up by representatives of the member States.

Like the network of control locations at frontiers, also the plants processing alimentary products in the Countries of recent entry in the Union must conform to Community rules. Some Countries have asked for transition periods in order to upgrade a limited number of plants. The plants who cannot benefit from a transition period and do not respond to the requirements laid down by Community rules have been closed on the date of entry in the European Union.

The new member States of the Union are also compelled to abide by specific rules regarding marketing and identification of the products coming from plants where upgrading is under way. Such products can only be sold in the internal market of the Country where the plant lies, and must be marked so as to differ from those which can be marketed in the whole of the territory of the Union.

In addition, the new member States have had to devise a control system based on laboratories certified according to good practice laboratory rules, such as ISO rules, and enact a monitoring of residues of substances such as pesticides, hormones, antibiotics, pollutants, and of the presence and diffusion of pathologies such as BSE, the control of which has imposed among others the prohibition to employ powdered bones in ruminant fodder.

Information sources

MEMO/03/88. The broadening of the EU: Questions and answers on aspects of alimentary safety. Bruxelles, 5 dicembre 2003
(http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/03/88&format=HTML&aged=0&language=IT&guiLanguage=en)
How a country joins the EU:
(http://ec.europa.eu/enlargement/enlargement_process/accession_process/how_does_a_country_join_the_eu/index_it.htm)

REGULATIONS FOR IMPORT OF GOODS FROM NON-EU COUNTRIES

European institutions can act within the powers conferred to them by the Treaties and in the manners prescribed by the latter. Such powers may be relevant to the relationships existing between the Community and the member States or may attain the relations between the Community and international bodies.

European institutions regulate the food industry on the basis of the rules governing the agricultural sector (common agricultural policy, CAP), the commercial sector and public health. There are also agreements relating to the fishing sector.

The Treaty founding the European Union (Maastricht Treaty, or EC Treaty, 1st November 1993) sets the aims of the CAP, such as increase of productivity, fair standard of living for agriculture operators, stabilization of the market, reasonable consumer prices. Furthermore, European Institutions also safeguard other aspects of common interest such as environment and human and animal health. Among the aims of CAP there are also the quality and healthiness of agricultural products, from which derive the rules regarding foodstuffs which are agricultural products or by-products of the latter, implemented through specific regulations.

The community policy regarding fishing, too, rests upon the founding Treaties of the Community itself. The first community organization for the market of fishing products has been set up in 1970. This agreement has then been amended various times, until its radical reform in 2002.

The key points of the new community policy for fishing are: long-term oriented management of fishing resources, reorganization of the fishing fleets of the various European Countries, by now oversized in comparison with the resources themselves, a revision of the rules and implementation of controls in commerce, and a greater involvement of the operators and of the scientific community, through the setting up of regional advisory Councils whenever these various characters may interact and coordinate themselves.

The advice of the regional Councils is not binding. The fishing shares allowed to each Country are in fact determined annually by the Council of competent Ministers of the member Countries. Also this procedure is anyway being subject to revision.

Europe in international trade

The European Community may enter into agreements with non-EU Countries and international organizations, many of which it is a member of.

The competence of the Community to enter in to commercial agreements relating to the alimentary sector are regulated by the EC Treaty.

Among the international organizations with which the Community keeps stable lies, or of which it is part, there are: the international Office for epizootics, which deals with promoting and coordinating research on animal infectious diseases ; the Alimentation and Agriculture Organization; the Codex Alimentarius, which deals with preparing standards and guidelines for every single foodstuff: the world Organization for standardization, which collaborates with the European Committee for Standardization, in order to issue technical rules conforming to European policy lines regarding free trade, safety etc.

The World Trade Organization

From the point of view of commercial trading, the World Trade Organization (WTO) is of great importance. The WTO, set up by the Marrakesh Treaty (15th April 1994) and of which the European Union is part, represents an institutional framework for the management of commercial relationships between member Countries.

The aims of the WTO are the signing and operation of trade agreements, the resolution of disputes regarding trade, promoting a coherent economic policy on a worldwide scale.

For this purpose in the Marrakesh Treaty, as well as the agreement to set up the WTO, there are other agreements regarding alimentary products, such as the agricultural Agreement, the sanitary and phytosanitary Agreement, the Agreement on technical barriers to trade, the Agreement on the aspects of trade-related intellectual property rights and the Agreement on rules and procedures governing the resolution of disputes.

In particular, the agricultural Agreement aims to enhance economic growth through liberalization of agricultural markets, to be obtained also by a reduction of state aids to agriculture, opening to import etc.

The sanitary and phytosanitary Agreement deals with the safeguarding of human, animal and vegetable health from the risks deriving from pathogens, parasites, toxins, contaminants present in foodstuffs and in fodder.

The Agreement on technical barriers to trade aims to reduce the hindrances to trade due to laws of the single States and commits the member Countries to guarantee that imported products receive the same legal treatment as national ones.

The Agreement on intellectual property deals with safeguarding copyright, trademarks, geographical indications. It establishes that each member State must guarantee all citizens of the other WTO Countries the same treatment its own citizens get, and moreover, that any favourable treatment allowed by a Country to the citizens of a certain State member of the WTO must be extended to the citizens of the other member States ("most favoured Country" clause).

In the following paragraphs the data on international trade of the European Union are listed, with particular reference to agroalimentary products. Such data, drawn from the site of the European Commission, are updated to 2005, when the EU was made up of 25 members. No reference is therefore made to Bulgaria and Romania, which joined the Union on 1st January 2007.

The foreign trade of the European Union

The commercial policy of the European Union is based upon art. 133 of the European Community Treaty. The Commission discusses with a special committee, whose meetings are weekly, the aims and the commercial strategies, as well as the problems concerning the markets of single products. Commercial policies at an international level are currently being discussed at WTO level.

The trend in commercial movements is recorded by the statistics of the European Commission. Such statistics are based upon two main sources: customs, which control the movements of products, and payment statistics, which record the transactions of the various States with the rest of the world. These statistics, regulated at legislation level, are drawn up in collaboration between the specific Community office (Eurostat) and the Institutes duly appointed by the various member States. As the statistics are intended to record the incoming and outgoing movements of products, they are centered on the products which may be carried.

The European trade movement

Europe is one of the main protagonists on the international economic scene, In fact, though the European Union counts less than 10% of world population, it moves about 20% of world production. In 2005 the European Union exported 19.2% of the goods produced worldwide, for an amount of € 1,070 billion, and imported 16% of same, for a total value of € 1,180 billion. Over 50% of European trade with the rest of the world pertains to means of transport and relevant equipment and industrial manufacture articles. There follow products of the chemical industry, foodstuffs and tobacco, etc.

The trade of the member States of the European Union takes place essentially within the Union itself, even though in different proportions among the single Countries. Greece, Italy and the United Kingdom are those representing the largest share of trade with non-EU Countries (over 40% of the total), while Czech Republic, Luxembourg and Slovakia are the most integrated in the Union.

As regards trade with non-EU Countries, the United States represent the main commercial partner of the EU: USA have in fact received 23.5% of Community export and have provided 13.9% of import. There follow China (excluding Hong Kong) which acquired 4.8% of European export and provided 13.4% of import, Russia, Japan and other Countries.

The agricultural and food sector

The agricultural and food industry (alimentary products and tobacco) represents a small share of Community trade: in 2005, in fact, alimentary products for € 63.82 billion (5.4% of total) have been imported, while export amounted to € 63.75 billion (5.9% of total), with a substantial balance of the budget.

The importance of this sector for European economy is declining: in 1995, in fact, when the Community was made up of 12 Countries, agriculture and food represented 9% of total commercial movement.

The European Union is mainly an importer of raw agricultural commodities, with a € 18 billion deficit. Such negative balance is due firstly to tropical products (€ 12 billion), then to oilseeds and oils (€ 8 billion), finally to fruit and vegetable products (€ 6.3 billion).

Export instead exceeds import in respect of milk by-products and cereals, while for meat and sugar there is a commercial balance.

Europe is also a great exporter of processed agricultural products, with a trade surplus of € 16.5 billion, due especially to spirits and food preparations.

As for the fishing sector, the budget (data of 2005) is highly negative: import in fact exceeds export by over € 10 billion.

The commercial partners

In 2005 the European Union had 54% of its import of agricultural products coming in from 10 Countries (pls refer to Table 1). Brazil was the main supplier with 14% of the total of imported goods, for an amount of € 9 billion. There are then the United States, from which 10% of import comes and Argentina, with 7%. China provided 4% of the import of agricultural products. Also important is the group of ACP Countries (Africa, Caribbean and Pacific, including South Africa) from which 14.2% of imported agricultural products was purchased.

Table 1 – Main suppliers of agricultural products to the European Union

Main commercial partners	Import (millions of Euros)	% of total import
Brazil	9,017	14%
USA	6,301	10%
Argentina	4,476	7%
Turkey	3,004	5%
China	2,545	4%
New Zealand	2,175	3%
Switzerland	2,015	3%
South Africa	1,799	3%
Australia	1,725	3%
Indonesia	1,634	2%
Rest of the world	29,127	46%

The EU export of agricultural and food products was directed in the rate of 56% towards 10 Countries (pls refer to Table 2). The most important purchasers were the USA, which received 21% of European goods, followed by Russia with 8%, and Switzerland with 7%.

In recent years China emerged as an important market for the European agricultural and food industry, acquiring in 2005 about 2% of exported commodities and becoming the eighth most important destination. In 2005 the role of India, with import amounting to only € 197 million, was instead still of little importance.

Table 2 – Main importers of agricultural products from the European Union

Main commercial partners	Export (millions of Euros)	% of total export
USA	13,355	21%
Russia	5,178	8%
Switzerland	4,262	7%
Japan	4,012	6%
Norway	1,882	3%
Canada	1,834	3%
Saudi Arabia	1,458	2%

(continues from the previous page)

Main commercial partners	Export (millions of Euros)	% of total export
China	1,234	2%
Hong Kong	1,229	2%
Australia	1,226	2%
Rest of the world	28,077	44%

As for fishing products, the EU purchased fro m 10 Countries 55% of its i mport (pls refer to Table 3). No rway b y itself provides 17% of goods . There follow Iceland, China, the USA and Morocco. Export is instead mainly directed towards Japan.

Table 3 – Main suppliers of fishing products to the European Union

Main commercial partners	Import (millions of Euros)	% of total import
Norway	2,386	17%
Iceland	1,082	8%
China	871	6%
USA	687	5%
Morocco	667	5%
Chile	479	3%
Thailand	429	3%
Ecuador	410	3%
Argentina	403	3%
India	372	3%

The market of alimentary products

In the following paragraphs the data regarding th e market trend of the main alimentary goods are listed. The data are updated to 2005.

- *Cereals (excluding rice)*

  Cereals account for ab out 12% of European ag ricultural pr oduce, with a harvest amounting to about 250 million tons. Cereals grown are mainly wheat, barley, maize.

The trade balance of the European Union as for cereals is positive, with import for an amount of € 1.67 billion and export for € 3.28 billion.

The main suppliers of cereals to Europe are USA and Canada, from which about 41% of total import comes. In recent years, anyhow, the USA have lost importance as a supplier, while Argentina, Ukraine and Russia have gained importance.

The EU export in the cereal sector is mainly directed to Arab Countries, while the Chinese market is becoming of lesser importance: it received only 3% of the total export.

- *Rice*

The world produce amounts to 400 million tons per year. Europe produces and consumes about 2 million tons per year, 0.5% of the above figure. Rice is therefore a fringe product in European economy.

The world market of rice moves about 30% of produce, concentrated at 70% in only four Countries: India, Pakistan, Thailand and Vietnam. The EU is an importer of rice (€ 403 million), especially from India. Pakistan, Thailand and USA. These Countries export to the EU various kinds of rice: basmati for example comes from India and Pakistan. European export of rice amount to only € 96 million, directed mainly to Turkey and Switzerland.

- *Fruit and vegetable products*

Fruit and vegetable account for about 17% of agricultural produce of the European Union. Such share is 14% of the total of a sector whose leaders are anyway Asiatic Countries, with 62% of global produce. The EU is the main importer in the world of fruit and vegetable products, and the second exporter after the USA and before China, third.

In 2005 the EU imported fruit and vegetables for almost € 11 billion, with an increase over the preceding years, while the value of export (€ 4.6 billion) remained unvaried. The trade balance is therefore negative, with a deficit of about € 6 billion. The most important commercial partners in this sector are USA and Turkey, each providing 14% of import, South Africa (9%), Morocco, Chile and China (7% each). In recent years Chinese export towards the EU have shown the highest rate of increase. Europe exports mainly towards Russia (20% of total), Switzerland, USA and Norway.

Import is mainly made up of tropical fruit (bananas), citrus fruit, apples, grapes, fruit juice, tomatoes, export of citrus fruit, apples, grapes, peaches, tomatoes.

- *Meat*

The market of meat is subject to cyclical fluctuations and is influenced by various factors, such as epidemics (bird flu, foot and mouth disease, BSE). Anyhow, the organization of this market keeps its stability, enhancing the compensation of losses of a sector with growth in another one: for example, during the BSE epidemic the consumption of beef decreased in favour of consumption of other kinds of meat. The commercial balance in 2005 remained substantially level, with export for a value of € 5.9 billion and import for € 5.6 billion.

In the beef sector EU import exceeded export, with a deficit of € 1.1 billion. The main suppliers are Brazil, with 55% of import, Argentina with 27% and Uruguay with 7%. The main importer of European beef is Russia.

The European Union is instead a an important producer of pork, with export amounting to € 2.5 billion and import for € 47 million in 2005. The main importers of EU pork were Japan and Russia.

The EU imports great quantities of poultry (€ 1.2 billion in 2005), while export reached a value of about 836 million. The most important suppliers are Brazil, with about 60% of import, and Thailand with 25%.

In the sector of mutton the EU is exclusively an importer, with goods purchased for € 1.1 million in 2005, almost entirely from New Zealand (83%). Export is almost negligible.

- *Milk and its by-products*

  Only 7% of milk produce is traded at an international level, owing to the high perishability of this product. Cheese, butter, powdered milk are the milk by-products which are mainly traded. Few big producers (EU, Australia and New Zealand) hold the monopoly of about 80% of trade in these commodities.

  The EU exports about 9% of its produce of milk, 30% of butter and 35-40% of cheese (highest share in the world). The main buyers are Russia, for powdered milk and butter, and the USA for cheese.

  European import of milk and its by-products is ruled by preferential agreements with the various producer Countries. Switzerland, with 26% of the total import, is the main supplier to the EU, followed by New Zealand (23%). In recent years Australia and Argentina are gaining importance among the Countries exporting to the European Union.

- *Fishing products*

  International trade moves about 38% of world produce in the sector of fishing products. As for EU, import is gaining more and more importance. Goods for € 13 billion have in fact been bought abroad while goods for € 2.3 billion have been exported.

  Among the imported products the largest share is made up by fish fillets (€ 2.7 billion) followed by crustacean (€ 2.2 billion) and fishing products preparations with € 2.1 billion. Export is instead made up mainly by fresh fish (€ 875 million) and deep-frozen fish (€ 303 million).

Conclusions

The agricultural and food market is presently affected by a violent crisis. The prices of such products are continually rising, with an increase of 24% from 2006 to 2007.

The causes are many. The increase in demand, brought on by the entry into the market of Countries in whirling development such as China and India, but also the rising cost of oil, which in practice affects directly the cost of any product (it has been calculated that a calory of oranges costs three calories of oil, while for 1 kcal of veal up to 180 are needed), the employment of increasing quantities of cereal for the production of biofuels, meteo conditions and investments, also speculative, in stock exchanges, are all making food products more expensive.

About 1 billion people live with 1 dollar a day, and a 20% increase of the expense needed for nourishment would add hundreds of millions to this level of extreme poverty. This can have devastating social effects: in many Countries the increase in price of basic food products has set off violent demonstrations.

This crisis has highlighted serious problems in the food chain. It is therefore necessary to provide a new balance to markets, liberalizing them. The system of subsidies has revealed itself a method to transfer the lack of balance of western national markets to international trade. Furthermore, it is necessary to simplify the agreements regarding circulation of goods made within the WTO: for example, a Country cannot resell abroad imported rice without permission of the Country from which it has imported the rice. This rule has recently caused a discussion between Japan (who wants to sell to the Philippines rice imported from the USA) and the USA, who do not agree.

This crisis can provide the occasion to modify agricultural policies and better the system of international agricultural and food trade. However its developments will be probably decided elsewhere, in the energy market, i.e. in the oil market. Moreover, all forecasts indicate that a period of recession is approaching, which could have serious effects on world economy.

The developments of the crisis and the market trend of alimentary products are therefore at present unpredictable.

The control on foodstuffs imported from non-EU Countries

Beyond the problems of a political and economical nature governed by the international Treaties, imported foodstuffs must conform to the provisions of alimentary legislation or to the conditions acknowledged as equivalent by the European Community (art. 11 of (EC) Reg. 178/2002, and art. 10 of (EC) Reg. 852/2004).

After the setting up of the Common Market, 1st January 1993, foodstuffs entering the European Union undergo controls carried out by specific authorities, which in Italy come under the Ministry of Health, necessary to be freely traded in the Community territory. Each of the authorities appointed to carry out the controls has a specific jurisdiction over a kind of foodstuff, vegetable, animal and deep-frozen product.

In the following paragraphs there are indications of the various tasks of the ministerial offices appointed to carry out controls on foodstuffs entering the European Union.

Offices appointed to carry out controls on alimentary products of vegetable origin

Vegetable products coming from outside the EU must conform to the hygienic and sanitary requirements which national and European laws provide for.

The controls on these products lie within the province of the State and are assigned to the Ministry of Health. They are carried out by the Harbour, Airport or border Medical Offices (USMA). Furthermore, the national phytosanitary service carries out tests against introduction into the European Union of organisms which may be noxious to vegetables and to the products therefrom derived.

The tests may be of a documentary, identity and/or analytic nature, according to the type of product, place of origin and specific laws.

Once verified the conformity of goods with ruling requirements, the USMA issues an import clearance certificate which authorizes the entry of the product into the EU. If instead the commodity should result dangerous for public health it will be declared not admissible for import. Non-idoneous products are rejected or destroyed, and non-conformity is communicated, through the specific central offices of the Ministry, to other USMA and to the member States of the EU.

Offices appointed to carry out controls on alimentary products of an animal origin

Countries outside the EU, in order to export in the Community territory, must:

- be acknowledged and included in a Community list;
- offer specific guarantees, relevant to every single product being exported, proved by a model of sanitary certificate, laid down in communitarian ambit and underwritten by the competent

authorities of the non-EU country, which must accompany the product up to its final destination.
- Have acknowledged production plants, included in a Community list.

The veterinary tests on products of an animal origin coming from non-EU countries rest on the State and namely on the Ministry of Health, and are carried out at the Border Inspection Posts (PIF), veterinary offices which are acknowledged and qualified to verify that in coming products hold the hygienic and sanitary requirements provided for by Community rules.

The tests, which may be of identity, documentary and material nature, are carried out at the external frontiers of the European Union, independently from the Member State of destination or from the fact that incoming products are in transit towards other non-EU Countries.

The modalities of tests are laid down by Community Directives 97/78/EC, enacted in the Italian legislation by Law by Decree 80/2000.

The PIF issues a Common Entry Veterinary Document (DVCE), essential to begin the import customs procedure. The arrival of shipments for which a DVCE has been requested must be notified in advance to the PIF.

In case of non-conformity measures such as annulment of accompanying documents, rejection of products, non-employment of the goods for human consumption.

Offices appointed to carry out controls on deep-frozen alimentary products

The tests on deep-frozen alimentary products imported from non-EU countries are carried out by several authorities. Deep-frozen products must:
- be manufactured according to laws equivalent to the communitarian ones;
- have been produced in factories which have been considered adequate by the ministry of Health and included in official lists notified to the Ministry by the authorities of the country of origin; Harbour, Airport and Border Medical Offices verify that the production plant is included in the list issued by the Ministry, tests for specific typologies of product unaltered.

More specifically, import from non-EU Countries of deep-frozen products of vegetable origin is subordinated to presentation, to the Ministry of Health, of a request for acknowledgement of the producing plant, together with specific documents regarding low-temperature producing system, activity, structure and equipment and sanitary control of personnel.

Regulations relevant to import of the various kinds of alimentary products

Here following is a general sketch of regulations governing import of alimentary products coming from Countries outside the EC.

Recently some Community Regulations have been issued containing rules about a common organization of agricultural markets.

(EC) Regulation 1234/2007 repealed the Regulations regarding various products: cereals, fruit and vegetables, sugar, oil, wine, meat, poultry, eggs, milk and by-products. The specific Regulations for these products have been published recently.

(EC) Regulation 1580/2007 governs the application of preceding rules relating to marketing of fruit and vegetable products.

(EC) Regulation 361/2008 repeals some regulations containing marketing rules about products such as fruit and vegetables, the application of which is now governed by (EC) Regulation 1580/2007.

Reference to repealed rules is intended to apply to (EC) Regulation 1234/2007.

- *CEREALS*

  – *Controls on products not of animal origin*
    - official controls intended to verify compliance to rules regarding fodder and food:
    - official controls on introduction of food from non-EU Countries: artt. from 15 to 25 of (EC) Reg. 882/2004
    - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
    - Import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004

  – *Cereals*
    - cereals (import licenses): artt. from 130 to 134 of (EC) Reg. 1234/2007
    - rice (import licenses): artt. from 130 to 134 of (EC) Reg. 1234/2007.

- *FRUIT AND VEGETABLE PRODUCTS AND PROCESSED BY-PRODUCTS OF SAME*

  – *Controls on products not of animal origin*
    - official controls intended to verify compliance to rules regarding fodder and food:
    - official controls on introduction of of food from non-EU Countries: artt. from 15 to 25 of (EC) Reg. 882/2004
    - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
    - Import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004

  – *Fresh fruit and vegetable products*
    - conformity inspection of fresh fruit and vegetable products to be put on the market: arts. 6 to 8 of (EC) Reg. 1148/2001.

      The modalities under which inspections must be carried out as to conformity to quality rules for fruit and vegetable products as per art. 6 of (EC) Reg. 1148/2001 are laid out respectively at points 3.4.4, 3.4.5 and 3.4.6 of the "Operative handbook of the procedures of inspections of conformity to common quality rules for fruit and vegetable products" drawn up by the Ministry for Agriculture and Forest Policies, as amended by Ministerial Decree 27th March 2007.

      As from 1st January 2008 (EC) Reg. 1148/2001 has been repealed and replaced by (EC) Reg. 1580/2007.

      Regulation 1580/2007 governs the compliance controls for the internal market at art. 10, those for export towards non-EU Countries at Art. 11, those for import from non-EU Countries at artt. from 12 to 18.
    - Fresh fruit and vegetable products: artt. 28 to 39 of (EC) Reg. 1182/2007
    - Fresh fruit and vegetable products: artt. 12 to 18 of (EC) Reg. 1580/2007
    - Fruit and vegetable products intended for processing: art. 19 of (EC) Reg. 1580/2007
    - Fresh fruit and vegetable products: art. 7 of Ministerial Decree 1st August 2005
    - Fruit and vegetable products (import licenses): artt. from 130 to 134 of (EC) Reg. 1234/2007

- Soil mushrooms, fresh and grown: art. 4 of Presidential Ruling by Decree 376/95
- Dried mushrooms: art. 5 of Presidential Ruling by Decree 376/95

– *Processed products*
  - processed products based on fruit and vegetables: artt. from 28 to 39 of (EC) Reg. 1182/2007

From 1st July 2008 (EC) Reg. 361/2008 has been issued, repealing (EC) Reg. 2200/96, 2201/96 and 1182/2007, application of which is governed by (EC) Reg. 1580/2007.
Reference to repealed Regulations are intended to apply to (EC) Reg. 1234/2007.

As for marketing of fruit and vegetable products and of processed products based on fruit and vegetables please refer in particular to art. 1 of (EC) Reg. 361/2008, point 24 (art. 113bis of (EC) Reg. 1234/2007) and point 43 (art. 203bis of Reg. 1234/2007).

▪ *COCOA, COFFEE, TEA, SUGAR*

– *Controls on products not of animal origin*
  - official controls intended to verify compliance to rules regarding fodder and food:
  - official controls on introduction of food from non-EU Countries: artt. from 15 to 25 of (EC) Reg. 882/2004
  - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
  - Import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004

– *Cocoa and chocolate*
  - cocoa and chocolate products: Law by Decree 178/2003

– *Coffee*
  - coffee and by-products of same: arts. 9 to 12 of Presidential Ruling by Decree 470/73 and subsequent amendments

– *Tea*
  - tea: the lots of imported tea must be accompanied by a certificate of origin issued to the exporter by the competent foreign offices

– *Sugar*
  - sugar (import licenses): art. 23 of (EC) Reg. 318/2006
  - sugar (import licenses): artt. from 130 to 134 of (EC) Reg. 1234/2007 (as from 1st October 2008; (EC) Reg. 318/2006 is repealed from this date onwards).

▪ *ORGANIC AGRICULTURE PRODUCTS*

– *Controls on alimentary products*
  - official controls intended to verify compliance to rules regarding fodder and food:
  - official controls on introduction of food from non-EU Countries: artt. from 15 to 25 of (EC) Reg. 882/2004
  - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
  - Import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004

– *Import of "organic agriculture" from non-EU Countries*
  - organic agri culture prod ucts: art. 11 of (EEC) Reg. 2092 /91 with am endments introduced by (EC) Reg. 1991/2006
  - import certificate for organic agriculture pr oducts in accordance with art. 11 of (EEC) Reg. 2092/91: artt. 1, 3, 4, 5, 6 of (EC) Reg. 605/2008
  - CM 3/2000 - Application of art. 11 of (EEC) Reg. 2 092/91, and of art. 6, c. 2 e 3 o f Law by Decree 220/95 – procedure passages
  - Ministerial Decree 04/08/2 000 – Enforc ement modalities of (EC) Regulation 1 804/99 on organic animal products (amendment of (EEC) Reg. 2092/91)
  - list of the non-EU Countries exporting organic agriculture produ cts: Encl. of (EEC) Reg. 94/92 with amendments introduced by (EC) Reg. 956/2007.

▪ *BRAND PRODUCTS*

– *Controls on alimentary products*
  - official controls intended to verify compliance to rules regarding fodder and food:
  - official controls on introd uction of foo d from non-EU Countries: artt. from 15 to 25 of (EC) Reg. 882/2004
  - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
  - import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004
  - derogation for plants making traditional products: art. 7 of (EC) Reg. 2074/2005

– *Import of products classified as "guaranteed traditional speciality", "protected geographical indication" and "protected designation of origin" from non-EU Countries*
  - registration of "guaranteed traditiona l speci ality" products: art. 7 of (EC) Reg. 509/2006
  - registration of "protected geograp hical indication " and "prot ected designation of origin" products: art. 5 of (EC) Reg. 510/2006 and art. 12 of (EC) Reg. 1898/2006
  - procedure at a national lev el for registration of "protected geographical indication" and "protected designation of origin" products: artt. 2 and 4 of Ministerial Decree 21st May 2007

▪ *MEAT AND MEAT BY-PRODUCTS*

– *Controls on products of animal origin*
  - documentary and veterinary inspections on animal products listed in enclosures to Law by Decree 28/93 and sub sequent am endments: artt. from 3 to 1 5 of Law by Decree 80/2000
  - sanitary police rules for animal products: arts. 7 to 10 of EC Directive 2002/99
  - art. 7 of Law by Decree 117/2005 (enacting EC Directive 2002/99)
  - labelling of beef: artt. from 13 to 15 (m andatory labelling s ystem) and art. 17 (facultative labelling system) of (EC) Reg. 1760/2000 and subsequent amendments
  - rules relating to hygiene of products of animal origin: art. 6 of (EC) Reg. 853/2004 and subsequent amendments

- import certificates for meat and meat by-products: art. 6, par. 1, lett. d) of (EC) Reg. 853/2004 with the amendments introduced by art. 1 of (EC) Reg. 1663/2006
- specific rules for the organization of official controls for products of animal origin: artt. from 10 to 12 of (EC) Reg. 854/2004 and subsequent amendments
- official controls intended to verify compliance to rules regarding fodder and food:
  - official controls on food incoming from non-EU Countries: art. 14 and artt. from 17 to 25 of (EC) reg. 882/2004
  - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
  - import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004
- import of foodstuffs of animal origin for which no harmonized sanitary condition has been established: art. 7 and 17 of (EC) Reg. 2076/2005
- import of foodstuffs containing products of vegetable origin and processed products of animal origin for which no harmonized sanitary condition has been established: art. 7 of (EC) Reg. 2076/2005

– *Meat and poultry*
- beef, mutton, pork and poultry (import licenses): artt. from 130 to 134 of (EC) Reg. 1234/2007
- import of meat obtained from cattle not older than 12 months: art. 1 of (EC) Reg. 361/2008, point 24 (art. 113ter of (EC) Reg. 1234/2007) and art. 7 of (EC) Reg. 566/2008
- import of poultry: art. 5 and 14 of (EC) Reg. 543/2008
- specific rules applying to official controls on presence of Trichinosis in meat: artt. from 13 to 15 of (EC) Reg. 2075/2005 and subsequent amendments

– *Measures of protection from zoonoses*
- protection from specific zoonoses and relevant list: Dir. 2003/99/EC
- controls on salmonella and other specific zoonotic agents present in foodstuffs: art. 10 of (EC) Reg. 2160/2003
- list of diseases for which control measures have been introduced: Encl. I of Law by Decree 117/2005
- provisions for prevention, control and eradication of certain infectious spongiform encephalopathies: Art. 16 of (EC) Reg. 999/2001 and subsequent amendments, with particular regard to those introduced by art. 1 of (EC) Reg. 1275/2007
- sanitary protection measures against infectious spongiform encephalopathies: artt. 4 and 5 of Ministerial Decree 16/10/2003

EEC Decision 418/2000 forbids import of meat products from non-EU countries in which presence of Bovine Spongiform Encephalopathy (BSE) is suspected.

▪ *FISHING PRODUCTS*

– *Inspections on products of animal origin*
- documentary and veterinary inspections on animal products listed in enclosures to Law by Decree 28/93 and subsequent amendments: artt. from 3 to 15 and, specifically for fishing products, art. 18 of Law by Decree 80/2000
- sanitary police rules for animal products: artt. from 7 to 10 of EC Directive 2002/99

- art. 7 of Law by Decree 117/2005 (enacting EC Directive 2002/99)
- rules regarding hygiene for products of animal origin: art. 6 of (EC) Reg. 853/2004 and subsequent amendments
- import certificates for fishing pro ducts and bivalve molluscs: art. 1 of (EC) Reg. 1664/2006 with the amendments introduced by art. 1 of (EC) Reg. 1663/2006
- specific rules for the organization of official controls for products of animal origin: artt. from 12 to 12, art. 13 (specifically for bivalve molluscs, echinoderms, tunicates and sea gastropods) and art. 15 (specifically for fishing prod ucts) of (EC) Reg. 854/2004 and subsequent amendments
- official controls intended to verify com pliance to legislation regarding fod der and foodstuffs:
  - official controls on fo od incoming from non-EU Countries: art. 14 and artt. from 17 to 25 of (EC) reg. 882/2004
  - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
  - import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004
- import of fo odstuffs of ani mal origin fo r which no harmonized sanitary conditi on has been established: art. 7 and 17 of (EC) Reg. 2076/2005
- import of foodstuffs containing products of vegetable origin and processed products of animal origin for which n o harmonized sanitary condition has been establishe d: art. 7 of (EC) Reg. 2076/2005

– *Fishing products*
- fishing products: art. 11 of (EC) Reg. 2406/96 and subsequent amendments
- prohibition of entry to t he market of poi sonous species and fishing products containing biotoxins: Encl. III, Chapt. II, part G of (EC) Reg. 854/2004 as amended b y Encl. VIII of (EC) Reg. 2074/2006

– *Seafarming products*
- seafarming products (sanitary policy rules): artt. from 18 to 21 of Presidential Decree 555/92
- seafarming products (sanitary policy rules): artt. from 22 to 25 of Dir. 2006/88/EC

– *- Measures of protection from zoonoses*
- protection from specific zoonoses and relevant list: Dir. 2003/99/EC
- list of diseas es for which control m easures ha ve been introduced: Encl. I of Law by Decree 117/2005

▪ *MILK AND BY-PRODUCTS OF SAME*

– *Controls on products of animal origin*
- documentary and veterinary inspections on animal products listed in enclosures to Law by Decree 28/93 and sub sequent am endments: artt. from 3 to 1 5 of Law by Decree 80/2000
- sanitary police rules for animal products: artt. from 7 to 10 of (EC) Directive 2002/99
- art. 7 of Law by Decree 117/2005 (enacting EC Directive 2002/99)
- rules relating to hygiene of products of animal origin: art. 6 of (EC) Reg. 853/2004 and subsequent amendments
- import certificates for milk and m ilk by-products: art. 6, par. 1, lett. d) of (EC) Reg. 853/2004 with the amendments introduced by art. 1 of (EC) Reg. 1663/2006

- specific rules for the organization of official controls for products of animal origin: artt. from 10 to 12 of (EC) Reg. 854/2004 and subsequent amendments
- official controls intended to verify compliance to rules regarding fodder and food:
  - official controls on food incoming from non-EU Countries: art. 14 and artt. from 17 to 25 of (EC) reg. 882/2004
  - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
  - import
  - conditions: artt. from 47 to 49 of (EC) Reg. 882/2004
- import of foodstuffs of animal origin for which no harmonized sanitary condition has been established: art. 7 and 17 of (EC) Reg. 2076/2005
- import of foodstuffs containing products of vegetable origin and processed products of animal origin for which no harmonized sanitary condition has been established: art. 7 of (EC) Reg. 2076/2005

– *Milk and by-products of same*
- milk and dairy products (import license): artt. from 130 to 134 of (EC) Reg. 1234/2007

– *Dehydrated milk, powdered and condensed milk*
- powdered milk: communication to the competent surveillance Authority of destination and employment of the milk itself (Law 138/74)

– *Measures of protection from zoonoses*
- protection from specific zoonoses and relevant list: Dir. 2003/99/EC
- list of diseases for which control measures have been introduced: Encl. I of Law by Decree 117/2005

▪ *EGGS AND BY-PRODUCTS OF SAME*

– *Controls on products of animal origin*
- documentary and veterinary inspections on animal products listed in enclosures to Law by Decree 28/1993 and subsequent amendments: artt. from 3 to 15 of Law by Decree 80/2000
- sanitary police rules for animal products: artt. from 7 to 10 of (EC) Directive 2002/99
- art. 7 of Law by Decree 117/2005 (enacting EC Directive 2002/99)
- rules relating to hygiene of products of animal origin: art. 6 of (EC) Reg. 853/2004 and subsequent amendments
- import certificates for eggs and egg by-products: art. 6, par. 1, lett. d) of (EC) Reg. 853/2004 with the amendments introduced by art. 1 of (EC) Reg. 1663/2006
- specific rules for the organization of official controls for products of animal origin: artt. from 10 to 12 of (EC) Reg. 854/2004 and subsequent amendments
- official controls intended to verify compliance to rules regarding fodder and food:
  - official controls on food incoming from non-EU Countries: art. 14 and artt. from 17 to 25 of (EC) reg. 882/2004
  - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
  - import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004
- import of foodstuffs of animal origin for which no harmonized sanitary condition has been established: art. 7 and 17 of (EC) Reg. 2076/2005

- import of foodstuffs containing products of vegetable origin and processed products of animal origin for which no harmonized sanitary condition has been established: art. 7 of (EC) Reg. 2076/2005

– *Eggs and by-products of same*
  - eggs (import license): artt. from 130 to 134 of (EC) Reg. 1234/2007
  - eggs: art. 30 of (EC) Reg. 557/2 007 with the amendments introduced by art. 1 of (EC) Reg. 1336/2007
  - eggs: art. 24, 30 of (EC) Reg. 589/2008
  - art. 3 of Ministerial Decree 13/11/2007

– *Measures of protection from zoonoses*
  - protection from specific zoonoses and relevant list: Dir. 2003/99/EC
  - list of diseases for which control measures have been introduced: Encl. I of Law by Decree 117/2005
  - control of salmonella and other specific zoonotic agents present in foodstuffs: art. 10 of (EC) Reg. 2160/2003

▪ *FROG LEGS AND SNAILS*

– *Controls on products of animal origin*
  - documentary and veterinary inspections on animal products listed in enclosures to Law by Decree 28/1993 and subsequent amendments: artt. from 3 to 15 of Law by Decree 80/2000
  - sanitary police rules for animal products: artt. from 7 to 10 of EC Directive 2002/99
  - art. 7 of Law by Decree 117/2005 (enacting EC Directive 2002/99)
  - rules relating to hygiene of products of animal origin: art. 6 of (EC) Reg. 853/2004 and subsequent amendments
  - specific rules for the organization of official controls for products of animal origin: artt. from 10 to 12 of (EC) Reg. 854/2004 and subsequent amendments
  - official controls intended to verify compliance to rules regarding fodder and food:
    - official controls on food incoming from non-EU Countries: art. 14 and artt. from 17 to 25 of (EC) reg. 882/2004
    - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
    - import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004
  - import of foodstuffs of animal origin for which no harmonized sanitary condition has been established: art. 7 and 17 of (EC) Reg. 2076/2005
  - import of foodstuffs containing products of vegetable origin and processed products of animal origin for which no harmonized sanitary condition has been established: art. 7 of (EC) Reg. 2076/2005

– *Fog legs and snails:*

  - import certificates for frog legs and snails : art. 1 of (EC) Reg. 1664/ 2006 with the amendments introduced by art. 1 of (EC) Reg. 1663/2006

- *HONEY*

  – *Controls on products of animal origin*
    - documentary and veterinary inspections on animal products listed in enclosures to Law by Decree 28/93 and subsequent amendments: artt. from 3 to 15 of Law by Decree 80/2000
    - official controls intended to verify compliance to rules regarding fodder and food:
      - official controls on food incoming from non-EU Countries: art. 14 and artt. from 17 to 25 of (EC) reg. 882/2004
      - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
      - import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004
    - import of foodstuffs of animal origin for which no harmonized sanitary condition has been established: art. 7 and 17 of (EC) Reg. 2076/2005
    - import of foodstuffs containing products of vegetable origin and processed products of animal origin for which no harmonized sanitary condition has been established: art. 7 of (EC) Reg. 2076/2005

  – *Honey*
    - honey: art. 3 of Law by Decree 179/2004
    - import certificates for honey: art. 1 of (EC) Reg. 1664/2006 with the amendments introduced by art. 1 of (EC) Reg. 1663/2006
    - honey (import licenses): artt. from 130 to 134 of (EC) Reg. 1234/2007

- *ALIMENTARY FATS*

  – *Inspections on products of animal origin*
    - documentary and veterinary inspections on animal products listed in enclosures to Law by Decree 28/93 and subsequent amendments: arts. 3 to 15 of Law by Decree 80/2000
    - official controls intended to verify compliance to rules regarding fodder and food:
      - official controls on food incoming from non-EU Countries: art. 14 and artt. from 17 to 25 of (EC) reg. 882/2004
      - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
      - import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004
    - import of foodstuffs of animal origin for which no harmonized sanitary condition has been established: art. 7 and 17 of (EC) Reg. 2076/2005

  – *Husk and olive oil*
    - designation of origin of extravirgin olive oil and of virgin olive oil: art. 3 of EC Reg. 2815/98
    - labelling of origin of extravirgin olive oil, of virgin olive oil and of olive oil: art. 1 of Law 313/98
    - mandatory labelling of virgin and extravirgin oil: art. 2 of Ministerial Decree 10/10/2007
    - olive oil and olive husk oil: art. 35 of EEC Reg. 136/66 and subsequent amendments and artt. from 3 to 6 of (EC) Reg. 1019/2002 and subsequent amendments
    - olive oil (import licenses): artt. from 130 to 134 of (EC) Reg. 1234/2007

- *ALCOHOLIC DRINKS*

  – *Wines*
    - wine (import licenses): artt. from 130 to 134 of (EC) Reg. 1234/2007
    - wine (import licenses): artt. from 73 to 84 of (EC) Reg. 479/2008
    - indications stating the foreign origin of wine: art. 61 of Presidential Ruling by Decree 162/65

  – *Beer*
    - beer: arts. 2, 12, 19 of Law 1354/1962 and subsequent amendments

  – *Spirits*
    - brandy: art. 12 of Law 1559/51 and subsequent amendments
    - art. 6 of (EC) Reg. 110/2008

  – *Vermouth wines and flavoured wines*
    - Vermouth wines and flavoured wines: art. 19 of Law by Decree 3/56 and subsequent amendments

- *DEEP-FROZEN ALIMENTARY PRODUCTS*

Subject to enforcement of specific rules for the various kinds of products, the following is the rule governing hygiene of deep-frozen products:

- deep-frozen products: art. 10 of Law by Decree 110/92
- application of art. 10 of Law by Decree 110/1992: point 3 of Ministerial Circular Letter 21/92

- *ALIMENTARY PRODUCTS MEANT FOR PARTICULAR DIETS AND INTEGRATORS*

- dietetic products, integrators and products for children and weaning: art. 7 of Law by Decree 111/92 and subsequent amendments
- authorization to import of dietetic products, integrators and products for children and weaning: art. 2 of Presidential Ruling by Decree 131/98 (enacting Law by Decree 111/92)
- cereal-based foodstuff and other food for babies and children: Dir. 2006/125/EC
- food for babies and older children: Dir. 2006/141/EC
- food integrators: art. 10 of Law by Decree 169/2004

- *IRRADIATED ALIMENTARY PRODUCTS*

  – *Controls on products not of animal origin*
    - official controls intended to verify compliance to rules regarding fodder and food:
      - official controls on food incoming from non-EU Countries: artt. from 15 to 25 of (EC) reg. 882/2004
      - Community controls in non-EU Countries: art. 46 of (EC) Reg. 882/2004
      - import conditions: artt. from 47 to 49 of (EC) Reg. 882/2004

- products treated with ionizing radiations (dried herbs, spices and vegetable dressings): art. 14 of Law by Decree 94/2001

- *MINERAL WATER*

  - mineral water: art. 13 of Law by Decree 105/92 and subsequent amendments.

Imported mineral water is subject to the sanitary surveillance rules provided for by Law by Decree 542/92 and subsequent amendments.

  - water intended for human consumption: Law by Decree 31/2001 and subsequent amendments

- *SALT*
  - kitchen salt: art. 6 of Ministerial Decree 106/97

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Appendix A

Tables of the characteristics of the various typologies of perishable goods

GARLIC

Description of the product

Originating from Central Asia, garlic (*Allium sativum*) is present in the Mediterranean region since ancient times. The domestication of this plant goes back to about 5000 years ago. Today the main production zone of garlic is represented by subtropical countries, but it is grown also in tropical and temperate regions. Garlic has a bulb shape, made up of sessile small bulbs, oblong (cloves). The leaves are flat. In its growing the small bulbs are planted in spring or in autumn; harvesting takes place in summer.

The flavour and the aroma, hot and bitter, of garlic are due to an oil rich in sulphides.

Main producers

The main countries producing garlic are China, South Korea, Thailand, India, Spain, Argentina.

Regulations

The trade of garlic in the EU territory is governed by Regulations 220/96, 1182/2007 and 1580/2007.

Other recommendations, such as for instance the US Grade Standard, are not essential at an international level.

The quality rules necessary for marketing in Italy are laid down in the operative Manual of procedures of controls of compliance with common rules of quality on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum Requisites

Garlic must be intact and clean. The bulb must be free from damages, burns, signs of diseases and rotting. The cloves must not be visible. Garlic must be completely dried without the pulp losing firmness. The bulb must be complete of all its cloves and free from foreign smells or flavours.

Packing and transport modalities

Wooden and/or aerated cartons, cases.

Main damages during transport and survey ascertainments

- Increase in temperature and/or variations in humidity (sweat or wetting included) due to excessive length of transport: sprouting;
- Excessive variations in humidity: development of rotting;
- Variations in temperature and/or humidity: development of fungi (in particular “aspergillus”, “botrytis cinerea”and “pennicillium”), usually already present on the product;
- Keeping at too low temperature or alterations (waxen oedema): decay.

Sprouting and formation of rootlets are evaluated according to their length and to the relevant firmness of the small bulbs of garlic.

As for all vegetable products, the length of transport, and therefore of the keeping in conditioned ambient, leads to degradation of the organoleptic characteristics also without alterations of the preservation parameters.

In case of formation of rotting, whatever the cause, the damaged zones must be separated and the quantity of goods involved must be evaluated, as generally these alterations are limited.

The surveyor, like in all cases, must inspect at least 10% of the product to obtain statistically significant indications as to the extent of damages.

It is useful to cut the garlic bulbs in equatorial section, to verify the firmness of same and the colour inside, so realizing the degree of deterioration of the product.

Particular attention must be paid to the age of the product, as non-fresh garlic may present sprouts or rootlets, softening, yellowing of the pulp of the small bulbs, superficial formations of fungi.

It therefore appears necessary to verify at the time of opening the loading area both the regularity of the physical parameters of preservation and the distribution of alterations within the mass being carried.

The above applies to fresh garlic. In the case of well parched garlic transport may be carried out with non-refrigerated vehicles, at ambient temperature, also with non-optimal ventilation (for instance in open top containers).

Maintaining quality

On shelves: at T 0 °C (32°F), relative humidity 65-70%: 6-7 months
at T 20 °C (68°F), relative humidity 60%: 3-4 weeks.

PINEAPPLE

Description of the product
Pineapple (*Ananas sativus*) is originary of tropical America. This plant has knit together leaves, even more than one meter long. The fruit forms on a short and strong stem (rachis) which sticks out from the central part of the plant. Pineapple is grown in all tropical regions.

Main producers
The main countries producing pineapples are Philippines, India, Brazil and several other countries of the central zones of Africa and America.

Regulations
Pineapple trade is not regulated by specific international laws. Recommendations such as for instance the US Grade Standard are not essential at an international level.

Minimum requisites
Pineapples must be fresh and compact. The crest of leaves must be green, not withered and without damages, the external surface must be yellow/green or golden with a golden, juicy and solid but not fibrous pulp. The fruit must not show signs of diseases or rotting, foreign smells or flavours. Pineapple should not show signs of freezing, such as flabby leaves and watery or blackened pulp.

Packing and transport modalities
Multilayer cartons. Presently transport is carried out also by aircraft.

Main damages during transport and survey ascertainments
- Increase in temperature, high levels of ethylene or prolonged preservation periods: excessive ripening with softening, sometimes superficial darkening, decay/withering of leaves, dehydrated rachis, increase in the sugar value and yellowing of the pulp;
- Increase in temperature and/or variations in humidity: development of fungi on the surface with propagation towards the inside of the pulp (these organisms anyway must be already present:: the variations in physical parameters enhance their development);
- Freezing due to temperature drop: darkening of the pulp, decay.

The surveyor should be equipped with a refractometer to measure the sugar value of the pulp of the fruit, so as to evaluate its commercial depreciation.
It is also advisable to cut the fruit equatorially and axially to verify firmness of the pulp, ascertain the absence of possible inherent vices, check the colour and juiciness.
In the case of pineapples, as for most tropical fruits, often shipments of various and heterogeneous productions are loaded; it is therefore possible that some of them may be older or already infested with pathogenic organisms, parasites or saprophytes.
It is therefore fundamental to carefully consider the distribution of degenerative phenomena and to immediately identify the codes of the various producers, including the dates shown on the packagings.

Maintaining quality
On shelves (the preservation temperature depends on the ripening period):
Unripe fruits: at T 10 °C (50°F): 2-3 weeks
Ripe fruits: at T 7-8 °C (44.6-46.4°F): 5-7 days
at T 20 °C (68°F): about 3 days

ORANGES

Description of the product

The orange tree (Citrus sinensis) is originary of South China. Although it is known in the Mediterranean area since ancient times, it became widely diffused with the Arab expansion (XI century). Orange is grown on a large scale since the end of the XVII century. Today there are several varieties. The orange tree is 5 to 12 meters high. The fruit (orange) is generally round, with a solid and rough peel which protects the pulp from desiccation. The pulp is juicy and of different colours according to variety, from red ("Moro" type orange) to striped red ("Tarocco") to orange ("Navel").

Main producers

The main producers of oranges are Brazil, United States, China, Italy.

Regulations

The orange trade in the territory of EU is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Other recommendations are not essential at an international level.

The quality regulations necessary for marketing in Italy are laid down in the operative Manual of the procedures of controls of compliance with common quality laws on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites

Fruits must be intact, firm, without damages due to freezing. No foreign matters must be present, nor anomalous aromas or flavours. The content in juice must be equal to at least 35% of the total weight of the fruit. Every box or packaging must contain only one variety of oranges.

Packing and transport modalities

Nets, wooden crates.

Main damages during transport and survey ascertainments

- Increase in temperature: development of moulds and/or rotting already present in the product (axis rotting); withering (these phenomena may be prevented by wrapping oranges in diphenyl paper).
- Rough handling: oleocellosis.
- Temperature drop below the physiopathologic threshold: dermatosis.
- Excessive drop of temperature: watery decay.
- Prolonged preservation: necrosis or loss of colour.

Survey ascertainments must be carried out on adequate quantities of product, so as to distinguish problems actually due to conditions or duration of transport from problems of different origin (increase in temperature etc.).

Citruses are somewhat difficult as they are among the products which present the greatest number of pre-shipment diseases.

Once ascertained the type and cause (depending or not on transport) of the disease, damage may be easily quantified. In fact, fruit subject to any form of alteration should be discarded.

All citruses (oranges, lemons, mandarins etc.) are subject to various diseases, attributable to climatic conditions during growing. Therefore the surveyor must ensure that he is dealing with a transport problem also taking into account other factors such as the conditions of the vehicle or the duration of the voyage.

Maintaining quality

On shelves:

0-5 °C (32-41°F), 85-90% relative humidity (it depends on the variety and on the place of origin)

BANANA

Description of the product

Banana is considered one of the most ancient plants grown. It originates from South East Asia, where many wild varieties may still be found.

The banana tree (Musa paradisiaca) is an herbaceous plant the leaves of which are knit together to form a sort of tree trunk. It is therefore a palm. After about 6 months it reaches its maximum height (4-10 meters); always in the same period the first fruits show up. Banana is a fruit, long and arched, called capsule, with tough peel and fleshy pulp with a sweet and aromatic taste. Harvest does not take place in a precise season.

It is carried out by cutting the tree and picking the unripe fruits. Bananas, once at final destination, undergo artificial ripening according to commercial demand.

Main producers

The main producers of bananas are Brazil, Ecuador, Indonesia, even though the major exporters towards the European market are India, Philippines, Colombia and Costa Rica.

Regulations

Trade in bananas in the EU territory is governed by Regulation 2257/94. (EC) Regulation 1234/2007 provides for the possibility to issue marketing rules for this product.

Minimum requisites

Bananas must be whole, without alterations in shape. The peel must be intact, without spots or signs of mechanical damages, and the pulp must not show. Bananas without these requisites should be discarded; moreover the smell and flavour must be typical of the ripening period. Freezing damage should be avoided, as it renders the fibres dark.

Packing and transport modalities

Ventilated carton crates with internal cellophane (Banavac or Polivac, with different permeability to gas produced in metabolic processes).

Main damages during transport and survey ascertainments

- Increase in temperature, excess of ambient ethylene or prolonged preservation: excessive ripening, with yellowing and development of the typical smell of ripe fruit;
- Stagnation of metabolic gas: suffocating (the product takes on a green colour and soft consistency);
- Overcooling ("chilling"): darkening of the tissue.

In transport of bananas duration is of the utmost importance, as this fruit has a mean life, after harvest, which is quite short. At the end of this period it begins to ripen independently from the preservation conditions. The surveyor should cut lengthwise the chosen fruits, verifying the colour and the consistency of the pulp. Yellowing starting from the centre of the fruit indicates that ripening process has begun, which may be due to temperature or to age limit.

Green soft product is typically due to accumulation of metabolic gas. Once excluded the possibility that there has been a packing defect, the surveyor, after an initial test of the characteristics of the packing polyethylene, should ascertain if air changes have been carried out as per instructions received and which are the gas residues in the surrounding air. Obviously this is not always necessary, as the incidence of this alteration is always very limited. Generally it is a phenomenon linked to excessive temperature, ageing.

As for the extent of damage, green and soft fruits must generally be discarded. The ripe ones, within certain limits, may still be marketed, unless the nationalization costs are too high.

In the case of bananas which arrive in a more or less incipient ripening phase, it is necessary, if their condition so permits, to immediately market them. In this case, as always, there will be a controversy between the purely technical damage and the commercial one.

By technical damage we mean in way of principle the incidence of ripening, that is how many simple sugars are present in the pulp as against superior sugars.

These parameters could be determined by laboratory tests, which allow to calculate the percentages of both and therefore to evaluate the degree of progress of ripening.

Obviously dark yellow bananas with simple sugars already nearing 15% have no commercial value at all.

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There exist empirical chromatic tables which allow to compare the colour of peel with standard colours and therefore broadly define the degree of ripening.
As for “chilling”, this problem may be of little extent (affecting limited quantities of bananas for a brief period, with not too low temperature values) or more serious, with an intense and long overcooling.
In the first case bananas ripen anyhow, even if they do not develop the typical colour any more, remaining more or less grey, and with an altered flavour owing to the unbalances in the metabolic process.
In the case of serious overcooling, unripe bananas darken with time and lose every value.

Maintaining quaity

On shelves:
Green bananas: at T 13 °C (55.4°F): 2-3 weeks
Some varieties such as Gros Michel may be stowed at 12 °C (53.6°F) for short periods.
At T 20 °C (68°F): 4-8 days.
Yellow bananas: at T 13 °C (55.4°F): 3-6 days; at T 20 °C (68°F) duration is 1-2 days.

FRESH AND REFRIGERATED MEAT

Description of the product

Broadly speaking fresh meat is the one that is carried by road for retail distribution or imported by short-distance voyages.
Refrigerated meat is the one that is carried mostly in containers, packed in anatomical cuts in cartons. The great part of meat being carried is beef.

Main producers

Among the Community countries the main producers of fresh meat are Belgium, Denmark, Germany; imported refrigerated meat comes mainly from Argentina and Brazil.

Regulations

Meat trade in the EU territory is governed by (EC) Regulations 853/2004 and 1234/2007. Commerce of meat obtained from cattle not older than 12 months is governed by (EC) Regulation 700/2007.
All rules regarding labelling must be complied with (Law by Decree 109/92 and subsequent amendments and integrations, (EC) Regulation 1760/2000 and subsequent amendments and integrations for beef)

Wrapping

The quarters may be wrapped in cellophane.

Packing and transport modalities

In quarters or halves, in controlled temperature vehicles.

Main damages during transport and survey ascertainments

Refrigerated meat

Usually it is cuts of beef and horsemeat, packed like frozen meat, which must be carried at about –1° C/+1° C.
In this case meat may be damaged both by an excessive cooling and an increase in temperature.
In the first case usually too low values of temperature are reached which begin the freezing process of meat, the long duration of which leads to formation of macrocrystals of ice between the muscular fibres, damaging the cell membranes and causing loss of nutrients in the product.
Obviously the degradation depends on the temperature reached, on the speed with which it is reached and on the duration of exposure to such values of temperature.
This meat nowadays travels only in containers. The phenomenon described above relates especially to meat positioned in packages stowed near the cold air intake.
Another problem is the loss of the vacuum-packed characteristics of the single plastic packages of the cuts, because of the increase in volume due to freezing of water.
Instead in case of heating the alterations are directly related to the levels of temperature reached and to their duration: damages go from meat which can be salvaged because it presents only a superficial darkening with slime, due to oxidization of haemoglobin and to increase in the bacteria content, to meat which is certainly no more fit for human consumption.
Containers nowadays are so sophisticated that it is difficult that thermic increases take place: in the worst hypothesis, units may remain turned off/unplugged in intermediate ports or in the discharge port, where owing to the excessive number of containers often units are plugged in rotation to the shore service of power supply. The most common case is the excess of cold as the temperature required for preservation during transport is very near to the one where freezing of the meat begins and therefore a slightly wrong calibration of the thermostat is sufficient to give rise to formation of ice.

Fresh meat

It is carried by road hanging from hooks in refrigerated vehicles for voyages which generally last from two to four days.
The surveyor should be able to attend unloading and even before that to inspect the refrigerating unit to verify its functions on the basis of:

- correspondence between the values recorded by the various thermometric detectors;
- control of the chronothermorecorder if present and if it may be extracted in case of computerized recording;
- presence of gas in the plant;
- variation of the operation pressures in connection with the cycle performed from time to time by the unit;
- efficiency of the manual and/or automatic defrostings.

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Once these parameters have been verified, along with the general conditions of the loading area, doors are opened with immediate check of the temperature of meat at three heights, of stowage and of the circulation of air.
Also for this kind of meat problems due to thermic increase or to freezing may arise, but also the case of preservation in asphyxiated environment caused by an incorrect positioning or by loading of an excessive amount of product, with ensuing inadequate circulation of cold air.
Heating causes sweating of tissues, their partial darkening, yellowing of fats, development of unpleasant smell.
Freezing in itself would not create great problems apart from commercial ones, but unfortunately it is always a very slow process which leads to formation of macrocrystals of ice which damage the cells of the muscular fibres and consequently lead to a product which has lost great part of its organoleptic and nutritional characteristics.
It is very important in the case of fresh hung meat that the surveyor checks temperatures during unloading in the various positions of stowage and above all that the same pieces (carcass, half, breast or other) are measured both on the surface and in depth, so as to understand, if it is necessary, if the problem is due to transport or to loading of meat not adequately pre-refrigerated.
An excessive loss in weight is also a sign of loading of meat not perfectly pre-refrigerated.
While saying that the driver should be furnished with a thermometer and instructed on the compliances provided for by law at the time of loading, the surveyor must anyway reconstruct in detail the course of loading and voyage, as it often happens that on the vehicle there are various shipments loaded in different slaughterhouses at different temperatures.
In such cases thermohygrometric unbalances take place inside the conveyance with formation of sweat which enhances the surface development of bacteria and therefore the deterioration of the product.
The effect of this phenomenon is similar to the one of detective or excessive stowage.
Theoretically the surveyor, once accomplished all necessary ascertainments, should go the next day to Consignee to see how and if meat is in a better condition after stay in a cold store with good ventilation and adequate temperature: many damages could be so avoided.

Maintaining quality
Temperature up to +7 °C.

DEEP-FROZEN/FROZEN MEAT

Description of the product

Deep-frozen/frozen meat is produced and eaten all over the world. The controlled temperature transport is carried out in different modalities. Generally beef travels in a frozen state, packed in anatomical cuts, more rarely in frozen quarters or halves; pork generally travels in anatomical cuts, while mutton both in anatomical cuts and in carcasses. The other kinds of meat (poultry, rabbits) are usually carried whole, singularly packed and often vacuum-packed.

The various by-products, like hamburgers or gastronomical products, travel already packed and usually ready-made for immediate marketing.

Main producers

The main producers of meat are Argentina, Brazil, Hungary, Germany, Denmark, Holland, Belgium, New Zealand, USA.

Regulations

The fresh product employed to obtain the deep-frozen/frozen product must be of very good quality, therefore in the European Community meat, whether fresh or frozen or deep-frozen, must comply with ruling laws regulating fresh meat (EC Regulations 853/2004 and 1234/2007). All rules regarding deep-freezing (Law by Decree 110/92 and Ministerial Decree 493/95) and labelling (Law by Decree 109/92 and subsequent amendments and integrations, (EC) Regulation 1760/2000 and subsequent amendments and integrations) must also be complied with.

Minimum requisites

While stating that meat must come from slaughterhouses/laboratories/producers officially authorized and acknowledged by our Ministry of Health, it is essential that the single products have the minimum organoleptic characteristics for a good quality. This depends, besides on the origin of the product and its manufacturing modalities, also on the deep-freezing or freezing system employed. Therefore the decrease in temperature must be carried out respecting the characteristics of each slaughtered species, respecting the timings and the values to be reached, Furthermore each kind of meat has its commercial destination, for example seasoned meat must not be employed in production of minced meat, raw foodstuff employed for deep-freezing must be of good quality and must be quite fresh.

The deep-freezing/freezing process must take place without interruptions and must be quick and effective. After thermic stabilization, the temperature of the product should be maintained at –18° C in all spots.

Packing

For frozen meat packing must be able to avoid loss of quality. The materials employed must have a low permeability to water vapour (WVR). For meat prone to oxidization and therefore to rotting, e.g. pork, permeability to oxygen must be low or very low. Vacuum-packing is often employed for retail sale of meat and steaks and for primary cuts; sometimes it is employed for minced meat.

Carcasses are often stored and carried without being packed, even though often packing with **thermocontracting** wrapping is used. Hamburgers, for instance, must be packed in cartons with or without internal plastic wrapping. However this type of packing should not be employed when preservation may last many months, as there is the risk of dehydration of “freeze burning”.

Packing and transport modalities

Pls refer to packing.

Main damages during transport and survey ascertainments

During sea transport frozen/deep-frozen goods now travel almost exclusively in integrally refrigerated containers, that is equipped with a refrigerating unit of their own, without bones and boxed in cartons. Sea transport of meat, nearly always mutton, from Oceania is sometimes still carried out in “ConAir” containers.

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They are mostly anatomical cuts wrapped one by one in polyethylene, vacuum-packed or not, packed in very strong cartons.
Each carton bears the dates of slaughtering, packing and expiry, besides the preservation temperature and the slaughterhouse of production, which must be present, as already stated, in the list of those acknowledged by the Ministry of Health.
The stowage of cartons within the containers takes place as already described, that is positioning them loose so that they lean against the side walls but remain at the right distance from the ceiling and the doors, so as to be enveloped by the thin layer of cold air moving around them.
Sea transport of loose cartons in refrigerated hold is now practically never used.
Usually meat so prepared arrives in Italy from South America and from Oceania with container carrier ships very well equipped and containers are now real technology wonders.
It may anyway happen that in the course of transport functioning defects of the unit take place, or that in some intermediate port same are not plugged to the shore power supply system, causing damages to the product.
Beef on the whole is among the products which suffer less because of possible increases in temperature and even though it must be carried at –18° C it fares well up to –7° C.
Obviously if such value is exceeded for quite a period of time it is possible to notice initial alterations of the surface organoleptic characteristics and anomalies in the system of packing.
In particular meat, above all the one richer in haemoglobin, begins to darken on the surface and fats tend to become yellow in proportion to the thermic increase and to its duration.
At temperatures nearing –2° C incipient defrosting may take place. In such case there will be loss of bloody serum and initial deformation and surface softening with deterioration of the organoleptic characteristics.
The effect of a thermic increase followed by a new lowering of the temperature is noticed, if superficial darkening is not yet present, by the formation of frost within the packages and/or the cartons and by the fact that the polyethylene sheets stick to the surface of the meat.
If upon opening of the doors of the thermal container the temperature of meat is the desired one, but problems are noticeable due to a previous thermic increase, attention must be paid to the distribution of the phenomenon within the cargo, as it could be an event preceding containerization, and this may be understood by following the destuffing of the container. Measuring temperatures and verifying the condition of goods in the various stowage positions, keeping in mind that the first alterations, the most serious ones, always begin from the outside of the mass, are indicators which constitute a valid help to be able to effect correct evaluations. A further aid will be given by the state of cartons with their degree and state of absorption, the presence of possible leakages, the presence or not of deformed cartons and/or cartons glued together owing to freezing.
The importance of following the destuffing of the container is therefore clear.
If instead upon opening of the doors the temperature of meat is not the correct one, it is probably an event attributable to transport, as, also taking into account the duration of the voyage and the stowage, a refrigerating unit of a container working properly may be able to lower the temperature of the product and therefore remedy a possible thermal anomaly at the time of loading: there derives the importance also in this case of verifying the distribution of temperatures in the loading area.
If, as it happens more and more frequently, it is not possible to arrive in time, for various reasons, to attend to destuffing of the container the facts, as already said, must be reconstructed interviewing those that were present and then inspecting goods, choosing a statistically significant number of cartons and taking care to respect the percentages of anatomical cuts and, if possible, the originary stowage.
Unfortunately now upon destuffing all warehouses, usually third parties, palletize cartons on the basis of cuts and dimensions and it is therefore practically impossible to be able to select the cartons to inspect respecting the initial stowage.
There derives the importance of being present at destuffing or managing to subsequently acquiring the temperature recordings.
Arriving on the spot when the container has already been destuffed and the above evaluations not being possible, one may try to arrange for a technical verification of the proper working order of the refrigeration machinery, hoping that an adequate electricity socket is available or that the truck which brought it to destination is equipped with an autonomous unit of its own.
The veterinary decides whether to carry out a visit at his discretion, on the basis of evaluation of the slaughterhouse of origin and of the available statistics. If the temperature of meat, though with clear signs of preceding thermal increases, is correct, generally the product is admitted to import, subject to prior ascertainment that there do not exist problems of hygienic-sanitary nature.

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If the temperature should not be the correct one samples must be taken which undergo microbiological analyses after which the destination of the product will be decided.
Usually meat, unless it arrives at a definitely irregular temperature (from –5° C upwards), strongly blackened on the surface, foul smelling, deformed or anyway covered by abundant frost, is admitted to the market. The litigation with the importer may only be solved arriving at an evaluation of the technical-commercial degradation of the product..
In fact it rarely happens that those who receive these shipments, once the border veterinary admits them, create further problems applying to the practice of self-control (HACCP): generally they accept the goods discussing their economical prejudice.
It is clear that, apart from the external appearance of meat and its packing, the variations in organoleptic characteristics lead also to a variation in the nutritional characteristics of products.
Among meat which is imported by sea in containers, integral or “ConAir”, there are then whole lambs (carcasses) which generally come from New Zealand.
These lambs, without their head, are frozen perfectly laid down and wrapped in a sack of polyethylene and covered by a cotton cloth called “stockinette” closed in correspondence of the rear legs.
The carcasses so protected are loaded in bulk in the container , and positioned lengthwise to obtain the maximum loading capacity.
In case of thermic increase the first ones to deteriorate are the carcasses stowed below: the bellies, as thin as parchment, deform and the rib cages get compressed.
It is therefore very easy to ascertain whether, in the course of transport, there have been temperature problems.
Particular attention must be paid to the possibility of finding traces of “freezer burn”, that is superficial dehydration very easy to verify given the type of meat and packing: this phenomenon is attributable with difficulty to transport except for particular cases which must be verified from time to time.
The dehydration by cold anyway is always very localized and limited and is solved, mostly, with a return to ambient temperature. Therefore this problem may lead as a maximum to a slight commercial decay.
Other meat, such as poultry and rabbits, also travel boxed and packed in packages easy to handle and to stack, like beef and usually the single parcels are vacuum-packed.
Apart from the aspects of a sanitary nature, what said above for the other frozen meat may be confirmed. However, the commercial problem is decisively more serious given the reduced dimensions of packages and the greater perishableness of the type of meat.
In these cases deformations are much more common so as the reddening of white meat.

Maintaining quality

On shelves:	Ideal temperature: -25 °C or colder	
	Requisites by law for transport:	
	ATP:	-18 °C or colder
	Tolerance:	-15 °C for brief periods
	EEC:	-18 °C or colder
	Tolerance:	-15 °C for brief periods

CARROT

Description of the product

Carrot (*Daucus carota*) originates from Turkey. It has been grown for centuries. Carrot is a biennial plant: the root, which is the part employed for consumption, develops during the first year. In the following year it becomes woody and no more edible. The carrot root has a pulp of crisp consistency and fresh flavour.

There exist many varieties of carrot, recognizable by the form and dimensions. Those with a cylindrical form or slightly cone-shaped are the most common, but there exist also round ones and ones with an intermediate shape.

Main producers

The main producers of carrots are China, Russia, United States, Poland and Japan.

Regulations

The trade of carrots in the EU territory is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Other recommendations, as for instance the US Grade Standard, are not essential at an international level.

The quality rules necessary for marketing in Italy are laid down in the Operative Manual of procedures of controls of compliance with common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites

Carrots must be intact, clean and without signs of infection, rotting or moulds. The roots must have a solid consistency and not woody, and must not present cracks. No aromas must be present nor anomalous flavours nor foreign materials. The colour must be yellow-orange without any greenish shades or discolorations.

Packing and transport modalities

Wooden small crates.

Main damages during transport and survey ascertainments

- Prolonged preservation: withering, sprouting, rotting;
- Fluctuations of temperature and humidity: rotting due to formation of sweat;
- Lowering of temperature: decay, darkening;
- Excess of ethylene in the atmosphere surrounding goods during storage: bitter taste (it is necessary to adequately ventilate goods);
- Increase in temperature: sprouting and formation of rootlets; development of bacteria and fungi;
- Mechanical damages: darkening of enzymatic oxidating type in correspondence with bruisings.

Also for carrots it should be remembered that any deterioration totally prejudices the product, causing its total loss of commercial value.

The formation of rootlets is acceptable if the carrot does not lose its consistency, and anyway subject to economical convenience of reconditioning or the possibility of marketing it as inferior quality product.

Maintaining quality

On shelves: T 0 °C (32°F),
Relative humidity 90-95%

BRUSSELS SPROUTS

Description of the product

Brussels sprouts (*Brassica oleracea var. gemmifera*) are a recent derivative of cabbage, obtained probably through cross-breedings in Belgium in the XVI century. Since then it spread across Europe, but large scale growing began only in the XIX century. Today there exist many varieties. This plant is biennial. During the first year it develops a vertical trunk as high as one meter and over. The leaves, round in shape, bear the sprouts. The sprouts may have a diameter of 3 cm at the time of harvesting, both manually and mechanically, cutting the stem.

Main producers

The main producers of Brussels sprouts are England, France, Holland, Belgium and United States.

Regulations

The trade in Brussels sprouts in the EU territory is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Other recommendations, such as the US Grade Standard, are not essential at an international level.

The quality rules for marketing in Italy are laid down in the operative Manual of procedures of controls of conformity to common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites

Brussels sprouts must be intact, fresh, firm and without earth and anomalous smells or flavours. The plant must be green, without yellow leaves. Signs of attack by insects must not be present, nor diseases, moulds or rotting, ice or mechanical damages.

Packing and transport modalities

Wooden small crates.

Main damages during transport and survey ascertainments

- Thermic increase reduces the possibility of preservation.
- Lowering the temperature may damage tissues, which lose colour and become soft up to loss of product; in this case it is necessary to locate the unit generating air which is too cold, and select goods.
- Increase in temperature: development of bacteria or fungi, which may lead to loss of the product;
- Increase in temperature or low relative humidity: yellowing/darkening and withering, which may lead to total loss of the product;
- As for all vegetable products it is fundamental to verify that the product has not been damaged by inadequate ventilation or change of air owing to stowage and/or packing, or to instructions by the shipper as to ventilation of the storing area; generally though as it is product which travels by road and for brief periods the only care is to keep open (where present) the little windows of the means of transport;
- Inadequate ventilation of the storage area: self-heating (quite frequent).

Maintaining quality

On shelves: at T from -1 °C to 0 °C (30/32°F), relative humidity 90-95%: 3-4 weeks

ONIONS

Description of the product

Onion (*Allium cepa*) probably originates from Central Asia, but is grown in Europe since ancient times. It is a plant composed by concentric layers of cylindrical leaves, empty and pointed (tunica). The most external ones have a paper consistency, the internal ones are fleshy. Onion has a strong aroma, due to a volatile sulphurate oil, and juicy consistency. There exist many varieties of onion, classified on the basis of shape (round, oval, compressed etc.), colour (white, red, violet, yellow) and dimensions. The various subspecies or the types grown may be grown all the year round: those harvested in spring-summer are more suitable for immediate consumption, those in autumn-winter are easier to keep.

Main producers

The main producers of onions are China, India, Russia, United States and Japan.

Regulations

The onion trade in the territory of the EU is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Other recommendations, such as the US Grade Standard, are not essential at an international level.

The quality rules for marketing in Italy are laid down in the operative Manual of procedures of controls of conformity to common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites

Onions must be intact, clean and without damages due to freezing and free from foreign substances. Furthermore, onions must be solid, well dry, without anomalous aromas or flavours. The external layers must be present. The surface must be humid and the stem should be no longer than 4 cm. Signs of ageing or growth should not be visible.

Insufficient essication and no initial selection are causes of alterations.

Packing and transport modalities

In wooden small crates and/or sacks.

Main damages during transport and survey ascertainments

- Increase in temperature or excessive duration of the preservation: sprouting;
- Alterations of the degree of humidity: rotting;
- Alteration of the preservation conditions (t and relative humidity): proliferation of fungi already present on the product;
- Freezing: decay;
- Formation of roots.

In general the same considerations made for garlic apply.

Onion is more resistant but in case of damage it is easier that the effects extend to a greater quantity of product.

Dried onions may be carried also in non thermically conditioned ambience, as long as it is well ventilated and with a low relative humidity.

Maintaining quality

On shelves: T from -2 to 0 °C (28.4/32°F),
relative humidity 70% (dry onions)

DATE

Description of the product

Date palm (*Phoenix dactylifera*) is a plant originating from the north coast of the Persian Gulf, wherefrom it then spread in the Middle East and on the African coast of the Mediterranean. It is an herbaceous plant the leaves of which are knit together to form a sort of trunk, and may reach an height of 20 m. From the great circle of leaves on top of the tree there spreads a series of pointed flowers pollinated by the wind. A bunch of fruits (dates) entirely developed may weigh about 25 kg. Dates have a resistant and smooth peel, brown in colour. The pulp has a sweet taste. There exist several varieties, classified as “soft” (oily when touched, sugary), “hard” (small, dry, less sweet).

Main producers

The main producers of dates are Egypt, Saudi Arabia, Iran, Pakistan, Algeria, Israel.

Regulations

The trade in dates is not regulated by specific international laws. Recommendations such as for instance the OECD Standard are not essential at an international level.

Minimum requisites

Fresh dates must be intact, firm and clean. They must not show signs of infection, rotting, moulds or damages caused by insects.

Packing and transport modalities

Sacks in material fit to preserve the characteristics of product or ready-made.

Main damages during transport and survey ascertainments

- It must be kept in mind that dates intended for export are generally those with a soft pulp, but dry; the dried ones are mostly employed locally. Export dates belong mainly to the variety “deglet nur”, the most valued one.
- Increase in temperature during transport (usually lasting only brief periods): softening of the pulp and loss of flavour owing to inversion of saccharose;
- Variations in temperature and humidity: development of moulds;
- Excessive lowering of temperature: decay of the pulp in the fresh product; no particular damage in dried product.
- Freezing iqf**:** defreezing does not lead to any damage if followed by a quick freezing, apart from formation of superficial frost; in the contrary case the date darkens; excess of humidity favours the development of micro-organisms with consequent rotting.

Dates are not usually subject to long voyages (in cases in which we are concerned). Transport in conditioned environment does not present particular problems. Possible anomalies must therefore be attributed to detective preparation of dates, which by the way is quite complex.
The problem arises when damage must be quantified because, the product being of very small dimensions, there is the risk that a possible selection may cause a loss of a commercial value even greater of damage itself.

Maintaining quality

On shelves: at T 0 °C (32°F), relative humidity 90%: 1-2 months;
the product may be frozen, but defreezing causes loss of water

FENNELS

Description of the product

Fennel (*Foeniculum vulgare*) comes from the Mediterranean area. It is employed as a spice in Western Asia and in the Mediterranean region since ancient times, but large scale growing has set in much more recently. The plant has a diameter between 6 an 10 cm. It is entirely edible. The leaves have a thick base and form a bulb, the pulp of which has a flavour similar to anise.

Main producers

The main producers of fennel are Italy, France, Spain and Greece.

Regulations

The trade of fennel is not regulated by any specific international laws. Recommendations such as EEC FFV-116 Standard are not essential at an international level.

Minimum requisites

Fennels must be clean, with a compact consistency, and light-coloured. They should not show any sign of discoloration, for example the darkening of vascularized leaves (the threads). Pulp must be crisp, whole and without hard fibres, mechanical damages must not be present. The top part must be cut neatly.

Packing and transport modalities

Wooden small crates.

Main damages during transport and survey ascertainments

- Micro-organisms: infection;
- Increase in temperature: withering, yellowing;
- Prolonged preservation;
- Ice damages, very frequent as the preservation temperature is near the freezing point.

If product is only withered it is possible to keep it fit for marketing by eliminating the external sheaf layers and cutting the damaged leaves.
The pieces subject to infections or frozen must be considered commercially lost.
Fennels must reach markets whole and intact. A possible selection may lead to a commercial loss greater that the damage itself.

Maintaining quality

On shelves: At T 0 °C (32°F), relative humidity 90%: 2-4 weeks
At T 20 °C (68 °C), relative humidity 60% : 2-3 days;
T 0 °C (32°F), relative humidity 90-95%

STRAWBERRY

Description of the product
Strawberry has unknown origins. Strawberry (*Fragaria vesca*) may be found in its wild variety in the mountains, at low heights, in almost all the world. There exist many species, which may be grown in various climatic conditions. The plant is perennial and does not need to be pollinated. The trunk is laid down on the ground; from it the leaves and the roots stem, from which flowers originate. The fruit of the strawberry is a "false fruit", made up by the receptacle of the flower which enlarges taking on a fleshy and juicy consistency and a red colour.

Main producers
The main producers of strawberries are the United States, Poland, Spain, Japan and Italy.

Regulations
The strawberry trade in the territory of the EU is governed by Regulations 2200/96, 1180/2007 and 1580/2007. Other recommendations, such as the US Grade Standard, are not essential at an international level.
The quality rules for marketing in Italy are laid down in the operative Manual of procedures of controls of conformity to common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites
Strawberries must be ripe, fresh, intact, clean. The fruit must present a green stem, be without damages due to freezing and foreign substances, of solid consistency, dry and without foreign smells or flavours.

Packing and transport modalities
In plastic trays and wooden small crates

Main damages during transport and survey ascertainments
- Increase in temperature: maceration and/or development of moulds;
- Ageing: becoming sour and formation of fungi, in particular grey mould;
- Freezing: darkening and decay.

In general, transport of fresh products has a limited duration; possible alterations in temperature prejudice the entire load, owing to the frailty of the fruit which is strongly affected also by the formation of sweat in the loading areas.

Maintaining quality
On shelves: at T 0 °C (32°F), relative humidity 90-95%.
at controlled T the duration is 5-6 days.

GROWN MUSHROOMS

Description of the product
Mushrooms are not actual vegetables, but belong to a group of their own. Grown mushrooms (*Psalliota biaspora*) grow freely in the woods and in the fields. They are cultivated since the XVII century.
Mushroom growing exploits their characteristics of saprophytes (organisms which feed on decomposing organic matter), and is spread worldwide. Nowadays they are the most common edible mushrooms.

Main producers
The main producers of mushrooms are United States, France, China. Holland and England.

Regulations
The mushroom trade in the EU territory is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Recommendations, such as the US Grade Standard, are not essential at an international level.
The quality rules for marketing in Italy are laid down in the operative Manual of procedures of controls of compliance with common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites
Grown mushrooms must present superficial colour tending to white, pale, without any dark spots. The mushroom must be closed, intact, compact, with a solid stem and umbrella. There must not be any earth. The roots must not present anomalous growths.
Mushrooms must not show signs of diseases or a darker colouring inside.

Packing and transport modalities
In wooden small crates, sometimes in plastic baskets.

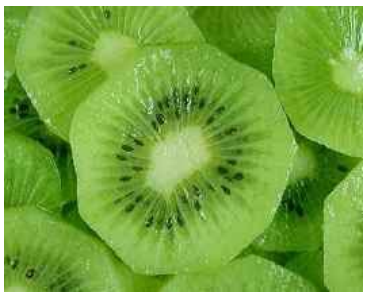
Main damages during transport and survey ascertainments
- Increase in temperature: ageing with withering, softening, discolouration;
- Excess of humidity: formation of rotting or moulds.

The quality of grown mushrooms is closely linked to the preservation temperature: they present just acceptable characteristics after 1-2 days at +10° C, good characteristics after 6-10 days at 0° C, but they are no more marketable after 2-3 days at +4° C/+5° C.

Maintaining qualità
On shelves: T 0 °C (32°F),
Relative humidity 90-95%.

KIWI

Description of the product



Kiwi is the fruit of actinidia (Actinidia chinensis) originating in South China. This plant was introduced in New Zealand at the beginning of the XX century, where thanks to a favourable climate growing on large scale began. Nowadays, besides New Zealand, one of the main producers of kiwis is Italy.

The fruit is a round berry, slightly oval, of about 5 cm in diameter. The rind is thin, with a rough surface, hairy and brown. The pulp is juicy, brilliant green, with various small and dark seeds. The fruit is harvested when still unripe and is left to ripen in adequate temperature conditions and letting ethylene in the atmosphere where the fruit is kept.

Main producers

The most important producer of kiwis is New Zealand, followed by Italy, Chile, United States, France and Israel.

Regulations

The kiwi trade in the EU Territory is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Recommendations, such as the US Grade Standard, are not essential at an international level.

The quality rules for marketing in Italy are laid down in the operative Manual of procedures of controls of conformity to common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

The EC Regulation 410/90 relevant to marketing of kiwis laid down in the above Manual has been repealed and replaced by EC Regulation 1673/2004.

Minimum requisites

The fruit must be intact and clean, without signs of breakages, pressure or mechanical damages. Moreover it must not be affected by rotting nor show signs due to freezing (for example, pulp soft to the touch) or to ethylene (pale green pulp).

Packing and transport modalities

In cartons or ventilated small crates (often also in *bins*).

Main damages during transport and survey ascertainments

- Increase in temperature or presence of ethylene in the ambient: ripening;
- Insufficient level of humidity in the ambient: wrinkling;
- Freezing: internal decay;
- Development of mould (*botrytis cinerea*) anyway already present at the time of harvesting;
- Damages due to carbon dioxide.

Generally, the surveyor finds himself ascertaining damages due to incipient ripening, which leads to an increase In the simple sugars content and softening of fruit.

These parameters may be evaluated through tools fit to evaluate the quantity of sugars in the tissues of the fruit and the consistency of tissues themselves.

There exist codified values which indicate the degree of ripening of kiwis in function of the hardness or resistance to penetrometer, and of the degree of refraction or sugar degree.

The harder the fruit, the lesser is the sugar degree: obviously if we are at the beginning of the campaign hardness is greater, while it diminishes with time.

In a normal atmosphere kiwis may be kept in cold store at about 0° C up to six months.

The fruit embarked, or anyway regularly loaded, may be then carried without problems as long as the preservation parameters are kept unaltered.

At the beginning of the season kiwis are accepted which at the time of discharge show hardness up to 14 lbs (6350.4 g) per **cm2**, then, as the season goes by, the parameters of acceptability vary, and at the season's end even fruit with hardness equal to 5-6 lbs (2495 g) per **cm2** are accepted.

These considerations are anyway relative and depend above all on the trend of the market.

It should be considered that New Zealand considers embarkable kiwis having a hardness of 2 lbs (907.2 g) per **cm2,** and that France accepts definitely soft kiwis.

In Italy the parameters adopted are very different, because who imports kiwis wants to be able to keep them for a long time, so as to market them throughout the season.

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Generally, unless fruit have a hardness of less than 2 lbs (907.2 g) per **cm2,** the problem is solved by a commercial depreciation of the product which takes into account the season at that time, the market trend, the quantity involved.

Ripening, as already stated, may be caused by temperature or by the high concentration of ethylene in the ambient.

Kiwi, the metabolism of which produces small quantities of ethylene, is however very sensitive to the action of this gas, which is in fact a phytohormone, able already at very small doses to noticeably affect its development, starting a process which self-feeds itself.

Now the surveyor faces kiwis which are carried in conditions which may appear not adequate: that is lacking change of air and at a temperature of about 0° C.

At this temperature the metabolism of kiwis is practically “still” and the ethylene and carbon dioxide are produced in very scarce quantities.

Especially the latter does not create any problems, as its accumulation is well tolerated: in fact, in preservation under controlled atmosphere exactly an excess of carbon dioxide as compared with the percentage of oxygen is employed.

What worries the most is the concentration of ethylene, but if the ambient is insulated and there are no other sources of this gas, the one produced by the metabolism of kiwis is not able to start a process of ripening.

These considerations are valid only if the temperature remains at regular values and if the surroundings are equipped of ethylene absorbers (for example vermiculite imbued with potassium permanganate) so as to keep under control both ethylene itself and carbon dioxide.

Obviously also the packing, and in particular the materials employed for the exchanges of gas produced by metabolism have a great importance on the beginning and regulation of the ripening process.

Also in the case of kiwis the extent of damage by ripening is evaluated verifying the degree of advancement of the process and its diffusion in the cargo.

It is extremely important that the surveyor analyses kiwis with the criterion of the maximum distribution of samples, selecting them from various packages chosen in the different stowage zones and at various heights, verifying the codes of producers and the dates of packing.

Furthermore, it is important to measure the refractometric degree because the correspondence between this and the hardness is a sign, besides the degree of advancement of ripening, also of possible unbalances in the relationships between exogenous and endogenous ethylene. From this it is possible to go back to the real causes of the problem.

Another important aspect is the presence of fungi development, especially grey mould (*Botrytis Cinerea*), which infesting cargo already before beginning of the voyage, may manifest itself during same thanks to favourable thermohygrometric conditions.

In case of freezing, the damaged fruit hardens and becomes lighter in colour, then softening and becoming gel when the temperature returns to the normal values: they are fruits which have lost every commercial value.

Maintaining quality

On shelves: at T 0 °C (32°F): 5-6 months.
at T 20 °C (68°F): 1-2 days.

APPLES

Description of the product

The apple tree (*Malus communis*) probably originates from Western India. Apple, its fruit, is known by man since the Neolithic.

Apple is a false fruit, as its pulp derives from the enlarging of the receptacle of the flower. The shape is usually round, with a diameter of 50-80 mm. Colour may vary from intense green to red to yellow. These characteristics depend on the species: nowadays there exist about 6000 varieties of apples, grown in the temperate regions of the whole world. Apple may be easily damaged by blows or dents, with ensuing blackening of the pulp. It is however easily kept at low temperatures, thanks to the resistant peel.

Main producers

The main producers of apples are Russia, China, United States, France, Germany, Chile.

Regulations

The apple trade in the EU territory is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Other Recommendations, such as the US Grade Standard, are not essential at an international level.

The quality rules for marketing in Italy are laid down in the operative Manual of procedures of controls of conformity to common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites

Apples must be intact and clean, with peel and pulp without spots or traces of parasites or rotting. Visible foreign matters must not be present, nor anomalous aromas or flavours.

Packing and transport modalities

In cartons or wooden small crates.

Main damages during transport and survey ascertainments

- increase in temperature: excessive ripening, wrinkling and other damages due to physiopathologies (bitter pockmarking, pink core);
- lowering of temperature: more frequent presence of brown core or soft heating;
- freezing: decay of the pulp;
- bruises: subcutaneous suberizations;
- alterations due to micro-organisms;
- increase in temperature and ageing: powdery decay;
- excess of carbon dioxide: brown core, internal decay;
- excess of relative humidity: internal decay, powdery decay, common heating.

Also in the case of apples, the surveyor may face several physiopathologies due mainly to problems already present in the product, and the manifestation of which during transport is facilitated by the excess of temperature and/or humidity.

Apple does not present particular problems, and endures well transports, in terms of thermic increases, of presence of ethylene and insufficient changes of air.

For the control of hardness a bigger penetrometer is employed, but usually it is not necessary.

Overcooling may damage the pulp, even though this does not affect definitively marketing of the product (powdery apples are frequent).

Obviously freezing of the whole pulp or of part of it completely damages the fruit, which is not any more marketable.

Maintaining quality

On shelves, maintaining depends on the type and the method of preservation

Golden Delicious:	at T 2 °C (35.6°F): 4 months	Preservation about 8 months
Granny Smith:	at T 0 °C (32°F): 4 months	Preservation about 7 months
Jonathan:	at T 4 °C (39.2°F): 3 months	Preservation about 5 months

AUBERGINE

Description of the product

Aubergine (*Solanum melongena*) probably originates in India, where it was grown already in the II millennium B.C. It arrived in Europe only around the XIII century, brought by the Arabs. It is an annual plant, with vertical, rigid trunk, high from 50 to 80 cm. Leaves are big, obovate, non brilliant green. The fruit is a fleshy berry. There exist several varieties ("common", "Palermo violet", "New York monstrous" etc.), long-shaped, curved, but also ovoidal or round, The peel, according to the varieties, is more or less intense violet, red or white. The pulp of the ripe aubergine is consistent, almost white-coloured. The flavour is bitter, but this taste is eliminated by cooking.

Main producers

The main producers of aubergines are China, Turkey, Indonesia, Italy and various countries of tropical Africa.

Regulations

The aubergine trade in the EU territory is governed by Regulations 2200/96, 1180/2007 and 1580/2007. Other Recommendations, such as the US Grade Standard, are not essential at an international level.

The quality rules for marketing in Italy are laid down in the operative Manual of procedures of controls of conformity to common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites

Aubergines must be intact, firm, clean and fresh. They must have reached the adequate level of ripening, with not hard pulp and without seeds excessively developed. The fruit must not show signs of infections, rotting, moulds or mechanical damages. No anomalous aromas or flavours must be present. Freezing may damage the product rendering some parts of the surface and of the pulp discoloured and dry.

Packing and transport modalities

Wooden small crates.

Main damages during transport and survey ascertainments

- bacteria infections, attacks by fungi, rotting;
- cooling: internal darkening, wrinkling, punctiform depressions on the peel;
- prolonged preservation: withering;
- increase in temperature: withering, development of micro-organisms, rotting.

As for all fresh vegetable products which are generally carried on refrigerator trucks for short distances and therefore in voyages of brief duration, possible alterations of the physical parameters of preservation may easily lead to the total loss of the commercial value.

In fact the transport of quantities equal to several tons of product, with metabolic heat more or less high, in a restricted space amplifies and distributes on the whole cargo any variation of the optimal conditions of temperature and humidity.

Goods must therefore be selected immediately, upon unloading, discarding the damaged parts, which are anyhow easily recognizable.

Maintaining quality

On shelves: At T 8 °C (32°F), relative humidity 90- 95%: up to 15 days

POTATO

Description of the product

Potato (*Solanum tuberosum*) originates in the andine regions of Central and South America, where it has been grown for millennia. It arrived in Europe in XVI century, brought by the Conquistadores, becoming very soon one of the most important cultivations. Potato is an herbaceous plant, about 50 cm high.

The edible part is its particular trunk (tuber), fleshy and developing underground. There exist many varieties of potatoes, with yellow or red peel and new potatoes. The tuber generally has a roundish shape; it is provided with a resistant peel, brown, yellowy brown or red, while pulp is generally yellow, more or less light (these are characteristics which depend on variety), and it is rich in starch.

The exposure of the tuber to the sun begins the synthesis of a toxic alcaloid, solanin, and makes the pulp take on a green colour. Low temperatures provoke hydrolysis of starch, and the potato takes on a sweetish taste.

Main producers

The main producers of potatoes are Russia, China, Poland, India and United States.

Regulations

The international trade of potatoes is not regulated by specific international laws. Recommendations such as for example EEC Standard no. FFV-31 and the US Grade Standard are not essential at an international level.

Minimum requisites

The tuber must be intact and clean, without earth and other foreign matters. It must be solid and must not have foreign aromas or flavours. The potato must not show signs of infection by “green colour” or regrowth, symptoms of diseases or rotting. It must then be free of mechanical damages, blackening or other defects, both on the surface and in the pulp.

Packing and transport modalities

Sacks of jute or plastic material.

Main damages during transport and survey ascertainments

- increase in temperature: sprouting up to rotting and liquefaction of the tuber;
- overcooling/freezing: decay, darkening of the pulp;
- exposure to light: pulp becoming green;
- ageing: rotting, wrinkling;
- micro-organisms: infections;
- lack of oxygen or excess of carbon dioxide: development of black core.

Sprouting may take place in a limited form, the sprouts that is may be short and not have altered the consistency of the tuber.

In this case, once evaluated the percentage of goods affected by the phenomenon, damage may be limited to the expenses for reconditioning of tubers and a loss in commercial value.

Problems of other nature are usually limited. Potato, furthermore, does not present particular difficulties, unless it is carried in great quantities, for long voyages by sea.

Maintaining quality

On shelves:	T 7 °C (44.6°F), relative humidity 90-95%

PEARS

Description of the product

The pear tree (*Pyrus communis*) is a plant probably originating in the Caucasic regions. Still nowadays it grows spontaneously in Northeast Europe. Its fruit, the pear, is known since ancient times. Pear is a false fruit (the pulp derives from the enlargement of the reticulum and not of the flower). There exist various varieties, which may be classified on the basis of the season of ripening (summer, autumn, winter pears) shape, aroma or flavour.

Pears generally have a diameter of 45-80 mm. The pulp is white or yellowish, very juicy, of sugary flavour. The pulp darkens very easily, if exposed to air or following blows.

Main producers

The main producers are China, Italy, United States, Russia, France, Germany, Argentina.

Regulations

The trade in pears in the EU territory is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Other recommendations, such as the US Grade Standard, are not essential at an international level.

The quality rules for marketing in Italy are laid down in the operative Manual of procedures of controls of conformity to common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites

The pear must be intact and clean. No visible foreign matters must be present, nor foreign aromas or flavours. The fruits must not show spots, signs of attack by pathogens or rotting on the rind or in the pulp.

Packing and transport modalities

Wooden small crates or ventilated cartons.

Main damages during transport and survey ascertainments

- freezing: decay;
- increase in temperature: ripening, furthermore favouring appearance of latent physiopathologies such as decay of the core, powdery decay or common heating;
- micro-organisms: infections;
- excess of carbon dioxide: brown core (favoured also by low temperatures) and internal decay.

Pears pose problems similar to those posed by kiwis. The surveyor may easily evaluate the state of ripening from the colour of the peel.

Among carried fruits, pears are those which, together with bananas and kiwis, pose the greatest problems both because the quantities which travel by sea are very great and because of the frailty of the fruit itself.

Differently from apples, every variety of pears has precise values of hardness. When the ripening has begun, the process is extremely fast, above all in qualities like “Williams”.

The principle for the evaluation of damages, of whatever nature, is always the same: statistically significant quantities of goods must be sampled, taking them from the various positions of stowage. On these samples the percentage incidence of the various alterations must be evaluated. Only in this way the results can be extended to the whole shipment.

In the particular case of goods carried in a ship hold the compartments involved should be segregated.

Maintaining quality

On shelves:

Pears must be kept at T from –0.5° C to 0° C (30/32°F), for periods from 1 to 6 months, depending on the varieties and the storing method.

Cold preservation:	Barlett:	2.5-3 months
	Anjou:	4-6 months
	C.A.Conference:	5-6 months
	Decana del Comizio:	3-4 months

DEEP-FROZEN POULTRY

Description of the product

Domestic poultry (chickens, turkeys, ducks, hens, guineafowls, geese) is preserved with the method of deep-freezing. It is eaten all over the world and is a very well accepted food, with high protein percentage and a low content of fats.

Main producers

China, Argentina, Eastern countries.

Regulations

The fresh product employed to obtain the deep-frozen/frozen product must be of very good quality, therefore in the European Community meat, whether fresh or frozen or deep-frozen, must comply with ruling laws regulating fresh meat (EC Regulations 853/2004 and 1234/2007). All rules regarding deep-freezing (Law by Decree 110/92 and Ministerial Decree 493/95) and labelling (Law by Decree 109/92 and subsequent amendments and integrations, Ministerial Decree 29/7/2004) must also be complied with.

Minimum requisites

Feeding, for example, chickens even with small quantities of food containing unsaturated acid fats may cause rancidity and an anomalous smell of meat. Slaughtering, including scorching, ripping and refrigeration must be carried out according to good manufacturing practices (GMP) and relevant rulings. For whole turkeys, a period of seasoning between refrigeration and freezing (12-24 hours at about 0° C) or after freezing renders meat more tender. For smaller birds like chickens, a seasoning period (2-4 hours) between refrigeration and freezing will increase tenderness. Roast meat, turkeys and ducks are usually cut into portions. The duration of preservation of portioned poultry is shorter that the one of whole poultry because it undergoes a further lavoration and is more prone to microbic contamination, which accelerates its degradation processes.

Packing

Whole chickens are usually packed after the refrigeration process and before freezing in thin plastic bags (polyethylene) closed by a clamp. This packing may cause damages to the plastic and white marks on meat due to local dehydration. Turkeys and ducks are vacuum-packed or placed in more expensive packing with plastic termocontracting wrapping, characterized by low permeability to oxygen and to water vapour. Turkeys require a good packing as they tend to grow rancid more easily than other poultry.

Packaging and transport modalities

See packing above. Moreover the packages are consolidated in packing made up by cartons.

Main damages during transport and survey ascertainments

The carriage of fresh poultry is limited to very brief voyages, generally of short duration and internal to the country. Given the particular frailty of meat an increase in temperature, even limited in value and time, may lead to the total loss of the cargo owing to deterioration. As we are dealing with small pieces (portions, packages) it is very difficult to proceed to salvage, the more so because white meat reddens easily owing to increase in temperature. More frequent problems arise in case of transport of deep-frozen products, which are usually effected in reefer containers: defrosting leaves little space for salvage, though partial, both because of the dimensions and the type of meat. An increase in temperature which does not lead to defrosting provokes the same serious damages because meat reddens easily and a subsequent lowering of temperature, causing formation of frost, noticeably alters its aspect. This implies that when brought back to ambient temperature meat shows clearly altered consistency and tenderness. The modalities of carrying out investigations aimed to define the causes of the damage, besides its extent, are always the same for all frozen/deep-frozen products.

Maintaining quality

On shelves: Ideal temperature: -24 °C

Requisites by law for transport:	ATP: -18 °C or colder	Tolerance: -15 °C for brief periods
	EEC: -18 °C or colder	Tolerance: -15 °C for brief periods

DEEP FROZEN/FROZEN/FRESH FISHING PRODUCTS

Description of the product

Fish and the other fishing products are marketed and carried deep-frozen or else fresh/refrigerated. Fishing products which must be carried by sea for long distances are usually frozen directly on the fishing boats, a guarantee of better quality; refrigerated fish is instead carried by insulated or refrigerator conveyances in containers containing ice or in solutions of brine at pre-determined temperature (tuna fish).

Main producers and distributors

Codfish: Scandinavia and Iceland.
Molluscs and crustaceans: Thailand, India, Morocco, Senegal, Argentina, Peru, USA.
Fresh fish: Holland and Great Britain.
Fish: South Africa and Argentina.
Tuna fish: Philippines and Japan.

Regulations

The commerce of fishing products in the EU territory is governed by Regulations 2406/96 and subsequent amendments and integrations, 104/2000, 853/2004
All rules regarding deep-freezing (Law by Decree 110792 and Ministerial Decree 493/95) and labelling (Law by Decree 109/92 and subsequent amendments and integrations) must also be complied with.
The Alimentary Code recommends keeping and transport at –29° C and recommends that the freezing process must not be considered complete until the temperature of –18° C or lower has been reached at the core of the product after thermal stabilization. The determination of the net content covered by frosting is described in the Standard Codes for crayfish/shrimps. The Alimentary Code has defined the international standards recommended for the following products: disemboweled salmon of the Pacific, perch fillets, sole fillets, shrimps and crayfish, lobsters, cod fillets.

Minimum requisites

Raw foodstuffs: the product must be of good quality and of the desired degree of freshness (e.g. just fished and/or refrigerated, that is to say preserved at a temperature of about 0° C).
Frozen fishing products have a mean duration shorter than frozen meat, These products contain high quantities of polyunsaturated acid fats and are therefore highly oxidizable; furthermore sea fish contain trimethylamine oxide (TMAO) which, following bacterial reactions taking place after death, is degradated in dimethylamine (DMA) and formaldehyde which confer the typical smell of fish that is no more fresh: they are therefore very good indexes of freshness. The processes of slicing, breadcrumbing etc. of fishing products must be carried out respecting the good hygienic practice.

Packaging

Low temperatures and an adequate packaging slow down the degradation. Packaging must be as uniform as possible and must have a low permeability to water vapour, as the surface of fish easily undergoes freezer burns.
For bigger fish it is necessary to employ wrappings with low permeability to oxygen: in particular vacuum packing is preferred. Fishing products must be protected by an ice frost on the surface to reduce oxidization and dehydration; this system is often employed for salmon, shrimps and for blocks of fish or fillets.
It must be taken into account that duration of the frosting is limited, and that its colour, its consistency and distribution are good indexes of the preservation state of the product.

Packing and transport modalities

Pls refer to packaging. In the case of deep-frozen fishing products packages are consolidated in packing made up of cartons.

Main damages during transport and survey ascertainments

Frozen products

Apart from frozen tuna fish, nowadays practically all fishing products travel packed in cartons, placed in refrigerated containers/loading areas.

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the most frequent damages are those due to increase in temperature with defrosting or reaching temperatures near the defreezing point, which may fire decomposition/transformation reactions (generally of an enzymatic nature) and cause chromatic alterations, as in the case of molluscs, or darkening of the heads, as in the case of crustaceans.
The law provides for maintaining frozen/deep-frozen fishing products at a temperature of -18° C except an increase of three degrees for brief periods, if it is transport for distribution.
The possible alterations in the case of fishing products carried in containers or by truck are due to an increase of temperature up to total defrosting: in this case the product is mostly totally lost. If the thermic increase does not reach the defrosting point, product may be salvaged, unless wholesomeness characteristics are altered and anyway in accordance with the provisions of the law on self-control.
As there is a very great number of fishing products, let us group the main ones for our needs according to their fundamental peculiarities:

- fish
- molluscs
- crustaceans

Fish. Common fish are meant, such as whiting, dory, dentex, sharklike fish which are now usually frozen immediately and singularly on board of the fishing boats after capture. Apart from defrosting, in fish richer in fats oxidization damages may be ascertained in case the temperature does not reach the defrosting point; there will be the so-called surfacing of fats, visible because of the yellowing of the flesh; it is clear that this phenomenon may arise also in the case of old goods, and in such case it is accompanied, almost always, by superficial dehydration. Moreover, the thermic increase and the possible going back to lower values cause the partial loss of the frost covering fish positioned in piles. Among the fishing products fish are anyway those which give the least problems.

Molluscs. Cuttle-fish, calamaries, octopuses in particular, are generally packed in cartons, frozen one by one (IQF); less frequent is freezing in block. The thermic increase may give rise to defrosting of product up to its decomposition with emission of characteristic unpleasant smells, or to softening with deformation and colour beginning to change (yellowing for cuttle-fish, reddening for calamaries and octopuses). These chromatic alterations are due to degradative enzymatic actions fired by the rise in temperature which go on in time, though very slowly, and may continue even if the temperature is brought back to regular values, especially in the case of octopuses.

Crustaceans. In general the same applies as for molluscs, remembering that crustaceans are even more perishable. The alterations, such as blackening of the heads, loss of frost with dehydration etc. greatly affect their high commercial value; there often arises the leakage of organic excrements.

In the case of damages due to non-regular transport temperature, the first check is carried out by the border veterinary who generally takes the necessary samples to evaluate the hygienic-sanitary condition of the product.
If alterations possibly caused by the rise in temperature have not given rise to problems of a sanitary nature, then everything is reduced to a technical-commercial matter due to the variation of organoleptic characteristics.
Among these an important role is played by the aspect and the conformation of packages and/or of the single packings and, in the case of products singularly frozen, the keeping or not of this characteristic.
For all frozen/deep-frozen products, whether animal or vegetable, it is fundamental, as repeated several times, to attend the discharge from the loading areas to verify, besides the distribution of temperature values, also the one of deformations of packages, of alterations in organoleptic characteristics, of the zones where there is a greater formation of frost and of disappearance of same, of the distribution of leakages, the presence and distribution of packages and/or products stuck together owing to superficial freezing forming more or less compact masses. Moreover, it is also important to verify if the decay effects or anyway the alterations are progressing from the external of the mass/package towards the interior or vice versa.
In general fishing products may not be reconditioned but, if they are judged still marketable/edible, it will have to be evaluated if a selection package per package is necessary/worth while or if it is sufficient to declass the product to a lesser commercial value.

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Fresh/refrigerated products

By “fresh” fish it is now meant especially the refrigerated product, besides the one just fished which constitutes a minimal part of it.

In fact it is possible to find “fresh” fish only in seaside towns while, generally because of the longer or shorter interval of time between capture and consumption, the respect of the cold chain is required also for preservation without freezing,

Non-preserved fishing products present the problem of easy deterioration.

Also in this case the veterinary service is called upon to evaluate the hygienic-sanitary conditions of fish, while the surveyor “retains” the duty to evaluate incidence on the residual possibility to market the product when it is not rejected/destroyed, and above all evaluate the cause of deterioration, whether due to transport or otherwise.

Often immediately marketing the product may allow to save a shipment.

Fresh fish is the one just fished, subject to few manipulations such as selection and placing in small crates with a layer of ice.

The main organoleptic parameters to define the freshness of fish are: rigidity, skin characteristics, eyes, gills, abdomen and smell.

For an evaluation of the freshness of fish also some chemical parameters may be employed, such as the concentration of istamin, total nitrogen and trimethylamine which increase as freshness decreases.

Given the alkaline character of these substances, Ph tends to increase quickly.

The main organoleptic parameters to define the freshness of molluscs are: state of the valves, reaction to stimuli, adherence of the animals to the valve, smell, colour and aspect.

The main organoleptic parameters to define freshness of crustaceans are: smell, colour and aspect. In particular, no black marks must be present on the head of the animal.

From the above it is clear that it is absolutely necessary to preserve the product in optimal conditions both as to duration and temperature, as the latter, increasing even of a few degrees, noticeably accelerates the decay processes in fishing products.

For an evaluation of the freshness of fishing products which are not frozen/deep-frozen EEC has issued a regulamented classification (EC Regulation 33/89) which is based solely on a sensorial evaluation of the general conditions.

Maintaining quality

On shelves:

Ideal temperature: -29 °C or colder, especially for fat fish

Requisites by law for transport:	ATP: -18 °C or colder	Tolerance: -15 °C for brief periods
	EEC: -18 °C or colder	Tolerance: -15 °C for brief periods

GRAPES

Description of the product
Vine (*Vitis vinifera*) is a plant probably originating from South-west Asia.
The fruit of the vine, grapes, is employed since the II millennium B.C. to produce wines or for fresh consumption.
The flowering of grapes takes place in bunches, made up of single grapes, linked to the grape-stalk (stem). The bunch may weigh from 100 to 1000 g.
The single grape has a skin, thicker in wine vines, covered by a layer of wax which protects it against essication. The pulp is juicy and sweet.

Main producers
The main producers of grapes are Italy, France, Russia, Spain and United States.

Regulations
The trade in grapes in the EU territory is governed by Regulations 2200/96, 1182/2007 and 1580/2007. Other recommendations, such as the US Grade Standard, are not essential at an international level.
The quality rules for marketing in Italy (relevant only to table grapes) are laid down in the operative Manual of procedures of controls of conformity to common quality rules on fruit and vegetable products, published by the Ministry of Agricultural and Forest Policies.

Minimum requisites
The bunch must be compact, clean and intact. The single grapes must be firmly attached to the grape-stalk. Grapes must not show signs of infections, or caused by insects or chemical agents. No foreign aroma or flavour must be present. The duration of preservation of grapes may be prolonged by treating it with sulphurous derivates. However, this procedure is illegal in some countries.

Packing and transport modalities
Wooden small crates or cartons.

Main damages during transport and survey ascertainments
- increase in temperature: development of fungi, withering/darkening of single grapes and precocious ascola, withering of the grapes-stalk;
- development of micro-organisms;
- freezing: decay of the single grapes;
- soft decay of the single grapes;
- damages due to excess of sulphurous anhydride.

Ascertainment by the surveyor of damages suffered by grapes may be more difficult in comparison with other types of fruit: withering and fading are often due to quantities of older product, not always easy to recognize, stored together with fresher products.
Obviously where a single bunch shows alterations, even limited to some single grapes, this must be considered not fit for marketing, as it is unthinkable to proceed to elimination of the damaged single grapes.

Maintaining quality
on shelves: T 0 °C (32°F), relative humidity 90-95%

FROZEN VEGETABLES

Description of the product

Several types of vegetables, such as peas, spinach, beans, Brussels sprouts, cauliflower etc., may be frozen. Salad vegetables, such as tomato, lettuce and cucumber, which are generally eaten raw, are not fit to be frozen

Main producers

In EEC countries the labelling and freezing directives must be complied with. The Recommended Standard Codes must be applied to the following vegetables: peas, spinach, broccoli, cauliflower, Brussels sprouts, green beans, leeks, whole maize.

Regulations

Deep-frozen vegetables commerce in the EU territory is governed by rules regarding deep-freezing (Law by Decree 110/92 and Ministerial Decree 493/95) and labelling (Law by Decree 109/92 and subsequent amendments and integrations).

Minimum requisites

Fresh products requisites.

Packaging

After freezing, some vegetables are wholesale packed, for example in pallets and polyethylene which may contain hundreds of kilograms of product or in patinated paper bags which contain 30 kg. The repacking for final consumers must be carried out according to the market requirements.

Deep-frozen vegetables are usually packed in heat-sealed sackets. More sophisticated packing may also be employed, such as alufoil thin sheets, which have a low permeability and reduce the degree of quality degradation process and lengthen the preservation period.

Spinach are usually packed in small containers before undergoing the freezing process.

Packing and transport modalities

Pls refer to packaging. Moreover packages are consolidated in packing made up by cartons.

Main damages during transport and survey ascertainments

The principles are the same in all cases: temperature may increase up to actual defrosting, or thermal increases may take place which cause thermohygrometric fluctuations which, in the case of subsequent return to lower values, lead to the formation of frost.

If defrosting of the product is reached, even if there is no damage from a sanitary point of view. it must be considered commercially lost.

If instead only superficial frost forms the product may be salvaged unless there are deformations and pieces are not stuck together owing to icing due to formation of frost.

A significant example is represented by deep-frozen peas, which owing to thermohygrometric fluctuations stick together forming masses.

If the single peas detach by simple pressure of fingers, then damage is trifling or even absent. if instead they do not detach, or it is very difficult to detach them, there may even arise a total loss.

Maintaining quality

On shelves: Ideal temperature: -18 °C or colder

Requisites by law for transport:

ATP:	-18 °C or colder	Tolerance: -15 °C for brief periods
EEC:	-18 °C or colder	Tolerance: -15 °C for brief periods

Appendix B
Laws

REGULATORY FRAMEWORK

Alimentary legislation is by now very ample and detailed, and it is being continually renewed. The followin g table, without aim ing to provide a co mplete view of it, indicates the main law provisions regarding alimentary pro ducts issued since Co mmunity Regulatio ns being part of the "Hygiene Package" were enforced. Provisions issued before these Community rules are also shown because they are still in force.

GENERAL LEGISLATION PROVISIONS	SUBJECT	REPERTORY	TRANSPORT	IMPORT FROM OUTSIDE EU
Law 283/62	Hygiene in production and sale of foodstuffs	G.U. n. 139 of 4/6/1962		
Presidential Ruling by Decree 404/79	Enactment law 264/77 – agreement transport perishable goods (ATP)	G.U. n. 232 of 24/8/1979		
Presidential Ruling by Decree 327/80 subs. Amendments	Enactment law 283/62 – hygiene in production and sale of foodstuffs	G.U. n. 193 of 16/7/1980	Art. 43-52; Encl C	
Ministerial Decree 28/2/84	Classification of vehicles for transport at controlled temperature	G.U. n. 71 of 12/3/1984		
Ministerial Order 2/3/2000	Requirements for commerce in public areas – definition of perishable foodstuff	G.U. n. 56 of 8/3/2000		
Law by Decree 80/2000	Enactment of Directives 97/78/EC and 96/93/EC - veterinary controls on products of animal origin imported from non-EU Countries	G.U. n. 82 of 7/4/2000		art. 3-15, 18
Dir. 2002/99/EC	Sanitary police rules for products of animal origin	G.U.C.E. n. L18 of 23/1/2003		Chap. II, art. 7-10
(EC) Reg. 178/2002	Principles of alimentary legislation – definition of foodstuff – traceability of alimentary products	G.U.C.E. n. L31 of 1/2/2002		Art. 11
Dir. 2004/41/EC	Rules for hygiene of products of animal origin – repeal of specific directives	G.U.C.E. n. L157 of 30/4/2004		
(EC) Reg. 852/2004 (rectification)	Hygiene of alimentary products	G.U.C.E. n. L226 of 25/6/2004		Art. 10
(EC) Reg. 853/2004 (rectification)	Hygiene of alimentary products of animal origin	G.U.C.E. n. L226 of 25/6/2004	Encl. III	Art. 6
(EC) Reg. 854/2004 (rectification)	Official controls on alimentary products of animal origin	G.U.C.E. n. L226 of 25/6/2004		Art. 11
(EC) Reg. 882/2004 (rectification)	Controls of compliance with rules on fodder, foodstuffs and rules on animal health and well-being	G.U.C.E. n. L191 of 28/5/2004		Art. 23, 46-50
(EC) Reg. 2073/2005	Microbiological criteria applicable to alimentary products	G.U.C.E. n. L338 of 22/12/2005		
(EC) Reg. 2074/2005	Amendments, integrations and enactment Regulations 852, 853, 854 and 882/2004	G.U.C.E. n. L338 of 22/12/2005		Encl. 6
(EC) Reg. 2076/2005	Transitional provisions for enactment of Regulations 853, 854 e 882/2004	G.U.C.E. n. L338 of 22/12/2005		art. 7, 17
Law by Decree 117/2005	Enactment Directive 2002/99/EC	G.U. n. 152 of 2/7/2005		Art. 7
Law by Decree 190/2006	Sanctions for violation Regulation 178/2002	G.U. n. 118 of 23/5/2006		

GENERAL LEGISLATION PROVISIONS *(continues from the previous page)*	SUBJECT	REPERTORY	TRANSPORT	IMPORT FROM OUTSIDE EU
(EC) Reg. 1662/2006	Amendments to Regulation 853/2004	G.U.C.E. n. L320 of 18/11/2006	Encl. III	
(EC) Reg. 1663/2006	Amendments to Regulation 854/2004	G.U.C.E. n. L320 of 18/11/2006		art.1
(EC) Reg. 1664/2006	Amendments to Regulation 2074/2005	G.U.C.E. n. L320 of 18/11/2006		art. 1
(EC) Reg. 1666/2006	Transitional provisions for enactment of Regulations 853, 854 e 882/2004; amendments to Regulation 2076/2005	G.U.C.E. n. L320 of 18/11/2006		art. 1
(EC) Reg. 1243/2007	Amendments to Encl. III Regulation 853/2004 – production gelatine	G.U.C.E. n. L281 of 25/10/2007		
(EC) Reg. 1244/2007	Amendments to Regulation 2074/2005 – official controls on meat	G.U.C.E. n. L281 of 25/10/2007		
(EC) Reg. 1246/2007	Amendments to Regulation 2076/2005 – import of fish oil (up to 31/10/2008)	G.U.C.E. n. L281 of 25/10/2007		art. 1
Law by Decree 193/2007	Enactment of Directive 2004/41/EC	G.U. n. 261 of 9/11/2007		
(EC) Reg. 1234/2007	Common organization of agricultural markets	G.U.C.E. n. L299 of 16/11/2007		Part III
(EC) Reg. 1441/2007	Amendments to Regulation 2073/2005	G.U.C.E. n. L322 of 7/12/2007		
(EC) Reg. 361/2008	Amendments to Regulation 1234/2007 – specific provisions for agricultural products	G.U.C.E. n. L121 of 7/5/2008		
NATIONAL GUIDELINES HYGIENE PACKAGE				
Guidelines (EC) Reg. 178/2002 – traceability	Application guidelines Regulation 178/2002	G.U. (S.O.) n. 294 of 19/12/2005		
Guidelines (EC) Reg. 852/2004	Application guidelines Regulation 852/2004	G.U. (S.O.) n. 259 of 7/11/2006		
Guidelines (EC) Reg. 853/2004	Application guidelines Regulation 853/2004	G.U. (S.O.) n. 259 of 7/11/2006		
Guidelines traditional products	Application guidelines Regulations 852 and 853/2004	G.U. (S.O.) n. 36 of 13/2/2007		
Guidelines (EC) Reg. 2073/2005	Application guidelines Regulation 2073/2005	G.U. (S.O.) n. 124 of 30/5/2007		
LABELLING				
Law by Degree 109/92 and subsequent amendments and integrations	Enactment Directives 89/395/EEC e 89/396/EEC			
Law by Decree 77/93	Nutritional labelling	G.U. n. 69 of 24/3/1993		
Dir. 2000/13/EC	Labelling of products intended for the final consumer	G.U.C.E. n. L109 of 6/5/2000		

LABELLING *(continues from the previous page)*	SUBJECT	REFERENCE	TRANSPORT	IMPORT FROM OUTSIDE EU
Dir. 2001/101/EC	Amendments to Directive 2000/13/EC	G.U.C.E. n. L310 of 28/11/2001		
Dir. 2002/67/EC	Labelling of foodstuffs containing quinine and caffeine	G.U.C.E. n. L191 of 19/7/2002		
Law by Decree 181/2003	Enactment of Directive 2000/13/EC	G.U. n. 167 of 21/7/2003		
Dir. 2003/89/EC	Amendments to Directive 2000/13/EC – indication of ingredients and allergens	G.U.C.E. n. L308 of 25/11/2003		
Law by Decree 157/2004	Urgent provisions for labelling of alimentary, agricultural and fishing products	G.U. n. 147 of 25/6/2004		
Law 204/2004	Conversion into law and amendments to Law by Degree 157/2004	G.U. n. 186 of 10/8/2004		
Law by Decree 114/2006	Enactment of Directive 2003/89/EC, 2004/77/EC, 2005/63/EC – indication of ingredients	G.U. n. 69 of 23/3/2006		
(EC) Reg. 924/2006 (rectification)	Nutritional and health indications provided on foodstuffs	G.U.C.E. n. L12 of 18/1/2007		
Dir. 2006/142/EC	Amendment Encl. 3 of the 2000/13/EC Directive - integration to list of allergens	G.U.C.E. n. L368 of 23/12/2006		
Law by Decree 178/2007	Amendments and integrations to Law by Decree 114/2006	G.U. n. 252 of 29/10/2007		
BSE, TSE, ZOONOSES				
(EC) Reg. 999/2001	Prevention, control and eradication of infectious spongiform encephalopathies	G.U.C.E. n. L147 of 31/5/2001		Art. 16
Dir. 2003/99/EC	Surveillance zoonoses	G.U.C.E. n. L325 of 12/12/2003		
(EC) Reg. 2160/2003	Control of Salmonella and other zoonotic agents	G.U.C.E. n. L325 of 12/12/2003		
(EC) Reg. 339/2006	Amendments Encl. XI Regulation 999/2001	G.U.C.E. n. L55 of 25/2/2006		
(EC) Reg. 1041/2006	Amendments Encl. III Regulation 999/2001	G.U.C.E. n. L187 of 8/8/2006		
(EC) Reg. 1275/2007	Amendments Encl. IX Regulation 999/2001	G.U.C.E. n. L284 of 30/10/2007		
CONTAMINANTS				
(EC) Reg. 401/2006	Sampling and analysis quantity of mycotoxins in foodstuffs	G.U.C.E. n. L70 of 9/3/2006		
Ministerial Decree 20/4/2006	Enactment Directive 2005/5/EC – sampling and analysis Ochratoxin A in foodstuffs	G. U. n. 147 of 27/6/2006		
(EC) Reg. 1881/2006	Maximum amounts of contaminants in foodstuffs	G.U.C.E. n. L364 of 20/12/2006		
(EC) Reg. 2377/90	Determination veterinary medicines residues in foodstuffs of animal origin	G.U.C.E. n. L224 of 18/8/1990		

MEAT	SUBJECT	REFERENCE	TRANSPORT	IMPORT FROM OUTSIDE EU
Presidential Ruling by Decree 32/02	Amendment Directive 90/539/EEC - Import poultry and eggs – Newcastle disease	G.U. n. 62 of 14/3/2002		
Ministerial Decree 29/7/2004	Application modalities voluntary labelling of poultry	G.U. n. 241 of 13/10/2004		
Ministerial Order 26/8/2005	Sanitary police measures for infectious and diffusive diseases of yardbirds	G.U. n. 204 of 2/9/2005		
Ministerial Order 26/8/2005 – amendments and integrations	Sanitary police measures for infectious and diffusive diseases of yardbirds			
(EC) Reg. 2075/2005	Specific rules applicable to official controls for presence of Trichinella in meat	G.U.C.E. n. L338 of 22/12/2005		Chapt. III
(EC) Reg. 1665/2006	Amendments Regulation 2075/2005	G.U.C.E. n. L320 of 18/11/2006		
Guidelines (EC) Reg. 2075/2005	Application guidelines Regulation 2075/2005 – Agreement between Health Ministry Regions and autonomous Provinces	G.U. (S.O.) n. 124 of 30/5/2007		
(EC) Reg. 1760/2000	Cattle identification system, meat and meat by-products labelling system	G.U.C.E. n. L204 of 11/8/2000		Artt. 4, 15, 17
(EC) Reg. 1825/2000	Application Regulation 1760/2000	G.U.C.E. n. L216 of 26/8/2000		Art. 8
Derogation production lagomorphs and birds	Derogation Encl. III Regulation 853/2004 – Slaughtering of partially gutted rabbits and birds			
(EC) Reg. 543/2008	Application Regulation 1234/2007 – Marketing of poultry	G.U.C.E. n. L157 of 17/6/2008		Art. 5, 14
(EC) Reg. 566/2008	Application Regulation 1234/2007 – Marketing of beef from cattle not older than 12 months	G.U.C.E. n. L160 of 19/6/2008		Art. 7
FISHING PRODUCTS				
Presidential Ruling by Decree 555/92 and subsequent amendments and integrations	Enactment Directive 91/67/EEC: sanitary police rules for fishfarming products	G.U. n. 28 of 4/2/1993	art. 4, 7, 8, 11	art. 18-21
(EC) Reg. 2406/96	Marketing of certain fishing products (excluding bivalves)	G.U.C.E. n. L334 of 23/12/1996		art. 11
Presidential Ruling by Decree 543/99	Enactment Dir. 98/45/EC – sanitary police rules for marketing of fishfarming animals and products	G.U. n. 40 of 18/2/2000		
(EC) Reg. 104/2000	Common organization of markets of fishing and fishfarming products	G.U.C.E. n. L17 of 21/1/2000		Title V
(EC) Reg. 790/2005	Amendment Regulation 2406/96 – Marketing of certain fishing products (excluding bivalves)	G.U.C.E. n. L132 of26/5/2005		
Dir. 2006/88/EC	Sanitary police conditions for fishfarming animals and products – prevention and control of certain diseases	G.U.C.E. n. L328 of 24/11/2006		Chapt. IV
Guidelines bivalve molluscs	Guidelines bivalve molluscs – Agreement Government, Regions, Autonomous Provinces	G.U. (S.O.) n. 36 of 13/2/2007		
Guidelines fishing products	Guidelines fishing products – Agreement Government. Regions, Autonomous Provinces	G.U. (S.O.) n. 68 of 22/3/2007		

MILK AND MILK BY-PRODUCTS	SUBJECT	REFERENCE	TRANSPORT	IMPORT FROM OUTSIDE EU
Ministerial Decree 20/8/2002	Labelling of fresh milk	G.U. n. 203 of 30/8/2002		
Law by Decree 49/2004	Enactment Directive 2001/114/EC – certain types of preserved milk intended for human consumption	G.U. n. 49 of 28/2/2004		
Ministerial Decree 27/5/2004	Traceability and expiry date of fresh milk	G.U. n. 152 of 1/7/2004		
Ministerial Decree 14/1/2005	Guidelines for business manual of milk traceability	G.U. n. 30 of 7/2/2005		
(EC) Reg. 79/2005	Enactment Regulation 1774/2002 – use of milk, milk products and by-products	G.U.C.E. n. L16 of 20/1/2005		
Guidelines for sale of raw milk	Guidelines hygiene package for sale of raw milk	G.U. (S.O.) n. 36 of 13/2/2007		
Guidelines for production of cheese	Guidelines Regulations 852-853/2004 – transitional derogations production of cheese (parmesan, fontina, Val d'Aosta cheese)	G.U. (S.O.) n. 36 of 13/2/2007		
Dir. 2007/61/EC	Amendment Directive 2001/114/EC – certain types of preserved milk intended for human consumption	G.U.C.E. n. L258 of 4/10/2007		
Guidelines milk control	Controls on milk to be thermically treated	G.U. n. 133 of 9/6/2008		
EGGS				
(EC) Reg. 557/2007	Rules for marketing of eggs	G.U.C.E. n. L132 of 24/5/2007		Art. 30
Ministerial Circular Letter 3 - 18/7/2007	Obligations for production and marketing of eggs	MIPAAF		
(EC) Reg. 1237/2007	Marketing of eggs from farms contaminated by Salmonella	G.U.C.E. n. L280 of 24/10/2007		
(EC) Reg. 1336/2007	Amendment Regulation 557/2006 – marketing of eggs	G.U.C.E. n. L298 of 16/11/2007		Art. 1
Ministerial Decree 13/11/2007	Application Regulations 557/07, Law by Decree 267/03	G.U. n. 297 of 22/12/2007		
(EC) Reg. 589/2008	Application Regulation 1234/2007 – Marketing of eggs	G.U.C.E. n. L163 of 24/6/2008		Art. 24, 30
OILS				
(EC) Reg. 1019/2002	Commercial rules for olive oil	G.U.C.E. n. L155 of 14/6/2002		
Ministerial Decree 14/11/2003	Commercial rules for olive oil	G.U. (S.O.) n. 266 of 15/11/1993		
Ministerial Decree 30/9/2004	Transport by sea of oils and fats	G.U. n. 271 of 18/11/2004	Enclosure	
(EC) Reg. 110/2006	Transitional measures regarding export licenses of olive oil towards non-EU Countries	G.U.C.E. n. L19 of 24/1/2006		
(EC) Reg. 1044/2006	Amendment Regulation 1019/2002 – Commercial rules for olive oil	G.U.C.E. n. L187 of 8/7/2006		
Ministerial Decree 10/10/2007	Mandatory indications on labels of virgin and extravirgin olive oil	G.U. n. 243 of 18/10/2007		Art. 1, 2
Ministerial Circular Letter 1/4/2008	Application Ministerial Decree 10/10/2007			

HONEY	SUBJECT	REFERENCE	TRANSPORT	IMPORT FROM OUTSIDE EU
Law by Decree 179/2004	Enactment Directive 2001/110/EC – production and marketing of honey	G.U. n. 168 of 20/7/2004		art. 1
Law 313/2004	Discipline of apiculture	G.U. n. 306 of 31/12/2004		
Ministerial Circular Letter 1/2005	Application Law by Decree 179/2004 – production and marketing of honey	G.U. n. 67 of 22/3/2005		
Ministerial Circular Letter 3 - 12/7/2007	Application Law by Decree 179/2004 – production and marketing of honey – wild honey	MIPAAF - Prot. N. 0010684		
FRUIT AND VEGETABLE PRODUCTS				
(EC) Reg. 1580/2007	Application Regulations 2200/96, 2201/96, 1182/2007	G.U.C.E. n. L350 of 31/12/2007		art. 12-18
MIPAF – Operative manual of the procedures of control of compliance with common quality rules on fruit and vegetable products – final version – 2005				
FLOUR PRODUCTS AND ALIMENTARY PASTA				
Presidential Ruling by Decree 502/98	Revision of rules for making and marketing bread	G.U. n. 25 of 1/2/1999		
Presidential ruling by Decree 187/2001	Revision of rules for making and marketing pasta and flour products	G.U. n. 117 of 22/5/2001	art. 9	
COCOA, TEA, COFFEE, SUGAR				
Dec. 2001/877/EC	International agreement on coffee	G.U.C.E. n. L326 of 11/12/2001		
Law by Decree 178/2003	Enactment Directive 2000/36/EC – cocoa and chocolate products	G.U. n. 165 of 18/7/2003		
Law by Decree 51/2004	Enactment Directive 2001/111/EC – types of sugar	G.U. (Suppl.) n. 49 of 28/2/2004		
(EC) Reg. 318/2006	Organization of the sugar market	G.U.C.E. L58 of 28/2/2006		Art. 21-31
ORGANIC PRODUCTS				
(EEC) Reg. 2092/91	Organic agriculture	G.U.C.E. n. 198/1 of 22/7/1991		
Law by Decree 220/95	Enactment art. 8-9 Regulation 2092/91 – organic agriculture production	G.U. (S.O.) n. 69 of 5/6/1995		
(EEC) Reg. 1804/99	Organic production (farming) - completing Regulation 2092/91	G.U.C.E. n. 22/1 of 24/8/1999		
(EEC) Reg. 1073/2000	Organic production	G.U.C.E. n. 119/28 of 20/5/2000		
Ministerial Decree 4/8/00	Enactment Regulation 1804/99	G.U. (S.O.) n. 211 of 9/9/2000		
Ministerial Circular Letter 3/2000	Import of organic products from non-EU Countries	G.U. n. 230 of 2/10/2000		
(EC) Reg. 605/2008	Control certificate for import of organic products from non-EU Countries according to art. 11 of Regulation 2092/91	G.U.C.E. n. L166 of 27/6/2008		Art. 1, 3-6
BRAND PRODUCTS				
(EC) Reg. 509/2006	Guaranteed traditional specialities	G.U.C.E. n. L93 of 31/3/2006		
(EC) Reg. 510/2006	Protection of geographical indications and origin denominations	G.U.C.E. n. L93 of 31/3/2006		

BRAND PRODUCTS *(continues from the previous page)*	SUBJECT	REFERENCE	TRANSPORT	IMPORT FROM OUTSIDE EU
(EC) Reg. 1898/2006	Application Regulation 510/2006	G.U.C.E. n. L369 of 23/12/2006		
Ministerial Decree prot. n. 5442	National procedure registration of DOP and IGP according to Regulation 510/2006			
(EC) Reg. 1216/2007	Application Regulation 509/2006 - STG	G.U.C.E. n. L275 of 19/10/2007		
(EC) Reg. 628/2008	Amendment Regulation 1898/2006	G.U.C.E. n. L173 of 3/7/2008		
PARTICULAR DIETS				
Law by Decree 111/92	Products for particular diets	G.U. (Suppl.) n. 39 of 17/2/1992		
Presidential Ruling by Decree 131/98	Enactment Law by Decree 111/92 – products for particular diets	G.U. n. 104 of 7/5/1998		Art. 2, 8
Dir. 2006/125/EC	Cereal-based foodstuffs and other food for babies and children	G.U.C.E. n. L339 of 6/12/2006		
Dir. 2006/141/EC	Food for babies and weaning foodstuffs- repeal of Directive 1999/21/EC	G.U.C.E. n. L401 of 30/12/2006		
FOOD INTEGRATORS				
Law by Decree 169/2004	Enactment Directive 2002/46/EC – food integrators	G.U. n. 164 of 15/7/2004		art. 10
GENETICALLY MODIFIED ORGANISMS				
(EC) Reg. 258/1997	New products and new food ingredients	G.U.C.E. n. L43 of 14/2/1997		
President of the Council of Ministers Decree 4/8/00	Prohibition to import certain GMO products	G.U. n. 184 of 8/8/2000		
(EC) Reg. 1829/2003	Genetically modified food and fodder	G.U.C.E. n. L268 of 18/10/2003		
FROZEN AND DEEP-FROZEN PRODUCTS				
Law by Decree 110/92	Enactment Directive 89/108/EEC: deep-frozen foodstuffs	Italian Institute for Deep-frozen Foodstuffs	art. 11	art. 10
Ministerial Circular Letter 21/92	Import deep-frozen products according to Law by Decree 110/92			art. 1
Decree 493/95	Enactment Directive 92/1/EEC (T control on deep-frozen products) and 92/2/EEC (sampling and analyses for control of T)	G.U. n. 272 of 21/11/1995	art. 1	
(EC) Reg. 37/2005	Control of transport and storing temperatures of deep-frozen products; repeal of Directive 92/1/EEC	G.U.C.E. n. L10 of 13/1/2005	art. 2	
Self-discipline code for commerce and marketing of deep-frozen products in Italy (Italian Institute for Deep-frozen Foodstuffs 1993)				
WATER				
Law by Decree 31/2001	Enactment Directive 98/83/EC - quality of water intended for human consumption	G.U. (S.O.) n. 31 of 3/3/2001		
Law by Decree 27/2002	Amendments to Law by Decree 31/2001	G.U. n. 58 of 9/3/2002		

ALCOHOLIC DRINKS	SUBJECT	REFERENCE	TRANSPORT	IMPORT FROM OUTSIDE EU
Law 1354/62	Production and commerce of beer	G.U. n. 17 of 17/9/1962		art. 19
Presidential Ruling by Decree 162/65	Wines	G.U. n. 73 of 23/3/1965		art. 60, 61
(EC) Reg. 110/2008	Spirits – Repeal Regulation 1576/89	G.U.C.E. n. L39 of 13/2/2008		art. 6
(EC) Reg. 479/2008	Common organization of the wine market	G.U.C.E. n. L148 of 6/6/2008		art. 73-84
IRRADIATED FOOD				
Law by Decree 94/01	Enactment Directive 1999/2/EC and 1999/3/EC – food and ingredients treated with ionizing radiations	G.U. (S.O.) n. 79 of 4/4/2001		art. 14
BIOLOGIC MATERIAL				
(EC) Reg. 1774/2002	Sanitary rules for by-products of animal origin not intended for human consumption	G.U.C.E. n. L273 of 10/10/2002		
Dir. 2004/68/EC (rectification)	Sanitary police rules for import of live ungulates – amendment to Directive 92/65/EEC (import of sperm, ova, embryos)	G.U.C.E. n. L226 of 25/6/2004		art. 3-16
Dir. 2005/24/EC	Amendment Dir. 87/328/EEC – sperm storing centres and use of breeding cattle ova and embryos	G.U.C.E. n. L78 of 24/3/2005		
Law by Decree 132/2005	Enactment Directive 2003/43/EC – exchanges and import of bovine sperm	G.U. n. 163 of 15/7/2005		art. 7
Law by Decree 175/2006	Amendments to Law by Decree 132/2005 - Enactment Directive 2003/43/EC – exchanges and import of bovine sperm	G.U. n. 111 of 15/5/2006		art. 1
ADDITIVES AND PRESERVATIVES				
Law by Decree 24/11/2004	Enactment Directive 2003/95/EC – requirements of additives other than colourants and sweeteners	G.U. n. 23 of 29/1/2005		
Ministerial Decree 28/2/2006	Enactment Directive 2004/45/EC – amendment Directive 96/77/EEC – requirements of additives other than colourants and sweeteners	G.U. n. 101 of 3/5/2006		
Ministerial Decree 229/2006	Enactment Directive 2003/114/EC – amendment Directive 95/2/EC – additives other than colourants and sweeteners – update Ministerial Decree 209/96	G.U. n. 160 of 12/7/2006		
Dir. 2006/52/EC	Amendment Directive 95/2/EC – alimentary additives other than colourants and sweeteners and 94/35/EC – sweeteners	G.U.C.E. n. L204 of 26/7/2006		
PACKING				
(EC) Reg. 1935/2004	Material in contact with food – repeal of Directives 80/590/EEC and 89/109/EEC	G.U.C.E. n. L338 of 13/11/2004		
(EC) Reg. 1895/2005	Restriction in the use of epoxy derivatives in material and objects in contact with food	G.U.C.E. n. L302 of 19/11/2005		
Dir. 2005/79/EC	Amendment Directive 2002/72/EC – plastic material and objects in contact with food	G.U.C.E. n. L302 of 19/11/2005		

PACKING *(continues from the previous page)*	SUBJECT	REFERENCE	TRANSPORT	IMPORT FROM OUTSIDE EU
Ministerial Decree 227/2006	Update Ministerial Decree 21/3/73 – Enactment Directives 2004/1/EC, 2004/13/EC, 2004/19/EC	G.U. n. 159 of 11/7/2006		
Ministerial Decree 230/2006	Enactment Directive 2004/14/EC – regenerated cellulose film packing	G.U. n. 160 of 12/7/2006		
Dir. 2007/19/EC (rectification)	Amendment Directives 2002/72/EC and 85/572/EEC – Plastic material in contact with food	G.U.C.E. n. L97 of 12/4/2007		
Ministerial Decree 76/2007	Aluminium material and objects in contact with food	G.U. n. 141 of 20/6/2007		
Dir. 2007/42/EC	Regenerated cellulose film material in contact with food	G.U.C.E. n. L172 of 30/6/2007		

Enclosures

Law dated 30th April 1962, No. 283 *(in Italian)*

Legge 30 aprile 1962, n. 283 (in Gazz. Uff., 4 giugno, n. 139). - Modifica degli artt. 242, 243, 247, 250 e 262 del T.U. delle leggi sanitarie approvato con R.D. 27 luglio 1934, n. 1265. Disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande (1) (2) (3).

(1) Vedi il DPR 26 marzo 1980, n. 327 di attuazione. L'art. 9, terzo comma, L. 24 novembre 1981, n. 689, stabilisce che ai fatti puniti dagli articoli 5, 6, 9 e 13 della presente legge, si applicano in ogni caso le disposizioni penali in tali articoli previste, anche quando i fatti stessi sono puniti da disposizioni amministrative che hanno sostituito disposizioni penali speciali.
(2) In luogo di Ministro/Ministero per le politiche agricole leggasi Ministro/Ministero delle politiche agricole e forestali, ex DPR 13 settembre 1999.
(3) Le violazioni previste come reato dal presente provvedimento, ad eccezione degli articoli 5, 6 e 12, sono trasformate in illeciti amministrativi soggetti alle sanzioni di cui agli artt. 2 (Sanzioni amministrative pecuniarie) e 3 (Sanzioni amministrative accessorie) del DL.vo 30 dicembre 1999, n. 507.

Preambolo

(Omissis).

Articolo 1

Sono soggette a vigilanza per la tutela della pubblica salute la produzione e il commercio delle sostanze destinate alla alimentazione. A tal fine l'autorità sanitaria può procedere, in qualunque momento e a mezzo dei competenti organi e uffici, ad ispezione e prelievo di campioni negli stabilimenti ed esercizi pubblici, dove si producano, si conservino in deposito, si smercino o si consumino le predette sostanze, nonché sugli scali e sui mezzi di trasporto. Essa può, altresì, procedere al sequestro delle merci e, ove dagli accertamenti eseguiti risulti necessario per la tutela della pubblica salute, alla loro distribuzione.
Gli esami e le analisi dei campioni sono compiuti dai laboratori provinciali di igiene e profilassi o da altri laboratori, all'uopo autorizzati (1). Quando dall'analisi risulti che i prodotti non corrispondono ai requisiti fissati dalla legge, il capo del laboratorio trasmetterà denuncia al medico o al veterinario provinciale, unendovi il verbale di prelevamento e il certificato di analisi. Contemporaneamente a mezzo di lettera raccomandata con avviso di ricevimento, comunicherà all'esercente presso cui è stato fatto il prelievo e all'autorità che ha disposto il prelievo stesso il risultato dell'analisi. Analoga comunicazione sarà fatta al produttore, nel caso che il prelievo riguardi campioni in confezioni originali (2).
Entro 15 giorni dalla data del ricevimento della comunicazione, gli interessati potranno presentare al medico o al veterinario provinciale istanza di revisione, in bollo, unendo la ricevuta di versamento, effettuato presso la Tesoreria provinciale, della somma che sarà indicata nel regolamento per ogni singola voce. Le analisi di revisione saranno eseguite presso l'Istituto superiore di sanità, entro il termine massimo di mesi due. In caso di mancata presentazione nei termini della istanza di revisione, o nel caso che l'analisi di revisione confermi quella di prima istanza, il medico o il veterinario provinciale trasmetteranno, entro quindici giorni, le denuncie all'Autorità giudiziaria.
Il medico o veterinario provinciale, qualora si tratti di frode tossica o comunque dannosa alla salute, trasmetterà immediatamente le denunce all'Autorità giudiziaria (3) (4).

(9) La Corte costituzionale, con sentenza 10 ottobre 1990, n. 434, ha dichiarato l'illegittimità costituzionale del presente comma, nella parte in cui non prevede che, per i casi di analisi su campioni prelevati da sostanze alimentari deteriorabili, il laboratorio provinciale di igiene e profilassi, od altro laboratorio all'uopo autorizzato, dia avviso dell'inizio delle operazioni alle persone interessate, affinché queste possano presenziare, eventualmente con l'assistenza di un consulente tecnico, alla esecuzione delle operazioni stesse.
(10) La Corte costituzionale, con sentenza 17 novembre 1971, n. 179, ha dichiarato l'illegittimità costituzionale del presente comma, limitatamente alla parte in cui esclude l'obbligo della comunicazione dell'esito dell'analisi a quei soggetti che in base agli atti di polizia giudiziaria già compiuti risultino indiziati di reato.
(11) La Corte costituzionale, con sentenza 3 dicembre 1969, n. 149, ha dichiarato l'illegittimità costituzionale del presente articolo, nella parte in cui per la revisione delle analisi esclude l'applicazione degli artt. 390, 304-bis, ter e quater del codice di procedura penale.
(12) Comma così sostituito dall'art. 1, L. 26 febbraio 1963, n. 441.

Articolo 2

L'esercizio di stabilimenti, laboratori di produzione, preparazione e confezionamento, nonché di depositi all'ingrosso di sostanze alimentari, è subordinato ad autorizzazione sanitaria. Il rilascio di tale autorizzazione è

condizionato dall'accertamento dei requisiti igienico-sanitari, sia di impianto, che funzionali, previsti dalle leggi e dai regolamenti.
I titolari degli stabilimenti e laboratori, nonché dei depositi all'ingrosso, di cui al primo comma, già esistenti alla data di entrata in vigore della presente legge, debbono, nel termine di tre mesi dalla detta data, richiedere la prescritta autorizzazione sanitaria, anche nel caso che fossero in possesso di autorizzazioni rilasciate da altri dicasteri in base a leggi speciali. I contravventori sono puniti con l'ammenda da lire 300.000 a lire 1.500.000 (1)(2).

(1) Comma così sostituito dall'art. 2, L. 26 febbraio 1963, n. 441.
(2) L'ammenda è stata così elevata dall'art. 113, terzo comma, L. 24 novembre 1981, n. 689.

Articolo 3

Le ispezioni e i prelievi di campioni, di cui all'art. 1, sono effettuati da personale sanitario o tecnico appositamente incaricato, dipendente dall'autorità sanitaria provinciale o comunale.
Le persone indicate nel comma precedente, nei limiti del servizio a cui sono destinate e secondo le attribuzioni ad esse conferite, sono ufficiali o agenti di polizia giudiziaria e possono, in ogni caso, richiedere, ove occorra, l'assistenza della forza pubblica.

Articolo 4

Chiunque produce, prepara, detiene, vende o pone in vendita sostanze destinate all'alimentazione, materiali e oggetti destinati a venire a contatto con sostanze alimentari, è tenuto a fornire gratuitamente alle persone di cui all'art. 3, i campioni di tali sostanze, materiali e oggetti, da prelevarsi nei limiti e secondo le modalità stabilite nel regolamento (1).
I contravventori sono puniti con l'ammenda da lire 30.000 a 300.000 (2), salvo l'esecuzione coattiva del prelievo.

(1) Comma così modificato dall'art. 7, DL.vo26 maggio 1997, n. 155.
(2) L'ammenda è stata così elevata dall'art. 113, terzo comma, L. 24 novembre 1981, n. 689.

Articolo 5

È vietato impiegare nella preparazione di alimenti o bevande, vendere, detenere per vendere o somministrare come mercede ai propri dipendenti, o comunque distribuire per il consumo sostanze alimentari: a) private anche in parte dei propri elementi nutritivi o mescolate a sostanze di qualità inferiore o comunque trattate in modo da variarne la composizione naturale, salvo quanto disposto da leggi e regolamenti speciali; b) in cattivo stato di conservazione; c) con cariche microbiche superiori ai limiti che saranno stabiliti dal regolamento di esecuzione o da ordinanze ministeriali; d) insudiciate, invase da parassiti, in stato di alterazione o comunque nocive, ovvero sottoposte a lavorazioni o trattamenti diretti a mascherare un preesistente stato di alterazione; e) (Omissis) (1);
f) (Omissis) (2); g) con aggiunta di additivi chimici di qualsiasi natura non autorizzati con decreto del Ministro per la sanità o, nel caso che siano stati autorizzati, senza l'osservanza delle norme prescritte per il loro impiego. I decreti di autorizzazione sono soggetti a revisioni annuali; h) che contengano residui di prodotti, usati in agricoltura per la protezione delle piante e a difesa delle sostanze alimentari immagazzinate, tossici per l'uomo. Il Ministro per la sanità, con propria ordinanza, stabilisce per ciascun prodotto, autorizzato all'impiego per tali scopi, i limiti di tolleranza e l'intervallo per tali scopi, i limiti di tolleranza e l'intervallo minimo che deve intercorrere tra l'ultimo trattamento e la raccolta e, per le sostanze alimentari immagazzinate tra l'ultimo trattamento e l'immissione al consumo.

(1) Lettera abrogata dall'art. 3, L. 26 febbraio 1963, n. 441.
(2) Lettera abrogata dall'art. 57, L. 19 febbraio 1992, n. 142, a partire dalla data di entrata in vigore del decreto di attuazione della direttiva n. 89/107/CEE e, comunque, con effetto dal 1° luglio 1992.

Articolo 6

La produzione, il commercio, la vendita delle sostanze di cui alla lettera h) dell'articolo precedente - fitofarmaci e presìdi delle derrate alimentari immagazzinate - sono soggetti ad autorizzazione del Ministero della sanità, a controllo e a registrazione come presìdi sanitari.
(Omissis) (1). Salvo che il fatto costituisca più grave reato, i contravventori alle disposizioni del presente articolo e dell'articolo 5 sono puniti con l'arresto fino ad un anno o con l'ammenda da lire seicentomila a lire sessanta milioni. Per la violazione delle disposizioni di cui alle lettere d) e h) dell'articolo 5 si applica la pena dell'arresto da tre mesi ad un anno o dell'ammenda da lire cinque milioni a lire novanta milioni (2).
In caso di condanna per frode tossica o comunque dannosa alla salute non si applicano le disposizioni degli artt. 163 e 175, Codice penale. Nei casi previsti dal precedente comma, la condanna importa la pubblicazione

della sentenza in uno o più giornali, a diffusione nazionale, designati dal giudice, nei modi stabiliti nel terzo comma dell'art. 36, Codice penale (3).

(1) Comma abrogato dall'art. 6, DPR 19 novembre 1997, n. 514.
(2) Comma così sostituito dall'art. 6, DL.vo30 dicembre 1999, n. 507.
(3) Articolo così sostituito dall'art. 4, L. 26 febbraio 1963, n. 441.

Articolo 7

Il Ministro per la sanità con proprio decreto, sentito il Consiglio superiore di sanità, può consentire la produzione e il commercio di sostanze alimentari e bevande che abbiano subìto aggiunte o sottrazioni o speciali trattamenti ivi compreso l'impiego di raggi ultravioletti, radiazioni ionizzanti, antibiotici, ormoni, prescrivendo, del pari, anche le indicazioni che debbono essere riportate sul prodotto finito.

Articolo 8

I prodotti alimentari e le bevande confezionate debbono riportare sulla confezione o su etichette appostevi, l'indicazione a carattere leggibili e indelebili, della denominazione del prodotto, nonché la indicazione del nome o della ragione sociale o del marchio depositato, e la indicazione della sede dell'impresa produttrice e dello stabilimento di produzione, con la elencazione degli ingredienti in ordine decrescente di quantità presente, riferita a peso o volume, secondo le norme che saranno stabilite nel regolamento di cui all'articolo 23, e infine il quantitativo netto in peso o volume. Il regolamento determinerà altresì l'elenco dei prodotti alimentari o delle bevande confezionati per i quali, oltre alle indicazioni di cui al comma precedente, dovrà essere riportata anche la data di confezionamento secondo le modalità da stabilirsi nel regolamento stesso. I prodotti alimentari o le bevande venduti sfusi debbono essere posti in vendita con l'indicazione degli ingredienti, elencati in ordine decrescente di quantità presente riferita a peso o volume, secondo le norme che saranno stabilite nel regolamento di cui all'articolo 23. I contravventori sono puniti con la sanzione amministrativa da lire 100.000 a lire 1.000.000 (1).

(1) Articolo così sostituito dall'art. 5, L. 26 febbraio 1963, n. 441. Sanzione depenalizzata ai sensi del combinato disposto degli artt. 32 e 34, primo comma, lettera e), L. 24 novembre 1981, n. 689, e così elevata dall'art. 38, quinto comma, della stessa legge.

Articolo 9

Le sostanze, il cui impiego non è consentito nella lavorazione di alimenti e bevande, non possono essere detenute nei locali stessi di lavorazione o comunque in locali che siano in diretta comunicazione con questi. I contravventori sono puniti con l'ammenda da lire 300.000 a lire 15.000.000 (1) (2).

(1) L'ammenda è stata così elevata dall'art. 113, terzo comma, L. 24 novembre 1981, n. 689.
(2) Comma così sostituito dall'art. 6, L. 26 febbraio 1963, n. 141.

Articolo 10

Il Ministro per la sanità, entro sei mesi dalla pubblicazione della presente legge, sentito il Consiglio superiore di sanità, approva con proprio decreto l'elenco delle materie coloranti che possono essere impiegate nella colorazione della carta o degli imballaggi destinati ad involgere le sostanze alimentari, nonché degli oggetti d'uso personale e domestico, i requisiti di purezza, i metodi di dosaggio negli alimenti, i casi di impiego e le modalità d'uso (1). Il Ministro per la sanità provvederà nello stesso modo ai successivi periodici necessari aggiornamenti.
Chiunque produce, vende o comunque mette in commercio sostanze alimentari o carta od imballaggi destinati specificatamente ad involgere le sostanze stesse, nonché oggetti d'uso personale e domestico, colorati con colori non autorizzati è punito con l'ammenda da lire 600.000 a lire 15.000.000 (2) (3).

(1) Comma così modificato dall'art. 57, L. 19 febbraio 1992, n. 142.
(2) L'ammenda è stata così elevata dall'art. 113, terzo comma, L. 24 novembre 1981, n. 689.
(3) Articolo così modificato dall'art. 7, L. 20 febbraio 1963, n. 441.

Articolo 11

È vietato produrre, detenere per il commercio, porre in commercio od usare utensili da cucina o da tavola, recipienti o scatole per conservare sostanze alimentari, nonché qualsiasi altro oggetto destinato a venire a contatto diretto con sostanze alimentari, che siano:

a) di piombo, zinco o di leghe contenenti più del 10 per cento di piombo ad eccezione dei tubi per l'acqua potabile;
b) stagnati internamente con stagno contenente piombo al di sopra dell'1 per cento;

c) rivestiti internamente con strati vetrificati, verniciati o smaltati, che, messi a contatto per 24 ore con una soluzione all'1 per cento di acido acetico, cedano piombo alla temperatura ordinaria;
d) saldati con lega di stagno-piombo, con contenuto di piombo superiore al 10 per cento; sono, tuttavia, tollerate, per la saldatura esterna dei recipienti, leghe contenenti piombo in misura superiore al 10 per cento, purché le aggraffature da saldare siano realizzate in modo da garantire la impenetrabilità da parte della lega saldante;
e) costituiti da materiale nella cui composizione si trovi più di tre centigrammi di arsenico per 100 grammi di materiale;
f) di materie plastiche o di qualsiasi altro prodotto che possano cedere sapori od odori che modifichino sfavorevolmente le proprietà organolettiche e rendano nocive le sostanze alimentari.

Per le sostanze che possono essere cedute dall'imballaggio al prodotto alimentare, il Ministro per la sanità, sentito il Consiglio superiore di sanità, stabilisce con proprio decreto entro sei mesi dalla pubblicazione della presente legge le eventuali condizioni, limitazioni o tolleranze di impiego ai fini indicati.
Le predette disposizioni si applicano altresì ai recipienti, utensili e apparecchi che possano venire a contatto diretto con le sostanze alimentari durante la loro lavorazione o preparazione, nonché ai recipienti destinati a contenere qualsiasi sostanza d'uso personale, domestico o igienico, che possa essere assorbita dalla cute o dalle mucose.
I contravventori sono puniti con l'ammenda da lire 300.000 a lire 9.000.000 (1) (2).

(1) L'ammenda è stata così elevata dall'art. 113, terzo comma, L. 24 novembre 1981, n. 689.
(2) Comma così sostituito dall'art. 8, L. 26 febbraio 1963, n. 441.

Articolo 12

È vietata l'introduzione nel territorio della Repubblica di qualsiasi sostanza destinata all'alimentazione non rispondente ai requisiti prescritti dalla presente legge.
I contravventori sono puniti con le pene previste dall'articolo 6 se le sostanze sono destinate al commercio. Negli altri casi si applica la sanzione amministrativa pecuniaria da lire un milione a lire sei milioni (1).

(1) Comma, da ultimo, così sostituito dall'art. 6, DL.vo 30 dicembre 1999, n. 507.

Articolo 12 Bis

Nel pronunciare condanna per taluno dei reati previsti dagli articoli 5, 6 e 12, il giudice, se il fatto è di particolare gravità e da esso è derivato pericolo per la salute, può disporre la chiusura definitiva dello stabilimento o dell'esercizio e la revoca della licenza, dell'autorizzazione o dell'analogo provvedimento amministrativo che consente l'esercizio dell'attività.
Le medesime pene accessorie possono essere applicate se il fatto è commesso da persona già condannata, con sentenza irrevocabile, per reato commesso con violazione delle norme in materia di produzione, commercio e igiene degli alimenti e delle bevande.
Le pene accessorie previste dal presente articolo si applicano anche quando i fatti previsti dagli articoli 5, 6 e 12 costituiscono un più grave reato ai sensi di altre disposizioni di legge (1).

(1) Articolo aggiunto dall'art. 6, DL.vo 30 dicembre 1999, n. 507.

Articolo 13

È vietato offrire in vendita o propagandare a mezzo della stampa od in qualsiasi altro modo, sostanze alimentari, adottando denominazioni o nomi impropri, frasi pubblicitarie, marchi o attestati di qualità o genuinità da chiunque rilasciati, nonché disegni illustrativi tali da sorprendere la buona fede o da indurre in errore gli acquirenti circa la natura, sostanza, qualità o le proprietà nutritive delle sostanze alimentari stesse o vantando particolari azioni medicamentose.
I contravventori sono puniti con l'ammenda da lire 600.000 a lire 15.000.000 (1) (2).
Alla stessa pena sono soggetti coloro che verbalmente, per iscritto, a mezzo della stampa e in qualsiasi modo, offrono in vendita sostanze di qualsiasi natura atte ad adulterare e contraffare alimenti e bevande.

(1) L'ammenda è stata così elevata dall'art. 113, terzo comma, L. 24 novembre 1981, n. 689.
(2) Comma così sostituito dall'art. 10, L. 26 febbraio 1963, n. 441.

Articolo 14

Il personale addetto alla presentazione, produzione, manipolazione e vendite di sostanze alimentari deve essere munito di apposito libretto di idoneità sanitaria rilasciato dall'ufficiale sanitario. Esso è tenuto a sottoporsi a periodiche visite mediche di controllo e ad eventuali speciali misure profilattiche nei modi e termini stabiliti ad esclusione della vaccinazione antitifico-paratifica. (1) È vietato assumere o mantenere in servizio per la produzione, preparazione, manipolazione e vendita di sostanze alimentari personale non munito del

libretto di idoneità sanitaria. I contravventori alla disposizione di cui al primo comma del presente articolo sono puniti con la sanzione amministrativa fino a lire 60.000 (2), e i contravventori alle disposizioni di cui al secondo comma con la sanzione amministrativa fino a lire 150.000 (3). Quest'ultima sanzione amministrativa si applica altresì a carico di chi, pur a conoscenza di essere affetto da manifestazioni di malattia infettiva diffusiva, continui ad attendere alla preparazione, produzione, manipolazione o vendita di sostanze alimentari.(4)

(1) Comma dapprima modificato dall'art. 32, L. 27 dicembre 1997, n. 449 e, da ultimo, dall'art. 10, L. 14 ottobre 1999, n. 362.
(2) Sanzione depenalizzata ai sensi del combinato disposto degli artt. 32 e 34, primo comma, lettera e), L. 24 novembre 1981, n. 689, e così elevata dall'art. 113 della stessa legge.
(3) Sanzione depenalizzata ai sensi del combinato disposto degli artt. 32 e 34, primo comma, lettera e), L. 24 novembre 1981, n. 689, e così elevata dall'art. 113 della stessa legge.
(4) Per la violazione prevista dal presente comma, l'art 38, comma 5, L. 24 novembre 1981 n. 689, ha disposto che si applichi la sanzione da lire 50.000 a lire 200.000.

Articolo 15

Il medico e il veterinario provinciale, secondo la competenza dei rispettivi uffici, indipendentemente dal procedimento penale, possono ordinare la chiusura temporanea fino a sei mesi e nei casi di recidiva o di maggiore gravità anche la chiusura definitiva dello stabilimento o dell'esercizio. Del provvedimento devono dare pubblicità a mezzo di avviso da apporre all'esterno dello stabilimento o dell'esercizio stesso per l'intero periodo di chiusura, con l'indicazione del motivo del provvedimento (1).
Contro il provvedimento del medico o del veterinario provinciale è ammesso il ricorso al Ministro per la sanità nel termine di quindici giorni.

(1) Comma così sostituito dall'art. 11, L. 26 febbraio 1963, n. 441.

Articolo 16

L'autorità sanitaria, quando accerti la nocività di sostanze di qualsiasi natura destinate all'alimentazione, ne ordina il sequestro e la distruzione, a meno che non ritenga di consentirne l'utilizzazione per scopi diversi dall'alimentazione umana.

Articolo 17

I contravventori alle disposizioni contenute nel regolamento generale di esecuzione della presente legge e ai vari regolamenti speciali sono puniti con l'ammenda fino a lire 1.500.000 (1).

(1) L'ammenda è stata così elevata dall'art. 113, terzo comma, L. 24 novembre 1981, n. 689.

Articolo 18

Le disposizioni di cui agli articoli 5, 9, 10, 11, 12 e 17 si applicano quando i fatti ivi contemplati non costituiscono reato più grave ai sensi di altre disposizioni.

Articolo 19

Le sanzioni previste dalla presente legge non si applicano al commerciante che vende, pone in vendita o comunque distribuisce per il consumo prodotti in confezioni originali, qualora la non corrispondenza alle prescrizioni della legge stessa riguardi i requisiti intrinseci o la composizione dei prodotti o le condizioni interne dei recipienti e sempre che il commerciante non sia a conoscenza della violazione o la confezione originale non presenti segni di alterazione.

Articolo 20

Sono abrogati gli articoli 242, 243, 247, 250 e 262 del testo unico delle leggi sanitarie approvato con regio decreto 27 luglio 1934, n. 1265, nonché qualsiasi altra disposizione incompatibile con la presente legge.

Articolo 21

La determinazione dei metodi ufficiali di analisi delle sostanze alimentari spetta al Ministero della sanità: a tale scopo è costituita, presso il Ministero della sanità una Commissione permanente, di cui fanno parte:

a) un rappresentante del Ministero della sanità che la presiede;
b) un rappresentante del Ministero delle politiche agricole e forestali;
c) un rappresentante del Ministero dell'industria e del commercio;
d) un rappresentante del Ministero delle finanze;
e) tre rappresentanti dell'Istituto superiore di sanità;

f) un direttore di sezione chimica di laboratorio provinciale d'igiene e profilassi;
g) un direttore di sezione medico-micrografica di laboratorio provinciale d'igiene e profilassi;
h) un rappresentante del laboratorio chimico centrale delle dogane;
i) un direttore di istituto di chimica agraria.

Gli elenchi dei metodi ufficiali di analisi dovranno essere revisionati almeno ogni due anni.

La Commissione ha la facoltà di avvalersi dell'opera di esperti particolarmente competenti nelle singole materie in esame.

Articolo 22

Il Ministro per la sanità, entro sei mesi dalla pubblicazione della presente legge, sentito il Consiglio superiore di sanità, pubblicherà, con suo decreto, l'elenco degli additivi chimici consentiti nella preparazione e per la conservazione delle sostanze alimentari, nel quale dovranno essere specificate, oltre le loro caratteristiche chimico-fisiche, i requisiti di purezza, i metodi di dosaggio negli alimenti, i casi di impiego e le dosi massime d'uso degli stessi (1). Entro un anno il Ministro per la sanità pubblicherà l'elenco dei metodi ufficiali d'analisi delle sostanze alimentari. Il Ministro per la sanità è autorizzato a provvedere con successivi decreti ai periodici necessari aggiornamenti.

(1) Comma così modificato dall'art. 12, L. 26 febbraio 1963, n. 441.

Articolo 23

La presente legge entra in vigore il giorno successivo alla sua pubblicazione nella Gazzetta Ufficiale.(Omissis) (1). È concesso il termine massimo di diciotto mesi dalla data della predetta pubblicazione per lo smaltimento dei prodotti alimentari disciplinati dall'art. 8 della legge non confezionati con le norme prescritte.

Entro un anno dall'entrata in vigore della presente legge il Governo emanerà il regolamento per la sua esecuzione (2).

(1) Comma abrogato dall'art. 28, L. 26 febbraio 1963, n. 441.
(2) Vedi DPR 3 agosto 1968, n. 1255 e DPR 26 marzo 1980, n. 327.

Presidentail ruling by decree dated 26th March 1980, No. 327
(in Italian)

Decreto del Presidente della Repubblica 26 marzo 1980, n. 327 (in *Gazzetta Ufficiale*, 16 luglio, n. 193). - Regolamento di esecuzione della L. 30 aprile 1962, n. 283, e successive modificazioni, in materia di disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande (1).

(1) Il DL.vo 19 febbraio 1998, n. 51, ha soppresso l'ufficio del pretore e, fuori dai casi espressamente previsti dal citato decreto, le relative competenze sono da intendersi trasferite al tribunale ordinario. Lo stesso decreto ha soppresso l'ufficio del pubblico ministero presso la pretura circondariale e ha provveduto a trasferirne le relative funzioni all'ufficio del pubblico ministero presso il tribunale ordinario. Inoltre, qualora il presente provvedimento attribuisca funzioni amministrative alternativamente al pretore e ad organi della P.A., le attribuzioni pretorili si intendono soppresse; sono altresì soppresse le funzioni amministrative di altre autorità giurisdizionali, eccezion fatta per il giudice di pace, se attribuite in via alternativa tanto al pretore che ad organi della P.A. Inoltre il potere del pretore di rendere esecutivi atti emanati da autorità amministrative è soppresso e gli atti sono esecutivi di diritto. Infine, qualora il presente provvedimento preveda l'obbligo di determinati soggetti di rendere giuramento innanzi al pretore per l'esercizio di attività, questo si intende reso innanzi al sindaco o ad un suo delegato.

Preambolo

(Omissis)

Articolo 1
Norma generale

Agli effetti del presente regolamento, il termine "legge" senza ulteriori precisazioni, si intende riferito alla legge 30 aprile 1962, n. 283, modificata dalla legge 26 febbraio 1963, n. 441 e dalla legge 6 dicembre 1965, n. 1367.

Articolo 2
Oggetto della vigilanza.

Ai fini della tutela della pubblica salute sono soggetti a vigilanza da parte dell'autorità sanitaria la produzione, il commercio e l'impiego:

1) delle sostanze destinate all'alimentazione;
2) degli utensili da cucina e da tavola;
3) dei recipienti per conservare le sostanze alimentari, nonché degli imballaggi e contenitori esterni che, pur non venendo a contatto diretto con le sostanze alimentari, per la natura di queste e per le condizioni di impiego, possono cedere i loro componenti alle sostanze stesse;
4) dei recipienti, utensili e apparecchi, che possono venire a contatto diretto con le sostanze alimentari nelle normali fasi della produzione e del commercio;
5) dei prodotti usati in agricoltura per la protezione delle piante e a difesa delle sostanze alimentari immagazzinate di cui al decreto del Presidente della Repubblica 3 agosto 1968, n. 1255.

Sono altresì soggetti a vigilanza da parte dell'autorità sanitaria:

a) i locali, gli impianti, gli apparecchi e le attrezzature usati nelle varie fasi della produzione e del commercio delle sostanze alimentari;
b) il personale addetto alla produzione, al confezionamento e al commercio delle sostanze alimentari;
c) i mezzi adibiti al trasporto delle sostanze alimentari.

Articolo 3
Individuazione delle autorità sanitarie competenti.

La vigilanza di cui all'art. 2 del presente regolamento è esercitata:

1) dal Ministero della sanità, attraverso i propri organi centrali, ovvero attraverso gli uffici di sanità marittima e aerea e gli uffici veterinari di confine, porto, aeroporto e dogana interna;
2) dall'organo delle regioni, o delle province autonome di Trento e di Bolzano, competente secondo il rispettivo ordinamento;
3) dai comuni, o loro consorzi, attraverso le unità sanitarie locali.

L'autorità sanitaria, per l'espletamento dei servizi di vigilanza sull'igiene degli alimenti, si avvale dell'opera, del personale all'uopo posto alle proprie dipendenze, nonché in particolari circostanze, e con l'osservanza delle norme vigenti, di personale di altre amministrazioni, previa intesa con le stesse amministrazioni.

Articolo 4

Attività informativa e di coordinamento operativo delle autorità sanitarie periferiche.

Spetta all'organo regionale o provinciale di cui al n. 2) del precedente art. 3, nell'ambito delle proprie attribuzioni, sentito il direttore del competente istituto incaricato della vigilanza per la repressione delle frodi nella produzione e nel commercio dei prodotti agrari:

1) coordinare la vigilanza di cui all'art. 2 del presente regolamento, attuando unità di interventi e di criteri nelle ispezioni, nel prelievo dei campioni e nelle denunce:
2) formulare proposte o suggerimenti di ordine tecnico al Ministero della sanità sulla base dei prelievi effettuati in occasione di interventi di competenza;
3) segnalare al Ministero della sanità nuove forme di infrazioni riscontrate nell'ambito della vigilanza.

Articolo 5

Ambito della vigilanza operativa.

Gli organi di vigilanza di cui all'art. 3 del presente regolamento, salvo quanto previsto al successivo art. 12, possono procedere in qualsiasi momento ad ispezioni o prelievi di campioni negli stabilimenti, nei laboratori di produzione e confezionamento, nei magazzini, nei depositi, nei mercati, negli spacci di vendita, negli alberghi, ristoranti, trattorie e altri pubblici esercizi, nonché nelle mense soggette ad autorizzazione sanitaria e amministrativa, e in genere ovunque si distribuiscono a qualsiasi titolo per il consumo e si smerciano sostanze alimentari.

La vigilanza si esercita altresì sulle merci, sia all'atto della spedizione che durante il trasporto, nonché al loro arrivo a destinazione. Nel caso di trasporti aerei, ferroviari e navali, le operazioni di ispezione o prelevamento si effettuano con l'assistenza del vettore negli impianti di partenza e di arrivo.

A tale scopo il personale delle amministrazioni ferroviarie nonché quello delle imprese di navigazione marittima, aerea, lacunale e fluviale e di trasporto stradale non può impedire le ispezioni e i prelievi di campioni ritenuti necessari dagli organi di vigilanza né può condizionarne l'esecuzione ad una preventiva autorizzazione amministrativa.

Articolo 6

Modalità e norme di prelevamento dei campioni da sottoporre ad analisi chimica.

Per il prelievo dei campioni destinati all'analisi chimica, salvo quanto previsto da norme speciali, nonché dal successivo art. 9, o quando ricorrano particolari esigenze di controllo, si applicano le modalità stabilite dall'allegato A del presente regolamento. Qualora non sia possibile applicare esattamente le modalità di cui al comma precedente deve essere fatta espressa menzione, nel verbale di prelevamento, dei motivi che vi hanno ostato.

Articolo 7

Contrassegni di identificazione dei singoli campioni.

Ciascuno dei campioni di cui al precedente art. 6 deve essere costituito di cinque parti equivalenti, ciascuna delle quali deve essere chiusa e sigillata, preferibilmente con piombini e con suggello recante impressa la dicitura dell'ufficio che ha disposto il prelievo. Il responsabile dell'esercizio od un suo rappresentante, o il detentore della merce, ha facoltà di apporvi un proprio timbro o sigillo e di ciò si deve far menzione nel verbale di prelevamento di cui al successivo art. 15.

Su ognuna delle parti costituenti il campione deve figurare, oltre all'intestazione dell'ufficio che ha disposto il prelievo, la data del prelievo, la natura della merce prelevata, il numero del verbale di prelevamento, nonché la firma di chi esegue il prelievo e del responsabile dell'esercizio o di un suo rappresentante o del detentore della merce. Ove questi ultimi dovessero rifiutarsi di firmare, del fatto deve farsi menzione nel verbale di prelevamento. Le indicazioni previste dal terzo comma del presente articolo possono essere riportate anche su di un cartellino assicurato al campione, o alle parti equivalenti che lo compongono in modo da impedirne il distacco.

Articolo 8

Prelevamenti di campioni dalle grandi partite.

Per eseguire il controllo di grandi partite di prodotti giacenti presso stabilimenti di produzione o depositi, si debbono prelevare campioni sufficientemente rappresentativi, idonei ad accettare i requisiti dell'intera partita. Con le procedure dell'art. 21 della legge, possono essere stabiliti i piani di prelevamento dei campioni.

Articolo 9

Adeguamento alle direttive della Comunità economica europea.

Fatte salve le competenze stabilite da leggi e regolamenti speciali, il Ministro della sanità in applicazione di direttive comunitarie, può, con proprio decreto, apportare modifiche agli allegati al presente regolamento

per quanto attiene al prelievo dei campioni (1). (1) Vedi anche i DM 20 dicembre 1980, 24 febbraio 1988, n. 149 e 8 novembre 1989, n. 435.

Articolo 10

Prelevamento e conservazione di campioni di sostanze di particolare natura.

Nel caso di sostanze alimentari, delle quali si debba controllare il contenuto di umidità, e di prodotti che per la loro natura, se posti in recipienti a chiusura ermetica siano soggetti ad alterazione, si applicano le speciali norme di prelevamento di cui all'allegato A, paragrafo 4, del presente regolamento. Il Ministro della sanità, su proposta della commissione di cui all'art. 21 detta legge, determina, con proprio decreto, le modalità di trasporto e conservazione dei campioni di sostanze alimentari da sottoporre a controlli chimici che, per la loro natura, sono soggette a subire alterazioni o variazioni dello stato in cui si trovano all'atto del prelievo.

Articolo 11

Operazioni di vigilanza, con prelievo di campioni durante il trasporto delle sostanze alimentari.

Nel caso di sostanze alimentari nazionali o nazionalizzate contenute in carri e altri mezzi di trasporto, gli incaricati della vigilanza chiedono l'intervento del vettore, nella persona del rappresentante in loco, e alla sua presenza provvedono a rimuovere gli eventuali sigilli, ad effettuare le operazioni di prelievo con relativo verbale, nonché ad apporre nuovi sigilli al carro e ad altro mezzo di trasporto.

Articolo 12

Operazioni di vigilanza, con prelievo di campioni durante il trasporto delle sostanze alimentari sotto vincolo doganale o "allo Stato estero".

Nel caso di trasporto sotto vincolo doganale, le operazioni di ispezione e prelevamento di campioni, salvo quanto previsto dalle vigenti disposizioni per gli alimenti di origine animale e per le sostanze soggette a controlli fitopatologici, si effettuano d'intesa con la dogana, che procede ai prescritti controlli sulle merci oggetto del trasporto. Il vettore od il suo rappresentante in loco assiste alle operazioni e controfirma il verbale di prelevamento, trattenendone una copia. Altra copia viene trasmessa al mittente e una al destinatario a cura degli incaricati della vigilanza.

Nel caso di sostanze alimentari "allo stato estero" il competente organo della vigilanza sanitaria - previo accertamento di tale condizione da parte delle competenti autorità doganali - può accedere agli spazi doganali, effettuando le operazioni di ispezione e campionamento in collaborazione con il personale del Ministero delle finanze e con l'assistenza del vettore o del suo rappresentante in loco.

Nei due casi suddetti lo operazioni di ispezione e di campionamento possono essere effettuate, con le medesime garanzie, presso le imprese destinatarie, se le merci sono importate con la procedura semplificata, a termini degli articoli 232 e seguenti del testo unico delle disposizioni legislative in materia doganale approvato con decreto del Presidente della Repubblica 23 gennaio 1973, n. 43.

Articolo 13

Prelevamento di campioni destinati ad analisi e controlli speciali.

I campioni da sottoporre ad analisi microbiologiche, parassitologiche e ad altri particolari controlli e accertamenti, che per la loro natura e il loro scopo esigano speciali modalità di prelevamento, debbono essere prelevati dal personale tecnico appositamente incaricato dall'autorità sanitaria di cui all'articolo 3 del presente regolamento.

Articolo 14

Prelevamento dei campioni destinati alla determinazione delle cariche microbiche.

Con le ordinanze previste dall'art. 5, lettera c), della legge e dall'art. 69 del presente regolamento, il Ministro della sanità, sentito il Consiglio superiore di sanità, nel determinare i limiti delle cariche microbiche, stabilisce altresì i criteri di campionamento delle varie sostanze alimentari e le modalità di prelievo, conservazione e trasporto dei campioni, nonché i relativi metodi di analisi.

Articolo 15

Verbale di prelevamento.

Il verbale di prelevamento da compilarsi in esecuzione dei precedenti articoli deve contenere:

a) il numero d'ordine per ciascun prelievo;
b) la data, l'ora e il luogo del prelievo;
c) le generalità e la qualifica della o delle persone che eseguono il prelievo;
d) il nome o la ragione sociale e l'ubicazione dello stabilimento, deposito od esercizio in cui è stato eseguito il prelievo, nonché le generalità della persona che ha assistito al prelievo della merce in qualità di titolare dell'impresa, di rappresentante o di detentore della merce;

e) l’indicazione della natura della merce, la descrizione delle condizioni ambientali di conservazione e le indicazioni con cui è posta in vendita, o le diciture apposte sulle etichette e la dichiarazione se la merce è posta in vendita sfusa o in contenitori originali, con particolare cenno all’eventuale originalità e integrità delle confezioni;
f) le modalità seguite nel prelievo;
g) la dichiarazione del prelevatore o dei prelevatori dalla quale risulti se si è proceduto o meno all’eventuale sequestro della merce da cui è prelevato il campione;
h) la dichiarazione che il titolare dell’impresa o un suo rappresentante o il detentore ha trattenuto una copia del verbale e un campione;
i) la dichiarazione che il verbale è stato letto alla presenza dell’interessato - titolare dell’impresa, rappresentante o detentore - e che è stato sottoscritto anche dal medesimo, o che lo stesso si è rifiutato di sottoscriverlo;
l) la firma del o dei verbalizzanti e quella del titolare dell’impresa o di un suo rappresentante, o del detentore della merce;
m) le eventuali dichiarazioni del titolare dell’impresa o del rappresentante o del detentore sul nome e residenza del fornitore della merce e sulla data della consegna della merce medesima;
n) le eventuali dichiarazioni del titolare dell’impresa, del rappresentante o del detentore sulle aggiunte o manipolazioni subite dalla merce dopo il ricevimento della stessa;
o) la specifica indicazione della merce eventualmente sequestrata, oggetto del prelievo;
p) le eventuali altre osservazioni o dichiarazioni, anche se fatte dal titolare dell’impresa, dal rappresentante o dal detentore;
q) l’eventuale peso lordo riportato sul campione;
r) l’indicazione di eventuali aggiunte o trattamenti subiti dalla merce all’atto del prelievo.

Il verbale viene redatto in quattro esemplari, tre dei quali vengono inviati al laboratorio che eseguirà gli accertamenti, mentre un quarto esemplare viene rilasciato all’interessato o a chi lo rappresenta.
In caso di prelievo di campioni di prodotti confezionati, dovrà essere redatto un quinto esemplare del verbale di prelievo che verrà spedito senza ritardo all’impresa produttrice, con lettera raccomandata a carico di quest’ultima.
Il laboratorio di analisi trattiene un esemplare del verbale e rimette gli altri all’autorità sanitaria che ha disposto il prelievo.

Articolo 16
Destinazione del campione.

Una delle parti del campione prelevato a norma dei precedenti articoli viene consegnata, al momento del prelievo, al responsabile dell’esercizio o ad un suo rappresentante o al detentore della merce, escluso l’eventuale vettore, sempre che non trattasi di spedizioniere doganale rappresentante del proprietario della merce ai sensi del testo unico delle disposizioni legislative in materia doganale approvato con Decreto del Presidente della Repubblica 23 gennaio 1973, n. 43. Le altre, insieme al verbale di prelevamento, vengono inviate per le analisi nel più breve tempo possibile al laboratorio pubblico competente per territorio o ad altro laboratorio autorizzato allo scopo ai sensi dell’art. 1 della legge. Una di tali parti è utilizzata per l’analisi di prima istanza, un’altra è destinata all’eventuale analisi di revisione e deve essere conservata per la durata di sessanta giorni a decorrere dalla data di comunicazione dell’esito dell’analisi all’interessato; e un’altra parte infine rimane di riserva per eventuali perizie ordinate dall’autorità giudiziaria. In caso di prodotti confezionati, una parte del campione sarà messo a disposizione dell’impresa produttrice, per la durata di sessanta giorni, presso il laboratorio di cui al precedente comma. Nel caso previsto dal precedente art. 11, una parte del campione viene tenuta presso il laboratorio di analisi competente, a disposizione del mittente per la durata di sessanta giorni.

Articolo 17
Autorizzazione di analisi presso laboratori diversi.

Con riguardo alle attività di controllo e di vigilanza di rispettiva pertinenza, il Ministro della sanità e le autorità di cui all’art. 3, comma primo, n. 2), del presente regolamento, possono affidare a tempo determinato, ai sensi dell’art. 1 della legge, gli accertamenti anche ad istituti e laboratori pubblici diversi da quelli pubblici ordinariamente competenti, previa valutazione della idoneità tecnica degli stessi a svolgere tale funzione.

Articolo 18
Comunicazione dei reperti analitici.

Non appena accertata, con l’esito delle analisi, la non conformità delle sostanze alle disposizioni di legge, il capo del laboratorio trasmette il certificato all’autorità sanitaria competente, unendovi il verbale di prelevamento. Contemporaneamente, a mezzo di lettera raccomandata con avviso di ricevimento, trasmette all’esercente e ad altri eventuali interessati e, ove l’analisi si riferisca a prodotti confezionati, al produttore, copia del certificato di analisi comunicando anche la metodica seguita, ai fini delle garanzie di

difesa di cui agli articoli 304, 304- bis, ter, quater e 390 del codice di procedura penale (1). Nell'ipotesi prevista dall'ultimo comma dell'art. 1 della legge, l'autorità sanitaria di cui all'art. 3 del presente regolamento procede alla denuncia all'autorità giudiziaria, senza attendere il termine previsto per la presentazione della istanza di revisione di analisi dandone contestuale comunicazione al Ministero della sanità. Nel caso in cui il risultato delle analisi non abbia messo in evidenza irregolarità, ciò deve essere comunicato all'autorità sanitaria che ha disposto il prelievo, affinché faccia le conseguenti comunicazioni all'esercente e, ove l'analisi si riferisca a prodotti confezionati, al produttore. In caso di mera irregolarità formale rilevabile dall'esame dell'etichetta o della confezione dei prodotti prelevati, l'autorità sanitaria ha facoltà di non richiedere l'analisi dei campioni.

(1) Vedi, anche, art. 223, DL.vo 28 luglio 1989, n. 271.

Articolo 19
Istanza di revisione di analisi.

L'istanza di revisione di analisi di cui al quarto comma dell'art. 1 della legge, è diretta all'autorità competente ai sensi dell'art. 3, comma primo, n. 2), del presente regolamento.
Qualora l'istanza di revisione riguardi analisi disposte dai medici o veterinari preposti rispettivamente agli uffici di sanità marittima e aerea e agli uffici veterinari di confine, porto, aeroporto e dogana interna, la stessa deve essere rivolta al titolare del servizio.
Le istanze di cui ai precedenti commi debbono indicare il numero e la data del verbale di prelevamento e contenere l'eventuale nomina di un difensore di fiducia.
All'istanza deve essere allegata la quietanza del deposito provvisorio effettuato presso la tesoreria provinciale per spese di analisi, nella misura di lire cinquantamila per ogni voce elencata nell'allegato A, paragrafo 1, del presente regolamento e a disposizione dell'Istituto superiore di sanità. L'esito della revisione sarà comunicato agli interessati, senza ritardo, a cura dell'autorità sanitaria competente ai sensi dell'art. 3 del presente regolamento.
Nel caso in cui la revisione non confermi le conclusioni dell'analisi di prima istanza, la quietanza della somma versata deve essere restituita ai fini del rimborso del deposito provvisorio; nel caso di conferma, la somma viene versata sull'apposito capitolo di bilancio dell'Istituto superiore di sanità, dopo la condanna definitiva o la oblazione. Nella procedura di revisione di analisi si applicano, in quanto compatibili, le garanzie stabilite per gli atti peritali dagli articoli 304, 304- bis, ter, quater e 390 del codice di procedura penale.

Articolo 20
Sequestro ed eventuale distruzione di sostanze destinate all'alimentazione.

Salvo quanto previsto da leggi o regolamenti speciali, il sequestro previsto dall'art. 1, primo comma, della legge, viene disposto, ove risulti necessario per la tutela della salute pubblica, dall'autorità sanitaria competente ai sensi dell'art. 3 del presente regolamento. In caso di necessità e urgenza può procedere al sequestro anche il personale di cui all'ultimo comma del predetto art. 3, salvo conferma, nel termine di 48 ore, da parte della autorità sanitaria. Quando sussista grave e imminente pericolo di danno alla salute pubblica, la merce sequestrata deve essere immediatamente distrutta, dopo che dalla stessa merce sia stato effettuato il prelevamento dei campioni. La distruzione, salvo quanto stabilito da norme particolari, viene disposta dall'autorità sanitaria di cui al n. 2) del precedente art. 3. Salvo che l'autorità sanitaria non disponga diversamente, la merce sequestrata è affidata in custodia, in quanto possibile, al proprietario o detentore, che è anche responsabile della sua corretta conservazione. Dell'operazione di sequestro deve essere compilato motivato e circostanziato verbale, da redigersi in più copie, delle quali una viene trattenuta dall'autorità sanitaria, una viene rilasciata al detentore, le altre vengono trasmesse, con raccomandata a carico al produttore della merce e ad altri eventuali corresponsabili.
I soggetti di cui al comma precedente, entro dieci giorni dalla data di ricezione del verbale di sequestro, possono far pervenire le proprie deduzioni scritte, ed eventuali istanze di dissequestro, all'autorità sanitaria competente. Trascorso il termine di cui al precedente comma, e acquisito il referto d'analisi sui campioni prelevati, l'autorità sanitaria competente ordina il dissequestro della merce che sia risultata conforme alle norme vigenti. In caso contrario, l'autorità sanitaria ne accerta la commestibilità, facendo ricorso, ove occorra, ad ulteriori specifiche indagini di laboratorio. Dall'esito dell'indagine è immediatamente informato il procuratore della Repubblica o il pretore competente, per i successivi provvedimenti.

Articolo 21
Destinazione ad impieghi non alimentari delle sostanze alimentari non commestibili.

Nell'ipotesi prevista dall'ultimo comma dell'articolo precedente, qualora la merce risulti non commestibile ma idonea ad altra destinazione od a trasformazione industriale per scopi diversi da quelli dell'alimentazione umana, l'autorità sanitaria competente di cui all'art. 3 del presente regolamento, può dichiarare consentita tale destinazione o trasformazione, che dovrà avvenire sotto il controllo degli organi di vigilanza e con l'osservanza delle prescrizioni impartite.

Prima che si proceda alla destinazione o trasformazione prevista nel precedente comma, la predetta autorità sanitaria informa il procuratore della Repubblica o il pretore competente, per gli eventuali provvedimenti necessari per il processo penale.

Articolo 22
Provvedimenti di chiusura temporanea o definitiva di stabilimenti ed esercizi.

I provvedimenti di chiusura temporanea o definitiva degli stabilimenti ed esercizi, previsti dall'art. 15 della legge, sono adottati con particolare riguardo allo stato di pericolo per la salute pubblica derivante dalla non igienicità delle operazioni di lavorazione o deposito, ovvero dalla natura o condizione delle sostanze prodotte o poste in vendita. Qualora ricorrano gli estremi per l'adozione di uno dei provvedimenti di cui al precedente comma, e non sussista grave e imminente pericolo per la salute pubblica, l'autorità sanitaria di cui al n. 2) dell'art. 3 del presente regolamento comunica all'interessato i fatti accertati, assegnandogli un termine, non superiore a dieci giorni, per fornire eventuali chiarimenti. Il provvedimento di chiusura definitiva non preclude la possibilità di autorizzazione di un nuovo esercizio.

Articolo 23
Sospensione dei provvedimenti di chiusura e nomina di un commissario.

Quando nel ruolo generale della pretura o, a seconda della competenza, della procura della Repubblica presso il tribunale, viene iscritto il carico pendente nei confronti del denunciato, l'autorità sanitaria competente di cui al n. 2) dell'art. 3 del presente regolamento, può sospendere - ai sensi dell'art. 14 della Legge 26 febbraio 1963, n. 441 - il provvedimento di chiusura temporanea di uno stabilimento o laboratorio di produzione o di un esercizio di vendita di sostanze alimentari, adottato ai sensi dell'art. 15 della legge, nominando un commissario per la vigilanza permanente sull'osservanza della disciplina igienico-sanitaria nell'ambito dell'attività svolta dal laboratorio o stabilimento o esercizio. Le mansioni di commissario non possono essere affidate al personale che svolge l'attività di vigilanza di cui all'art. 3 del presente regolamento.

Articolo 24
Compiti del commissario per la vigilanza.

Il commissario di cui all'articolo precedente:

1) deve risiedere nell'ambito della provincia nella quale ha sede lo stabilimento, deposito o esercizio e deve possedere le capacità tecnico-scientifiche richieste dal tipo di attività dello stabilimento o dell'esercizio;
2) assume la responsabilità dell'igiene delle lavorazioni effettuate anche per quanto riguarda i procedimenti tecnologici;
3) ha diritto ad un compenso forfetario a carico del titolare dello stabilimento o esercizio, da stabilirsi di volta in volta con decreto del Ministro della sanità, d'intesa con il Ministro dell'industria, del commercio e dell'artigianato, in relazione alla potenzialità dello stabilimento o esercizio, alla sua produzione durante il periodo di gestione commissariale e all'impiego richiesto dalla vigilanza. Tale compenso, comprensivo di qualsiasi indennità o rimborso, non può in alcun caso superare la somma di lire trentamila giornaliere; è, tuttavia dovuta una indennità di missione per gli spostamenti fuori comune, corrispondente a quella degli impiegati dello Stato di qualifica pari al parametro 387. Il predetto compenso viene liquidato e pagato alla scadenza dell'incarico, od anche in corso di gestione quando questa si protragga per oltre un mese. La nomina del commissario può essere revocata in ogni momento con provvedimento motivato. Il commissario cessa comunque dall'incarico allo scadere del periodo di chiusura dello stabilimento, od esercizio, che era stato fissato dall'autorità sanitaria competente nel provvedimento adottato ai sensi dell'articolo 15 della legge, ovvero quando sia intervenuta sentenza di proscioglimento.

In caso di necessità, di cui peraltro deve essere fatta menzione nelle premesse del decreto di nomina del commissario, si può prescindere dal requisito della residenza previsto al n. 1) del presente articolo.

Articolo 25
Autorizzazioni sanitarie per stabilimenti e laboratori di produzione e depositi all'ingrosso di sostanze alimentari.

È soggetto ad autorizzazione sanitaria l'esercizio di stabilimenti di produzione, preparazione e confezionamento, nonché di depositi all'ingrosso di sostanze alimentari. Salvi i casi in cui la legge, nonché leggi e regolamenti speciali, ne prevedano il rilascio da parte del Ministro della sanità, l'autorizzazione di cui al comma precedente è rilasciata: a) dall'organo delle regioni, o delle province autonome di Trento e di Bolzano, competente secondo il rispettivo ordinamento in materia medica, nel caso di laboratori e stabilimenti per la produzione, preparazione e confezionamento delle sostanze alimentari di origine vegetale e nei casi previsti in deroga alla successiva lettera b);

b) dall'organo delle regioni, o delle province autonome di Trento e di Bolzano, competente secondo il rispettivo ordinamento in materia veterinaria, nel caso di impianti di macellazione e di laboratori e stabilimenti per la produzione, la preparazione e il confezionamento delle sostanze alimentari di origine animale, o miste di origine prevalentemente animale, ad eccezione degli stabilimenti che trattano latte e prodotti derivati, sostanze alimentari miste di origine prevalentemente vegetale, e di carattere dolciario; c) dal comune, o consorzio di comuni, attraverso le unità sanitarie locali, nel caso di depositi all'ingrosso di alimenti di origine vegetale e animale e nel caso di piccoli laboratori artigianali annessi ad esercizi di somministrazione di sostanze alimentari e bevande.

Articolo 26
Modalità di inoltro delle richieste di autorizzazione.

Le domande per il rilascio delle autorizzazioni di cui all'articolo precedente debbono contenere
a) il nome e la ragione sociale e la sede dell'impresa;
b) l'indicazione dell'ubicazione dello stabilimento o del laboratorio di produzione, preparazione e confezionamento o del deposito all'ingrosso;
c) l'indicazione per generi merceologici delle sostanze alimentari che si intendono produrre, preparare, confezionare o tenere in deposito;
d) la descrizione e gli estremi di deposito degli eventuali marchi depositati che valgano ad identificare l'impresa;
e) l'eventuale carattere stagionale delle lavorazioni;
f) l'indicazione del presumibile termine di approntamento dello stabilimento o del laboratorio di produzione, preparazione e confezionamento o del deposito all'ingrosso.

Le domande debbono, inoltre, essere corredate:
1) dalla pianta planimetrica dei locali, in scala non superiore a 1:500. In casi particolari potranno essere richieste piante più dettagliate;
2) dalla descrizione sommaria dei locali, degli impianti e delle attrezzature;
3) dall'indicazione relativa all'impianto di approvvigionamento idrico, alla idoneità della rete di distribuzione, nonché dalla documentazione sulla potabilità dell'acqua, qualora non si tratti di acquedotti pubblici;
4) dall'indicazione relativa all'impianto di smaltimento dei rifiuti solidi e liquidi, e, ove necessario, ai mezzi impiegati per la depurazione delle acque;
5) dall'indicazione dei sistemi scelti per assicurare la salubrità e la conservazione delle sostanze alimentari, nonché dalla documentazione di tali sistemi, ove richiesta;
6) da un esemplare degli eventuali marchi depositati.

I titolari di depositi all'ingrosso sono esonerati dall'obbligo di produrre le dichiarazioni previste dalle lettere d) ed e) del primo comma e dai punti 3) e 6) del secondo comma del presente articolo.
I titolari degli stabilimenti o laboratori di produzione che si trovano nelle condizioni previste dall'art. 48 del decreto del Presidente della Repubblica 19 marzo 1956, n. 303, concernente norme sull'igiene del lavoro, sono tenuti ad effettuare le notifiche prescritte dalla suddetta norma.

Articolo 27
Rilascio delle autorizzazioni.

L'autorità sanitaria competente, entro trenta giorni dal ricevimento della comunicazione dell'interessato di avvenuto approntamento dei locali e degli impianti destinati alla produzione, preparazione, confezionamento e deposito di sostanze alimentari, rilascia l'autorizzazione di cui all'art. 2 della legge, previo accertamento dell'osservanza delle disposizioni del presente regolamento e leggi e regolamenti speciali. L'autorizzazione di cui al comma precedente deve contenere:
a) il nome o la ragione sociale e la sede dell'impresa;
b) l'indicazione dell'ubicazione dello stabilimento o laboratorio di produzione, preparazione, confezionamento, o del deposito all'ingrosso delle sostanze alimentari;
c) l'indicazione delle sostanze alimentari di cui è autorizzata la produzione, preparazione, confezionamento e detenzione;
d) la dichiarazione di rispondenza dei locali e degli impianti ai requisiti igienico-sanitari prescritti;
e) l'indicazione degli eventuali marchi depositati e degli estremi relativi al deposito degli stessi;
f) le altre indicazioni e condizioni ritenute necessarie al fine di assicurare che le sostanze prodotte siano idonee, sotto il profilo igienico-sanitario.

L'impresa titolare dell'autorizzazione deve dare comunicazione all'autorità sanitaria competente di eventuali variazioni degli elementi di cui alle lettere a) ed e) del precedente comma. Nel caso di variazione degli elementi di cui alla lettera e) l'impresa interessata dovrà darne comunicazione all'autorità sanitaria competente dopo l'avvenuta registrazione e prima del loro impiego. La variazione degli elementi di cui alle lettere a) ed e) comporta l'aggiornamento da parte dell'autorità sanitaria competente, dell'autorizzazione precedentemente rilasciata.

Qualora l'impresa titolare dell'autorizzazione intenda variare taluno degli elementi di cui alle lettere b) e c), o apportare modifiche ai locali e impianti di cui alla lettera d), deve darne preventiva comunicazione all'autorità sanitaria competente.
La variazione degli elementi di cui alle lettere b) e c) comporta il rilascio di una nuova autorizzazione.
Le modifiche ai locali e impianti di cui alla lettera d) possono essere effettuate previo nulla osta dell'autorità sanitaria competente, da rilasciarsi entro sessanta giorni dal ricevimento della comunicazione da parte dell'impresa interessata. Qualora, trascorso il predetto termine, l'autorità sanitaria non si sia pronunciata, almeno in via interlocutoria il nulla osta si intende concesso.
L'autorità sanitaria competente annota su apposito registro gli estremi delle autorizzazioni rilasciate, le variazioni intervenute e gli eventuali provvedimenti adottati in conseguenza di trasgressioni.

Articolo 28

Requisiti minimi obbligatori per gli stabilimenti e laboratori di produzione e confezionamento.

L'autorità sanitaria competente deve accertare che gli stabilimenti e i laboratori di produzione, reparazione e confezionamento di cui all'art. 25, fatti salvi i requisiti stabiliti da leggi o regolamenti speciali, siano provvisti di locali distinti e separati:
a) per il deposito delle materie prime;
b) per la produzione, preparazione e confezionamento delle sostanze destinate all'alimentazione;
c) per il deposito dei prodotti finiti;
d) per la detenzione di sostanze non destinate all'alimentazione.

I locali debbono essere in numero adeguato al potenziale produttivo e alle caratteristiche dello stabilimento e del prodotto o dei prodotti finiti, con separazioni e attrezzature idonee a garantire l'igienicità di prodotti in lavorazione.
Tutti i locali ai quali si può accedere dall'interno dello stabilimento o del laboratorio, ivi compresi i locali adibiti ad abitazione od uffici, sono soggetti ad accertamento dei requisiti igienico-sanitari.
Nel caso di imprese che effettuano anche la vendita al dettaglio per il consumo è obbligatorio che le lavorazioni avvengano in banchi diversi da quelli di vendita, con separazioni e attrezzature idonee a garantire l'igienicità dei prodotti.
L'autorità sanitaria può consentire in particolari casi, anche in relazione alle esigenze tecnologiche del processo produttivo, che i locali di cui alle lettere a), b), c) e d) siano riuniti in un unico locale di adeguata ampiezza.
L'autorità sanitaria deve inoltre accertare che i predetti locali siano:
1) costruiti in modo tale da garantire una facile e adeguata pulizia;
2) sufficientemente ampi, cioé tali da evitare l'ingombro delle attrezzature e l'affollamento del personale;
3) rispondenti ai requisiti razionali sotto il profilo igienico-sanitario, con valori microclimatici atti ad assicurare condizioni di benessere ambientale anche in relazione alle peculiari esigenze di lavorazione; aerabili - naturalmente o artificialmente - sia per prevenire eventuali condensazioni di vapore, sia per evitare lo sviluppo di muffe; con sistema di illuminazione - naturale o artificiale - tale da prevenire, in ogni caso, la contaminazione delle sostanze alimentari;
4) con pareti e pavimenti le cui superfici siano in rapporto al tipo della lavorazione che viene effettuata, facilmente lavabili e disinfettabili;
5) muniti di dispositivi idonei ad evitare la presenza di roditori, e altri animali od insetti;
6) adibiti esclusivamente agli usi cui sono destinati, secondo quanto indicato nella pianta planimetrica allegata alla domanda di autorizzazione.

Per particolari esigenze di taluni prodotti, quali i formaggi e i salumi, nonché i vini, gli aceti, i liquori e le acquaviti, l'autorità sanitaria competente potrà prescrivere requisiti diversi da quelli di cui ai precedenti punti 3) e 4) limitatamente ai locali di conservazione, di stagionatura e di invecchiamento.
Per i depositi di cereali e di prodotti ortofrutticoli non trasformati potrà derogarsi a quanto previsto dal precedente n. 4).
Gli stabilimenti elaboratori di produzione devono essere inoltre provvisti:
a) di impianti, attrezzature e utensili riconosciuti idonei sotto profilo igienico-sanitario e costruiti in modo da consentire la facile, rapida e completa pulizia. Le superfici destinate a venire a contatto con le sostanze alimentari nelle varie fasi della produzione, preparazione e confezionamento, debbono essere in materiale idoneo ai sensi dell'art. 11 della legge e relativi decreti di attuazione;
b) di depositi o magazzini dotati di attrezzature di refrigerazione idonee alla sosta delle materie prime o dei prodotti finiti, qualora la natura e il tipo di lavorazione degli stessi lo renda necessario;
c) di acqua potabile in quantità sufficiente allo scopo.
Ove non sia disponibile una quantità sufficiente di acqua potabile si può ricorrere ad acqua con caratteristiche chimico-fisiche diverse, ma in ogni caso corrispondenti ai requisiti microbiologici e, relativamente alle tolleranze ammesse per le sostanze nocive, a quelli chimici prescritti per le acque potabili. È vietata l'utilizzazione di tali acque non potabili nel ciclo di lavorazione delle sostanze alimentari e nella pulizia degli impianti, delle attrezzature e degli utensili destinati a venire a contatto con tali sostanze, salvo quanto previsto al successivo art. 29.

L'autorità sanitaria accerterà che le reti di distribuzione interna delle acque potabili e non potabili siano nettamente separate, indipendenti e riconoscibili, in modo da evitare possibilità di miscelazione;

d) di servizi igienici rispondenti alle normali esigenze igienico-sanitarie non comunicanti direttamente con i locali adibiti a lavorazione, deposito e vendita delle sostanze alimentari.
I locali adibiti a servizi igienici e il locale antistante dotato di porta a chiusura automatica, debbono avere pareti e pavimenti costruiti in materiale impermeabile e facilmente lavabile e disinfettabile.
Ove i procedimenti di lavorazione lo richiedano, deve essere previsto un numero di lavabi, con comando non manuale dell'erogazione dell'acqua, facilmente raggiungibili dal luogo di lavorazione.
I gabinetti debbono essere in numero adeguato al personale addetto alla lavorazione: dotati di acqua corrente in quantità sufficiente e forniti di vaso a caduta di acqua, di lavabo con erogazione a comando non manuale (a pedale o con altri accorgimenti tecnici), con distributori di sapone liquido od in polvere e con asciugamani elettrici o con asciugamani non riutilizzabili da cestinare dopo l'uso.
Gli spogliatoi devono essere forniti di armadietti individuali lavabili, disinfettabili e disinfestabili, a doppio scomparto per il deposito, rispettivamente, degli indumenti personali e di quelli usati per il lavoro.
Le docce debbono essere di numero adeguato a seconda del tipo di lavorazione e al numero di persone addette alla lavorazione;

e) di dispositivi per lo smaltimento dei rifiuti, rispondenti alle esigenze dell'igiene sia per lo smaltimento delle acque di rifiuto industriale e delle acque luride, sia dei rifiuti solidi che debbono essere rimossi al più presto dalle aree e dai locali di lavorazione e confezionamento;

f) di contenitori di rifiuti e immondizie, e ove necessario, di inceneritori od altri mezzi atti ad assicurare lo smaltimento dei rifiuti stessi, posti a congrua distanza dai locali di lavorazione in aree opportunamente protette. I laboratori di produzione, preparazione e confezionamento annessi agli esercizi di vendita al dettaglio di sostanze alimentari destinate prevalentemente ad essere vendute nei predetti esercizi, ancorché muniti di attrezzature, impianti e utensili in conformità alle prescrizioni contenute nei regolamenti locali d'igiene, devono adeguarsi alle disposizioni del presente articolo, in relazione alle effettive esigenze igieniche dell'attività svolta accertate di volta in volta dall'autorità sanitaria competente ai sensi dell'art. 25.

Articolo 29
Norme igieniche per i locali e gli impianti.

I locali, gli impianti, le attrezzature e gli utensili di cui agli articoli precedenti, debbono essere mantenuti nelle condizioni richieste dall'igiene mediante operazioni di ordinaria e straordinaria pulizia. Essi, dopo l'impiego di soluzioni detergenti e disinfettanti, e prima della utilizzazione, debbono essere lavati abbondantemente con acqua potabile per assicurare l'eliminazione di ogni residuo.
La corrispondenza delle acque impiegate negli stabilimenti e laboratori, non provenienti dai pubblici acquedotti, ai requisiti previsti dall'art. 28 del presente regolamento deve essere accertata dall'autorità sanitaria competente mediante periodici controlli, eseguiti dai laboratori provinciali di igiene e profilassi.
Per le particolari esigenze e le caratteristiche di taluni settori della produzione, in caso di insufficiente disponibilità di acqua potabile, può essere ammesso l'uso di altra acqua, ma comunque rispondente ai requisiti microbiologici e, relativamente alle tolleranze ammesse per le sostanze nocive, a quelli chimici prescritti per le acque potabili. Tale acqua potrà essere utilizzata anche oltre i limiti di impiego di cui al precedente art. 28 previa autorizzazione della competente autorità sanitaria.
La stessa autorità sanitaria potrà esonerare da tali obblighi per le lavorazioni in cui, a causa di particolari necessità tecnologiche, possa essere giustificato l'impiego di acque non rispondenti ai requisiti di cui sopra, purché il procedimento tecnologico assicuri in ogni caso l'assoluta salubrità del prodotto finito.Nei locali di cui alla lettera d) del primo comma dell'articolo precedente è consentita la detenzione di sostanze il cui impiego è determinato da esigenze di manutenzione, disinfezione e disinfestazione degli impianti e dei locali, nei quantitativi ragionevolmente necessari per tali usi e sempreché disposizioni speciali non ne vietino l'uso e la detenzione. Le materie coloranti, gli additivi e i coadiuvanti tecnologici debbono essere custoditi in depositi separati da quelli destinati alla custodia delle sostanze chimiche e degli utensili usati per la pulizia e disinfezione.

Articolo 30
Requisiti dei depositi all'ingrosso.

I depositi all'ingrosso debbono possedere caratteristiche di costruzione nonché impianti e attrezzature tali da soddisfare le esigenze di una buona conservazione delle sostanze alimentari, in rapporto alla natura e alle caratteristiche dei prodotti in deposito.Ai depositi suddetti si estendono, in quanto ricorrano le condizioni per la loro applicabilità le disposizioni di cui al precedente art. 28.

Articolo 31
Requisiti degli esercizi di vendita e di somministrazione di sostanze alimentari e bevande.

Gli spacci di vendita e i banchi di generi alimentari debbono essere forniti, sia nelle mostre che negli eventuali depositi, di mezzi idonei ad una adeguata conservazione delle sostanze alimentari, in rapporto

alla loro natura e alle loro caratteristiche. Nei pubblici esercizi e nelle mense soggette ad autorizzazione sanitaria e amministrativa, i locali destinati a cucina e magazzini, nonché gli impianti e i servizi, debbono essere riconosciuti idonei a norma dell'art. 231 del regio decreto 27 luglio 1934, n. 1265, modificato dalla legge 16 giugno 1939, n. 1112. Le apparecchiature, gli utensili, le attrezzature e i materiali che comunque sono destinati a venire a contatto con gli alimenti debbono essere conformi alle norme vigenti.Le norme particolari concernenti l'igiene degli spacci, delle mescite, delle trattorie e degli altri esercizi pubblici nei quali vengono manipolate e somministrate sostanze alimentari, sono stabilite dai regolamenti comunali d'igiene.

I regolamenti medesimi fissano altresì i requisiti igienici necessari per la vendita promiscua di alimenti.

La vendita ambulante di sostanze alimentari, ove non espressamente vietata dalle norme vigenti, deve essere effettuata con mezzi idonei ad assicurare la conservazione igienica delle sostanze alimentari, in rapporto alla loro natura od alle loro caratteristiche.

Gli alimenti deperibili con copertura, o farciti con panna e crema a base di uova e latte (crema pasticciera), yogurt nei vari tipi, bibite a base di latte non sterilizzato, prodotti di gastronomia con copertura di gelatina alimentare, debbono essere conservati a temperatura non superiore a +4 °C.

Gli alimenti deperibili cotti da consumarsi caldi (quali: piatti pronti, snacks, polli, ecc.) debbono essere conservati da +60 °C a +65 °C. Gli alimenti deperibili cotti da consumarsi freddi (quali: arrosti, roast-beef, ecc.), e le paste alimentari fresche con ripieno debbono essere conservati a temperatura non superiore a +10 °C.

Articolo 32

Distributori automatici o semiautomatici di sostanze alimentari e bevande.

I distributori automatici o semiautomatici di sostanze alimentari e bevande debbono corrispondere ai seguenti requisiti:

1) essere di facile pulizia e disinfettabili, sia all'interno che all'esterno, o tali da garantire l'igienicità dei prodotti distribuiti;
2) avere le superfici destinate a venire a contatto con le sostanze alimentari, di materiale idoneo ai sensi dell'art. 11 della legge e resistente alle ripetute operazioni di pulizia e disinfezione;
3) avere le sorgenti interne di calore collocate in modo tale da non influire negativamente sulla conservazione delle sostanze alimentari e bevande;
4) avere, salvo quanto previsto da norme speciali, una adeguata attrezzatura che garantisca la buona conservazione:
   delle sostanze alimentari di facile deperibilità ad una temperatura non superiore a +4 °C;
   delle sostanze alimentari surgelate ad una temperatura non superiore a -18 °C;
   delle bevande e piatti caldi ad una temperatura di +65 °C, o comunque non inferiore a + 60 °C, e avere inoltre un congegno automatico che blocchi la distribuzione delle sostanze alimentari quando la temperatura di conservazione si allontani dai limiti stabiliti;
5) essere collocati in maniera tale da non essere situati in vicinanza di sorgenti di calore;
6) avere la bocca esterna di erogazione non esposta ad insudiciamenti od altre contaminazioni.

Ove la natura dell'alimento o della bevanda lo richieda, si deve provvedere alla sistemazione di recipienti o di portarifiuti che debbono essere tenuti in buone condizioni igieniche e svuotati o sostituiti con la necessaria frequenza.

Della installazione dei suddetti distributori deve essere data comunicazione scritta all'autorità cui spetta l'esercizio della vigilanza igienico-sanitaria, ai sensi dell'art. 3, comma primo, n. 3), del presente regolamento.

Articolo 33

Requisiti delle sostanze alimentari e delle bevande poste in vendita a mezzo di distributori automatici o semiautomatici.

Le sostanze alimentari e le bevande poste in vendita a mezzo di distributori automatici o semiautomatici debbono:

1) essere prodotte in stabilimenti o laboratori provvisti dell'autorizzazione sanitaria di cui all'art. 25 del presente regolamento;
2) corrispondere per caratteristiche e requisiti alle rispettive denominazioni legali, ove previste, o merceologiche che le caratterizzano e con le quali vengono poste in vendita.

Le imprese responsabili della vendita di sostanze alimentari a mezzo di distributori automatici e semiautomatici sono tenute ad accertarsi che le stesse corrispondano ai requisiti igienico-sanitari previsti dalla legge e abbiano le caratteristiche merceologiche proprie del prodotto.

Sui distributori automatici o semiautomatici debbono essere riportate in lingua italiana, in modo ben leggibile e ben visibile all'acquirente, per ciascuna delle sostanze alimentari poste in distribuzione, le indicazioni di cui ai numeri da 1) a 4) dell'art. 64 del presente regolamento, nonché l'indicazione dell'eventuale presenza di additivi e coloranti, secondo le vigenti disposizioni.

Articolo 34

Idoneità sanitaria del personale addetto al rifornimento dei distributori.

Il personale che effettua il rifornimento dei distributori o che venga a contatto con le sostanze alimentari poste in distribuzione, anche se in confezioni chiuse, deve essere in possesso del libretto di idoneità sanitaria di cui all'art. 37 del presente regolamento.

Articolo 35

Mezzi di lotta contro gli insetti e gli animali nocivi.

Nei locali di cui all'art. 2, lettera a), del presente regolamento debbono essere attuati efficaci mezzi di lotta e di precauzione contro gli insetti, i roditori e altri animali nocivi.Tali mezzi non debbono costituire pericolo di danno anche indiretto per l'uomo, a causa di contaminazione delle sostanze alimentari.

Articolo 36

Sostanze alimentari deperibili in deposito in stato di alterazione.

Le sostanze alimentari deperibili che si trovino in stato di alterazione non possono essere tenute in deposito. Tuttavia, qualora sia dimostrabile l'impegno del fornitore al loro ritiro, ovvero l'assolvimento degli obblighi previsti da disposizioni speciali in materia, tali sostanze debbono essere tenute in locali, o parti di locali, separati da quelli di conservazione delle sostanze alimentari, destinate alla vendita o somministrazione. Le suddette sostanze debbono essere contraddistinte da cartelli indicanti la destinazione al ritiro da parte del fornitore.

Articolo 37

Libretto di idoneità sanitaria.

Il personale addetto alla produzione, preparazione, manipolazione e vendita di sostanze alimentari - ivi compresi il conduttore dell'esercizio e i suoi familiari che prestino attività, anche a titolo gratuito, nell'esercizio stesso - destinato anche temporaneamente od occasionalmente a venire in contatto diretto o indiretto con le sostanze alimentari, deve essere munito del libretto di idoneità sanitaria previsto dall'art. 14 della legge, rilasciato dall'autorità sanitaria del comune di residenza, competente ai sensi dell'art. 3, comma primo, n. 3), del presente regolamento, previa visita medica e accertamenti idonei a stabilire che il richiedente non sia affetto da una malattia infettiva contagiosa o da malattia comunque trasmissibile ad altri, o sia portatore di agenti patogeni.

Il libretto di idoneità sanitaria distribuito al sensi del successivo art. 40 ha validità un anno che permane anche in caso di trasferimento del titolare da un comune all'altro.

Per il rilascio del libretto di idoneità sanitaria, nel caso che il lavoratore provenga da altro comune, deve essere prodotta una dichiarazione della competente autorità del comune di provenienza, attestante che all'interessato non era stato rilasciato in precedenza ovvero era stato negato, e per quali motivi, il libretto di idoneità sanitaria. Presso il comune che rilascia il libretto di idoneità sanitaria è istituito apposito schedario tenuto costantemente aggiornato. L'autorità sanitaria competente ai sensi dell'art. 3, comma primo, n. 3), del presente regolamento, può disporre in ogni momento accertamenti sullo stato sanitario del personale di cui al primo comma del presente articolo e adottare i provvedimenti che ritenga necessari ai fini della tutela della salute pubblica.

Articolo 38

Profilassi del personale.

1. Il personale di cui all'articolo 37 è sottoposto ai trattamenti di profilassi che siano ritenuti necessari dall'autorità sanitaria competente, a salvaguardia della salute pubblica, ad esclusione della vaccinazione antitifico-paratifica (1).

(1) Articolo così sostituito dall'art. 32, comma 10, L. 27 dicembre 1997, n. 449 e poi così modificato dall'art. 10, L. 14 ottobre 1999, n. 362.

Articolo 39

Accertamenti sanitari preventivi.

Le visite mediche per il rilascio del libretto di idoneità sanitaria, quello di rinnovo, come pure quelle eseguite nell'ambito dell'attività di controllo, sono effettuate dai medici in servizio presso le unità sanitarie locali. Per le indagini e gli accertamenti microbiologici, sierologici, radiologici e per ogni altro accertamento ritenuto necessario a completamento della visita per il rilascio del libretto e di quello successivo di rinnovo o controllo, l'autorità sanitaria competente si avvale dei servizi sanitari comunali o provinciali, che sono tenuti ad eseguire gli accertamenti e le indagini richieste o a verificarne i risultati.

Articolo 40

Caratteristiche del libretto di idoneità sanitaria.

Il libretto di idoneità sanitaria, redatto secondo il modello E allegato al presente regolamento, viene distribuito gratuitamente entro un anno dall'entrata in vigore del presente regolamento.

Nel libretto debbono essere annotati:

a) la data e i risultati della prima visita di accertamento e delle indagini complementari a tale scopo eseguite;
b) la data e i risultati delle visite mediche di controllo o per il rinnovo del libretto nonché delle relative indagini complementari;
c) la data delle vaccinazioni obbligatorie e facoltative praticate, il tipo di vaccino usato, la via di somministrazione e le eventuali reazioni.

Articolo 41

Prescrizioni supplementari e garanzie richieste in caso di malattia del personale.

I libretti di idoneità sanitaria del personale debbono essere conservati sul posto di lavoro a cura del titolare o conduttore dell'esercizio, il quale ha altresì l'obbligo di presentarli ad ogni i richiesta degli organi di vigilanza. I titolari o conduttori dell'esercizio hanno l'obbligo di segnalare immediatamente all'autorità sanitaria i casi sospetti di malattie infettive e contagiose del personale dipendente per l'adozione degli eventuali provvedimenti conseguenziali, ivi compresa l'eventuale sospensione dell'attività lavorativa. I titolari o conduttori dell'esercizio hanno altresì l'obbligo di richiedere al personale assentatosi per causa di malattia per oltre cinque giorni il certificato medico dal quale risulti che il lavoratore non presenta pericolo di contagio dipendente dalla malattia medesima. A tal fine, i medici curanti od i medici di cui all'art. 5, terzo comma, della legge 20 maggio 1970, n. 300, sono tenuti a rilasciare l'attestazione sopra richiesta.

Articolo 42

Igiene, abbigliamento e pulizia del personale.

Negli stabilimenti industriali e nei laboratori di produzione il personale di cui al primo comma dell'art. 37 deve indossare tute o sopravesti di colore chiaro, nonché idonei copricapo che contengano la capigliatura. Il personale addetto alla preparazione, manipolazione e confezionamento di sostanze alimentari negli esercizi di vendita deve indossare adeguata giacca o sopraveste di colore chiaro, nonché idoneo copricapo che contenga la capigliatura.

Le tute, le giacche, le sopravesti e i copricapo debbono essere tenuti puliti; inoltre, il personale deve curare la pulizia della propria persona e in particolare delle mani e deve eseguire il proprio lavoro in modo igienicamente corretto. L'autorità sanitaria può disporre particolari misure per determinate lavorazioni e in casi specifici.

Articolo 43

Idoneità igienico-sanitaria dei mezzi di trasporto di sostanze alimentari in generale.

Il trasporto delle sostanze alimentari deve avvenire con mezzo igienicamente idoneo e tale da assicurare alle medesime una adeguata protezione, in relazione al genere delle sostanze trasportate, evitando ogni causa di insudiciamento o altro danno che possa derivare alle sostanze alimentari trasportate dagli agenti atmosferici o da altri fattori ambientali. È fatto obbligo di provvedere alla pulizia del mezzo di trasporto adoperato, in materia tale che dal medesimo non derivi insudiciamento o contaminazione alle sostanze alimentari trasportate. È vietata la promiscuità di carico di sostanze alimentari con altre sostanze alimentari od anche non alimentari che possano modificare le caratteristiche dei prodotti o possano comunque inquinarli, salvo che si faccia uso di confezioni o imballaggi atti ad evitare qualsiasi contaminazione o insudiciamento.

Ai fini e secondo la procedura del presente regolamento, l'esercizio della vigilanza igienico-sanitaria sui mezzi di trasporto in circolazione sulla rete dell'Amministrazione delle ferrovie dello Stato è affidato al servizio sanitario dell'amministrazione medesima.

Articolo 44

Autorizzazione sanitaria preventiva dei mezzi adibiti al trasporto terrestre.

Sono soggetti ad autorizzazione sanitaria:

a) le cisterne e gli altri contenitori adibiti al trasporto delle sostanze alimentari sfuse a mezzo di veicoli;
b) i veicoli adibiti al trasporto degli alimenti surgelati per la distribuzione ai dettaglianti;
c) i veicoli adibiti al trasporto delle carni fresche e congelate e dei prodotti della pesca freschi e congelati.

L'autorizzazione viene rilasciata:

1) dall'organo della regione, o delle province autonome di Trento e di Bolzano, competente secondo il rispettivo ordinamento in materia medica, per le cisterne e gli altri contenitori di cui alla lettera a) e per i veicoli di cui alla lettera b);

2) dall'organo della regione, o delle province autonome di Trento e di Bolzano, competente secondo il rispettivo ordinamento in materia veterinaria, per i veicoli di cui alla lettera c).

Per i veicoli adibiti al trasporto nel solo ambito del territorio comunale l'autorizzazione viene rilasciata dall'autorità sanitaria competente ai sensi dell'art. 3, comma primo, n. 3), del presente regolamento. È fatto salvo quanto diversamente previsto, per i trasporti di carni nell'ambito del territorio comunale, dalle disposizioni speciali del regio decreto 20 dicembre 1928, n. 3298, e successive modificazioni.

La competenza territoriale al rilascio dell'autorizzazione di cui al presente articolo è determinata in relazione alla residenza del proprietario del veicolo risultante dall'iscrizione al pubblico registro automobilistico.

Le disposizioni del presente articolo non si applicano ai mezzi di trasporto in circolazione sulla rete dell'Amministrazione delle ferrovie dello Stato.

Articolo 45

Presentazione delle domande per il rilascio delle autorizzazioni preventive dei mezzi adibiti al trasporto.

Le domande per il rilascio dell'autorizzazione di cui al precedente articolo debbono contenere:

a) il nome o la ragione sociale e la sede dell'impresa;
b) gli estremi d'identificazione del veicolo;
c) l'indicazione delle sostanze alimentari al cui trasporto si intende destinare il veicolo;
d) l'indicazione dei luoghi ove di norma l'impresa ricovera il veicolo ai fini delle operazioni di lavaggio, disinfezione e disinfestazione.

Le domande debbono essere corredate da una dichiarazione della ditta costruttrice attestante che i materiali impiegati, se destinati a venire a contatto con le sostanze alimentari trasportate, sono conformi ai requisiti di legge.

Le domande relative ai veicoli già in esercizio per trasporto alimentare possono non essere corredate dalla dichiarazione di cui al comma precedente. La disposizione si estende anche ai mezzi di trasporto prodotti nei sei mesi successivi all'entrata in vigore del presente regolamento.

Articolo 46

Validità o registrazione delle autorizzazioni sanitarie.

L'autorizzazione, rilasciata ai sensi del precedente art. 44, è valida per due anni dalla data del rilascio.

Le autorità sanitarie annotano su apposito registro gli estremi delle autorizzazioni rilasciate, le variazioni concernenti l'idoneità sanitaria delle cisterne e dei contenitori e gli eventuali provvedimenti adottati in conseguenza di trasgressioni. Un elenco delle autorizzazioni revocate o non rinnovate, corredato di tutti gli elementi necessari all'identificazione del veicolo, delle cisterne o del contenitore e del luogo di abituale custodia, viene inviato semestralmente, in duplice copia, al Ministero della sanità.

Articolo 47

Mantenimento dell'idoneità igienico-sanitaria dei mezzi di trasporto.

Il trasportatore è tenuto a mantenere il veicolo nella condizione di idoneità di cui all'art. 43 e a sospenderne l'utilizzazione in caso di inidoneità. L'autorità sanitaria ove accerti direttamente e a mezzo degli organi di vigilanza che il veicolo non è più idoneo al trasporto delle sostanze alimentari specificate nell'autorizzazione sanitaria, provvede all'immediato ritiro dell'autorizzazione stessa, dandone notizia al comando di polizia stradale della provincia in cui è stata rilasciata.

Articolo 48

Requisiti delle cisterne e dei contenitori.

1) Le cisterne e i contenitori adibiti al trasporto di sostanze alimentari debbono avere:
2) rivestimento interno costruito con materiale che risponda ai requisiti specifici previsti dall'art. 11 della legge e dei relativi decreti di attuazione;
3) serbatoio ad unico o più scomparti, costruito con pareti interne ad angoli o spigoli smussati, o raccordati in modo che le operazioni di lavaggio e disinfezione si possano eseguire agevolmente e l'acqua di lavaggio possa fuoriuscire senza ristagni;
4) apertura che consenta un facile accesso all'interno;
5) portelli con idonee guarnizioni a tenuta;
6) quando necessario, protezione termica e se del caso verniciatura esterna metallizzata;
7) attacchi di carico e scarico e ogni altro accessorio utilizzato per dette operazioni facilmente smontabili, in modo da poter essere sottoposti senza difficoltà al lavaggio e alla disinfezione.

   Le cisterne e i contenitori asportabili e intercambiabili debbono essere punzonati o recare un contrassegno metallico inasportabile con gli estremi dell'attestazione di idoneità.

   Dopo ogni scarico e prima di ogni carico, le cisterne e i contenitori debbono essere sottoposti alle operazioni di pulizia e disinfezione con mezzi idonei, seguite da lavaggio con acqua potabile.

8) Le cisterne e i contenitori non possono essere impiegati per il trasporto di sostanze diverse da quelle indicate nell'autorizzazione rilasciata ai sensi dell'art. 44. Copia dei verbali compilati per le infrazioni alle norme di cui sopra deve essere trasmessa all'autorità che ha rilasciato l'autorizzazione. Qualora le norme tecniche internazionali concordate in sede interferroviaria prevedano idonei requisiti igienico-sanitari, ai trasporti ferroviari si applicano le norme medesime.

Articolo 49

Requisiti dei mezzi di trasporto delle carni dei prodotti ittici.

I veicoli destinati al trasporto delle carni debbono essere a chiusura ermetica e debbono:

a) avere le pareti interne e ogni parte che possa venire a contatto con le carni in materiali resistenti alla corrosione e rispondenti ai requisiti previsti dalle vigenti disposizioni. Inoltre le pareti debbono essere lisce e di facile pulizia e disinfezione con angoli e spigoli arrotondati;
b) essere muniti, per il trasporto delle carcasse, mezzene e quarti, di dispositivi di sospensione in materiali resistenti alla corrosione, fissati ad altezza tale che le carni non tocchino il pavimento; salvo che non si tratti di carni confezionate o provviste di imballaggio.

I veicoli o mezzi adibiti al trasporto dello carni non possono essere usati per il trasporto di animali vivi. Inoltre nessuna altra merce può essere trasportata contemporaneamente alle carni in uno stesso veicolo, tranne che si tratti di carni confezionate e poste in appositi contenitori.

Per il trasporto delle carni dei volatili, dei conigli allevati e della selvaggina si applicano le disposizioni di cui all'art. 11 del decreto del Presidente della Repubblica 10 agosto 1972, n. 967.

Le frattaglie e i visceri debbono essere trasportati in recipienti costruiti con materiali rispondenti ai requisiti stabiliti dall'art. 11 della legge e dai relativi decreti di attuazione. Le trippe, in caso di trasporto promiscuo, debbono essere altresì lavate e semicotte o cotte.

I veicoli destinati al trasporto dei prodotti della pesca debbono essere a chiusura ermetica e possedere oltre ai requisiti di cui al primo comma, lettera a), del presente articolo, dispositivi atti ad assicurare la raccolta dell'acqua di fusione del ghiaccio ed evitarne il ristagno sul pavimento.

Al trasporto dei prodotti della pesca si applicano le prescrizioni di cui al precedente quarto comma.

La pulizia e la disinfezione dei veicoli adibiti al trasporto delle carni e dei prodotti della pesca deve aver luogo al più presto dopo ultimato lo scarico. Qualora le norme tecniche internazionali concordate in sede interferroviaria prevedano idonei requisiti igienico-sanitari, ai trasporti ferroviari si applicano le norme medesime.

Articolo 50

Idoneità igienico-sanitaria dei veicoli e dei contenitori impiegati per i trasporti di sostanze alimentari, immatricolati all'estero.

Ferma restando l'applicazione delle norme tecniche concordate in sede internazionale, le disposizioni del presente regolamento si applicano anche ai veicoli e ai contenitori

provenienti dall'estero impiegati per il trasporto di sostanze alimentari. I mezzi di trasporto di cui al comma precedente possono transitare attraverso i posti di confine dietro esibizione di attestato rilasciato dall'autorità competente del Paese di origine, dal quale risulti l'idoneità igienico-sanitaria del veicolo o contenitore. Nel caso che la legislazione del Paese di provenienza del veicolo o contenitore, pur dettando prescrizioni specifiche analoghe a quelle previste nel presente regolamento, non preveda né consenta il rilascio dell'attestato di cui al precedente comma, l'impresa estera di trasporto può chiedere tale attestazione al Ministero della sanità che la rilascia direttamente o attraverso un organo da esso delegato previo esame comparato delle rispettive legislazioni.

Nel caso che la legislazione del Paese di provenienza del veicolo o contenitore non stabilisca requisiti specifici di carattere igienico-sanitario, l'attestazione può essere rilasciata dal Ministero della sanità direttamente o attraverso un organo da esso delegato previo esame di documentata domanda dell'impresa estera di trasporto.

Articolo 51

Temperatura delle sostanze alimentari durante il trasporto.

Il trasporto delle sostanze alimentari elencate nell'allegato C al presente regolamento deve essere effettuato con modalità atte a garantire il mantenimento delle condizioni di temperatura fissate nell'allegato stesso. Il Ministro della sanità, sentito il Consiglio superiore di sanità, può aggiornare con proprio decreto l'allegato di cui al precedente comma.

Articolo 52

Sostanze alimentari per cui sono prescritte, ai fini del trasporto, specifiche dichiarazioni di scorta.

Il Ministro della sanità, sentito il Consiglio superiore di sanità, stabilisce con proprio decreto l'elenco delle sostanze alimentari per il trasporto delle quali, in considerazione di particolari esigenze di natura igienico-sanitaria, è necessario adottare le misure che seguono. Le sostanze alimentari di cui al precedente

comma devono essere accompagnate da una dichiarazione o altro documento equipollente del venditore o dello spedizioniere nella quale sono indicati:

1) il nome o la ragione sociale e il domicilio o la sede del venditore o dello spedizioniere;
2) il nome o la ragione sociale e il domicilio o la sede del destinatario;
3) la località di destinazione;
4) l'indicazione precisa delle sostanze alimentari trasportate e il loro quantitativo;
5) la dichiarazione che le sostanze alimentari sono conformi alle norme vigenti.

La dichiarazione di cui al precedente comma deve essere esibita ad ogni richiesta degli organi di vigilanza e consegnata a fine viaggio al destinatario che è tenuto a conservarla per almeno trenta giorni a disposizioni dei predetti organi di vigilanza. Nel caso di tentata vendita all'ingrosso, nella dichiarazione di cui sopra sono omesse le indicazioni previste ai punti 2) e 3) e che sono sostituite dalla indicazione che la merce è destinata alla tentata vendita. L'incaricato della vendita è tenuto a comunicare entro dieci giorni al fornitore il nome o la ragione sociale, la sede, il domicilio dell'acquirente e la località di consegna o, nel caso in cui la tentata vendita non sia conclusa, delle persone alle quali è stata effettuata la consegna. Il fornitore è tenuto a conservare per almeno sessanta giorni tale comunicazione.

Articolo 53

Sequestro, durante il trasporto, di sostanze alimentari potenzialmente nocive.

Qualora gli organi di vigilanza, a seguito dei controlli effettuati sui trasporti delle sostanze alimentari, rilevino che le sostanze stesse non rispondano ai requisiti della legge o di norme e regolamenti speciali e vi siano ragionevoli sospetti di pericolo per la salute pubblica, l'autorità sanitaria può disporre il sequestro delle sostanze alimentari trasportate con l'osservanza delle disposizioni di cui al quarto comma dell'art. 20 del presente regolamento.

L'eventuale trasferimento delle sostanze poste sotto sequestro deve avvenire sotto scorta sanitaria. A tal fine, l'autorità sanitaria dispone che il mezzo venga accompagnato dal personale sanitario di cui all'ultimo comma dell'art. 3, all'uopo incaricato con l'ordine di servizio di cui nel successivo comma.

Detto personale è responsabile della regolarità del trasferimento delle sostanze alimentari poste sotto sequestro e dell'ottemperanza alle norme che verranno impartite al riguardo con speciale ordine di servizio, dall'autorità che ha disposto il sequestro e il trasferimento delle sostanze predette.

L'ordine di servizio deve essere redatto in quattro copie, una delle quali viene rilasciata al trasportatore, una viene trattenuta dall'autorità sanitaria che ha disposto il trasferimento delle sostanze sotto scorta sanitaria e le altre vengono consegnate, all'inizio del servizio, al personali di scorta. Su queste due copie debbono essere annotati a cura del predetto personale gli eventuali inconvenienti verificatisi durante il trasferimento. Una delle due copie, che debbono essere firmate dall'autorità sanitaria destinataria per la presa in consegna delle sostanze alimentari sequestrate, viene rilasciata al personale di scorta, la restituzione all'autorità sanitari che ha posto il servizio e la seconda viene trattenuta l'autorità sanitaria destinataria. L'autorità sanitaria territorialmente competente riguardo alla località di destinazione delle sostanze alimentari poste sotto sequestro verrà immediatamente informata del trasferimento le sostanze stesse, da parte dell'autorità sanitaria che ha disposto il sequestro e il trasferimento e è, a sua volta, tenuta ad informare quest'ultima degli ulteriori provvedimenti adottati.

Articolo 54

Confezioni delle materie coloranti.

Le materie coloranti indicate nell'elenco di cui all'art. 10 della legge, destinate ad essere impiegate nella colorazione delle sostanze alimentari, debbono essere poste in commercio in confezioni chiuse all'origine su cui debbono essere riportate le seguenti indicazioni:

a) nome o ragione sociale e sede della ditta produttrice o confezionatrice e sede dello stabilimento di produzione o confezionamento; oppure, ove trattisi di prodotti fabbricati nell'ambito della CEE, il nome o ragione sociale e la sede della ditta commerciale responsabile dell'immissione in commercio del prodotto, individuata in base alla legislazione dello Stato membro della CEE;
b) la dicitura "colorante" da aggiungere alle sostanze alimentari per le quali ne è sentito l'impiego, oppure "per sostanze alimentari (uso limitato)";
c) la denominazione dei coloranti secondo la nomenclatura indicata nell'elenco di cui al citato art. 10 della legge;
d) il peso netto.

Articolo 55

Sostanze alimentari trattate con materie coloranti.

Le sostanze alimentari colorate debbono recare sulla confezione e, se vendute sfuse, sull'apposito cartello di cui all'art. 66 del presente regolamento denominante le sostanze alimentari, la dicitura: "colorato con..." seguita dalla denominazione o dalla corrispondente sigla della sostanza colorante, secondo la nomenclatura riportata nei decreti ministeriali di cui all'art. 10 della legge.

L’osservanza dell’obbligo stabilito dal comma precedente esime dall’osservanza degli obblighi concernenti l’indicazione della colorazione stabilita da altre norme regolamentari.

Articolo 56
Sostanze naturali che esplicano un effetto colorante secondario.

Le disposizioni previste dagli articoli 54 e 55 del presente regolamento non si applicano alle sostanze naturali dotate di proprietà aromatiche, saporose o nutritive che esplicano un effetto colorante secondario quali la paprica, la curcuma, lo zafferano e il legno di sandalo.
L’aggiunta di tali sostanze deve essere indicata tra gli ingredienti sulla confezione o su etichetta appostavi e, nel caso di sostanze alimentari vendute sfuse, sull’apposito cartello di cui al successivo art. 66 denominante le sostanze alimentari, secondo le modalità e nei casi previsti dal terzo e quarto comma dell’art. 63 del presente regolamento.

Articolo 57
Impiego di ingredienti e di semilavorati colorati nella preparazione di sostanze alimentari composte.

Nella preparazione di prodotti alimentari risultanti dalla mescolanza di più sostanze possono essere impiegate sostanze colorate a norma di legge anche quando non è autorizzata la colorazione del prodotto alimentare finito, purché non si determini la colorazione di massa del prodotto stesso.
I semilavorati destinati alla preparazione di sostanze alimentari di cui è ammessa la colorazione possono essere colorati, fermo restando per essi quanto stabilito dal precedente art. 55.

Articolo 58
Impiego di additivi chimici autorizzati nella produzione di sostanze alimentari.

Con decreto emanato ai sensi dell’art. 22 della legge il Ministro della sanità stabilisce apposite norme per l’impiego di additivi chimici autorizzati, in particolare per quanto riguarda le miscele degli stessi, le mescolanze di additivi chimici con diluenti e solventi, supporti, sostanze alimentari, nonché il loro impiego nei semilavorati. Fino a quando non saranno emanate le disposizioni di cui al comma precedente e per quanto non previsto dal presente regolamento in materia di impiego degli additivi chimici, si fa rinvio al decreto ministeriale del 31 marzo 1965, e successive modificazioni, in materia di disciplina di additivi chimici consentiti nella preparazione e per la conservazione di sostanze alimentari.

Articolo 59
Autorizzazione alla produzione, al commercio e deposito all’ingrosso di additivi chimici.

(Omissis) (1).

(1) Articolo abrogato dall’art. 6, DPR 19 novembre 1997, n. 514.

Articolo 60
Domande di autorizzazione.

(Omissis) (1).

(1) Articolo abrogato dall’art. 6, DPR 19 novembre 1997, n. 514.

Articolo 61
Indicazioni per le confezioni di additivi.

Gli additivi chimici debbono essere posti in commercio in confezioni chiuse all’origine sulle quali sono riportate, salvo deroghe previste da altre norme, le seguenti indicazioni:

a) il nome o la ragione sociale e la sede dell’impresa produttrice o confezionatrice e la sede dello stabilimento di produzione, preparazione e confezionamento; oppure, ove si tratti di prodotti fabbricati in altri Paesi della CEE, il nome o la ragione sociale e la sede dell’impresa commerciale responsabile dell’immissione in commercio del prodotto, individuato in base alla legislazione dello Stato membro della CEE in cui essa risiede;
b) la dicitura “additivo” da aggiungere solo alle sostanze alimentari per le quali ne è consentito l’impiego, oppure la dicitura “per alimenti (uso limitato)”;
c) la indicazione del gruppo di appartenenza, seguita dalla denominazione chimica o dalla corrispondente sigla, secondo la nomenclatura riportata nei decreti di cui all’art. 22 della legge e, nel caso di miscele, anche le relative percentuali;
d) il peso netto. Le indicazioni di cui alla lettera c) vengono stabilite, per gli aromi, dai decreti ministeriali emanati ai sensi dell’art. 22 della legge.

Articolo 62

Indicazioni per le sostanze alimentari trattate con additivi chimici.

Salvo quanto previsto nei decreti del Ministro della sanità emanati ai sensi dell'art. 22 della legge, le sostanze alimentari trattate con gli additivi chimici o che, comunque li contengano, debbono recare sulla confezione o, se venduti sfusi, sull'apposito cartello di cui all'art. 66 del presente regolamento, denominante la sostanza alimentare, oltre alle indicazioni di cui all'art. 64, anche l'indicazione del gruppo funzionale di appartenenza dell'additivo (es. conservativi, antiossidanti, ecc.) seguito dalla denominazione o dalla corrispondente sigla secondo la nomenclatura riportata nei predetti decreti.

È fatto divieto di adoperare o aggiungere denominazioni differenti da quelle con le quali gli additivi figurano nell'apposito elenco. Le indicazioni di cui al primo comma non sono obbligatorie per i prodotti disciplinati dal decreto del Presidente della Repubblica 12 febbraio 1965, n. 162, contenente norme per la repressione delle frodi nella preparazione e nel commercio dei mosti, vini e aceti.

Articolo 63

Disposizioni particolari per le sostanze aromatizzanti naturali o artificiali.

Nell'autorizzazione di cui all'art. 25 del presente regolamento è compresa la facoltà di estrarre con mezzi fisici aromi naturali da parte delle imprese alimentari che utilizzano i detti aromi unicamente nella produzione degli alimenti e bevande di propria produzione. In tal caso la domanda di cui all'art. 26 del presente regolamento deve contenere anche le indicazioni previste dal precedente art. 59, quinto e ultimo comma. Le sostanze aromatizzanti di cui al precedente comma possono essere impiegate sia singolarmente che in miscela. Le sostanze alimentari aromatizzate debbono riportare sulla confezione o sul cartello di cui all'art. 66, denominante la sostanza alimentare allo stato sfuso, la dicitura "aromi naturali" e/ o "aromi artificiali", a caratteri leggibili e indelebili, senza obbligo di specificare la sostanza aromatizzante. Nel caso dell'aromatizzazione complementare prevista dalle norme vigenti la dicitura "aromi naturali" non è obbligatoria per i liquori i vini aromatizzati e le bevande disciplinate dal regolamento approvato con il decreto del Presidente della Repubblica 19 maggio 1958, n. 719, e per le acquaviti.

Articolo 64

Indicazioni obbligatorie per le sostanze alimentari confezionate.

[Le sostanze alimentari poste in commercio in confezioni debbono riportare sulla confezione o su etichetta saldamente appostavi le seguenti indicazioni:

1) denominazione legale, ove prevista, o merceologica, che caratterizza il prodotto; nel caso di prodotti tipici regionali o esteri, anche se di produzione nazionale, che non abbiano una corrispondente denominazione italiana è consentito riportare la denominazione originaria;
2) nome o ragione sociale o marchio depositato dall'impresa produttrice o dall'impresa confezionatrice;
3) sede dello stabilimento di produzione e di confezionamento o di solo confezionamento; nel caso in cui l'impresa disponga di più stabilimenti, situati in località diverse, è consentito indicare sull'etichetta tutti gli stabilimenti purché quello effettivo di produzione e di confezionamento venga evidenziato mediante punzonatura o altro segno particolare; nel caso dell'impresa che provvede alla distribuzione e vendita di sostanze alimentari prodotte da terzi per suo conto deve essere indicato anche l'indirizzo dello stabilimento di produzione e confezionamento;
4) gli ingredienti, in ordine decrescente, determinato in base alla quantità rispettivamente ponderale o volumetrica dei singoli ingredienti impiegati a seconda che il contenuto sia espresso in peso o volume;
5) in quantitativo netto in peso o volume espresso in base al sistema metrico decimale indicato con maggiore e immediata evidenza rispetto a quelli impiegati per l'indicazione dei singoli ingredienti.

Salvo quanto previsto da norme speciali, ai fini della prescrizione di cui al precedente punto 5), sulle confezioni di prodotti alimentari ai quali siano stati aggiunti i liquidi di governo, l'indicazione del contenuto netto complessivo deve essere accompagnata da quella del peso del prodotto sgocciolato. Si intende per liquido di governo quello di copertura ordinariamente non destinato alla consumazione.

Le indicazioni di cui ai numeri 3), 4) e 5) del primo comma possono essere omesse quando si tratta di confezioni di sostanze alimentari non destinate alla vendita al dettaglio purché risultino nei documenti di vendita e di consegna; dette indicazioni debbono risultare dai documenti di vendita e di consegna, anche nel caso dei prodotti alimentari non confezionati, oggetto di commercio internazionale o di scambio tra produttori e utilizzatori professionali che vengono venduti al dettaglio previa trasformazione e frazionamento. In entrambi i casi l'eventuale presenza di additivi deve risultare dai documenti di accompagnamento.

L'indicazione del peso (o volume) netto non è obbligatoria per i prodotti destinati alla vendita al dettaglio a peso, purché sugli involucri sia riportata la dizione "da vendersi a peso".

La denominazione legale costituisce denuncia di ingredienti. Le indicazioni di cui al punto 1) del presente articolo debbono essere riportate di seguito, con caratteri di dimensioni uniformi.

Tutte le indicazioni obbligatorie debbono essere riportate sulla confezione o sull'etichetta in lingua italiana e in modo ben visibile, con caratteri facilmente leggibili e indelebili salvo quanto previsto al punto 1) del presente articolo.

Le indicazioni richieste specificamente da leggi o regolamenti speciali debbono essere riportate quando non costituiscono indicazioni equipollenti a quelle prescritte dal presente regolamento.
Gli imballaggi di qualsiasi specie, anche se comprendenti una singola unità di vendita al dettaglio e contenenti prodotti confezionati eterogenei, possono non riportare le indicazioni previste nel presente articolo, purché esse figurino sulle singole confezioni dei prodotti contenuti.
I prodotti omogenei confezionati contenuti in unico imballaggio costituente una singola unità di vendita al dettaglio possono non riportare le predette indicazioni, purché esse figurino sull'imballaggio stesso. L'indicazione del peso netto può essere riferita al contenuto complessivo della unità di vendita] (1).

(1) Le prescrizioni del presente articolo sono da intendersi abrogate in virtù di quanto stabilito dall'art. 18, DPR 18 maggio 1982, n. 322. Vedi, anche sent. Cass. Pen., sez. VI, 1° dicembre 1984, n. 10729.

Articolo 65
Indicazione della data di confezionamento per talune sostanze alimentari.

[Le sostanze alimentari elencate nell'allegato B al presente regolamento, oltre alle indicazioni di cui all'articolo precedente, debbono riportare la data di confezionamento in chiaro, riferita a giorno, mese e anno, se incluse nella sezione I, o riferita soltanto a mese e anno, se incluse nella sezione II di tale allegato] (1).

(1) Le prescrizioni del presente articolo sono da intendersi abrogate in virtù di quanto stabilito dall'art. 18, DPR 18 maggio 1982, n. 322. Vedi, anche sent. Cass. Pen., sez. VI, 1° dicembre 1984, n. 10729.

Articolo 66
Indicazioni obbligatorie per le sostanze alimentari sfuse o poste in vendita in confezioni non più integre.

[Le sostanze alimentari non confezionate vendute allo stato sfuso e quelle confezionate all'origine la cui confezione non sia più integra, debbono essere munite di apposito cartello in cui siano riportate le indicazioni di cui ai punti da 1) a 4) del primo comma dell'art. 64. Tale cartello deve essere tenuto bene in vista, possibilmente applicato al recipiente contenente la sostanza alimentare cui si riferisce, e le varie indicazioni obbligatorie debbono figurare in lingua italiana, a caratteri ben leggibili e indelebili.
Le confezioni non superiori a g 40 possono riportare la sola indicazione del nome o ragione sociale del produttore, o il marchio depositato, sempreché sul loro contenitore figurino le indicazioni previste per i prodotti confezionati] (1).

(1) Le prescrizioni del presente articolo sono da intendersi abrogate in virtù di quanto stabilito dall'art. 18, DPR 18 maggio 1982, n. 322. Vedi, anche sent. Cass. Pen., sez. VI, 1° dicembre 1984, n. 10729.

Articolo 67
Tolleranza di peso o volume.

[Nella determinazione del peso o del volume sono fatte salve le tolleranze relative al contenuto previste da leggi e regolamenti speciali per determinate sostanze, nonché quelle previste per pesi, misure, bilance e riempitrici automatiche. Qualora in sede di analisi sia emersa una deficienza di peso o volume rispetto al dichiarato, il relativo controllo, ai fini dell'accertamento di una eventuale violazione dell'art. 8 della legge, deve essere effettuato, salvo il caso previsto al quarto comma del presente articolo, su una campionatura da prelevarsi in fabbrica o presso esercizi pubblici diversi, formata da dieci confezioni dello stesso tipo, qualora si tratti di confezioni di peso o volume non superiore a g 250 o ml 250, da cinque confezioni dello stesso tipo, qualora si tratti di confezioni di peso o volume superiori a g 250 o ml 250, e da tre confezioni qualora si tratti di confezioni di peso o volume superiore a g 1000 o ml 1000. L'indicazione del peso o volume netto è considerata irregolare quando il contenuto complessivo, all'atto del controllo di cui al comma precedente, risulti inferiore tenuto conto delle tolleranze previste per ciascun tipo di prodotto nella prima parte dell'allegato D al presente regolamento, rispettivamente, al decuplo, quintuplo o triplo, del peso o volume indicato sulle confezioni. Per ogni singolo recipiente il contenuto netto in peso o volume non potrà in ogni caso essere inferiore ai limiti previsti, per i vari tipi di prodotti, nella seconda parte del suddetto allegato D. Ove a seguito dell'analisi di primo grado emerga una irregolarità nel peso o volume netto, in caso di mancata presentazione della domanda di revisione di analisi nei termini previsti oppure di conferma dei risultati dell'analisi di prima istanza, l'autorità sanitaria competente trasmette denuncia all'autorità giudiziaria] (1).

(1) Le prescrizioni del presente articolo sono da intendersi abrogate in virtù di quanto stabilito dall'art. 18, DPR 18 maggio 1982, n. 322. Vedi, anche sent. Cass. Pen., sez. VI, 1° dicembre 1984, n. 10729.

Articolo 68

Disciplina igienica degli oggetti destinati a venire a contatto con gli alimenti.

Le imprese che producono oggetti destinati a venire a contatto con sostanze alimentari son tenute a controllare la rispondenza degli stessi alle rispettive disposizioni sanitarie e a dimostrare in ogni momento di avere provveduto ai controlli e accertamenti necessari. L'utilizzazione in sede industriale o commerciale di oggetti di cui al precedente comma, è subordinata all'accertamento della loro idoneità allo scopo cui sono destinati.

Articolo 69

Limiti di cariche microbiche negli alimenti.

Il Ministro della sanità, sentito il Consiglio superiore di sanità, stabilisce con proprie ordinanze i limiti delle cariche microbiche di cui all'art. 5, lettera c), della legge. Con le ordinanze vengono indicati i criteri di valutazione delle risultanze degli accertamenti microbiologici effettuati sui singoli campioni prelevati. L'assenza dei germi patogeni nelle sostanze alimentari deve intendersi riferita a quantità determinate di prodotto che saranno all'uopo fissate con le ordinanze di cui al presente articolo. Qualora i valori emersi dagli accertamenti microbiologici risultino tali da rendere configurabile l'ipotesi prevista dall'articolo 5, lettera d), della legge, deve esserne fatta specifica menzione nel referto di analisi. La eventuale revisione di analisi, in materia di cariche microbiche, non comporta necessariamente la ripetizione delle analisi. Ove venga proposta istanza di revisione, il laboratorio di primo grado deve fornire una relazione dettagliata indicando le modalità operative degli accertamenti effettuati. In funzione della particolare natura delle sostanze alimentari, le ordinanze di cui all'art. 5, lettera c), della legge, stabiliscono in quali casi si addiviene alla ripetizione dell'analisi e in quali altri ad un giudizio di revisione sulla base degli elementi emergenti dall'analisi di primo grado.

Articolo 70

Detenzione, per ragioni di studio, di sostanze non conformi alle prescrizioni vigenti.

La detenzione di additivi chimici, sostanze aromatizzanti, materie coloranti, coadiuvanti tecnologici e sostanze comunque non consentite nella lavorazione di alimenti è ammessa nei laboratori di ricerca annessi agli stabilimenti produttori con l'osservanza delle prescrizioni di cui all'art. 9 della legge e a condizione che la loro quantità sia rapportata alle esigenze di studio e che in ogni caso tali sostanze non siano impiegate nella produzione di alimenti da immettere al commercio.

La detenzione delle sostanze di cui al comma precedente deve essere autorizzata dall'autorità sanitaria e per esse deve essere tenuto un registro di carico e scarico.

Articolo 71

Detenzione, per ragioni tecnologiche, di sostanze non conformi alle prescrizioni vigenti.

È ammessa la detenzione di specifiche sostanze usate nella preparazione di terreni di coltura o come supporti. La detenzione di tali sostanze deve essere autorizzata dall'autorità sanitaria e per esse deve essere tenuto un registro di carico e scarico.

Articolo 72

Importazioni in Italia di sostanze alimentari.

Gli importatori di sostanze alimentari sono responsabili della natura, del tipo, della quantità, della omogeneità, dell'origine dei prodotti presentati all'importazione nonché della rispondenza dei requisiti igienico-sanitari previsti dalle vigenti disposizioni in materia di sostanze alimentari.

Resta salva l'osservanza delle modalità prescritte da altre leggi o regolamenti speciali, nonché da convenzioni internazionali concernenti particolari sostanze alimentari (1).

(1) Articolo così sostituito dall'art. 11, DPR 8 maggio 1985, n. 254.

Articolo 73

Disposizioni per gli esercizi già autorizzati in regola con le prescrizioni del regolamento.

I titolari degli stabilimenti, dei laboratori o dei depositi all'ingrosso, di cui al presente regolamento, già in corso di esercizio, sono tenuti, ancorché in regola con le prescrizioni previste dal presente regolamento, a rinnovare entro novanta giorni dalla data di entrata in vigore del presente regolamento, la domanda di autorizzazione sanitaria, all'autorità competente secondo le modalità di cui ai precedenti articoli 25 e 26. L'autorità competente, effettuati gli opportuni accertamenti, provvede entro centottanta giorni dal ricevimento della domanda a rilasciare la relativa autorizzazione, la quale, decorso tale termine, si intende rilasciata sempreché lo stabilimento, il laboratorio o il deposito corrispondano alla prescrizione di cui al presente regolamento.

Resta comunque a carico dell'autorità competente l'onere di emanare il provvedimento formale di autorizzazione. Le disposizioni di cui ai precedenti commi si applicano anche agli esercizi di cui all'art. 59 tenuto conto delle modalità previste dall'art. 60.

Articolo 74

Disposizioni per gli esercizi già autorizzati non in regola con le prescrizioni del regolamento.

I titolari di stabilimenti, laboratori o depositi già in corso di esercizio, che abbiano necessità di adeguarsi alle prescrizioni contenute nel presente regolamento ne danno comunicazione all'autorità competente, entro sessanta giorni dalla entrata in vigore del presente regolamento, indicando contestualmente il periodo di tempo per effettuare le necessarie modifiche.
Tale periodo non può essere superiore ad un anno, qualora occorra adempiere alle prescrizioni di cui all'art. 59, comma quinto. Nel caso in cui occorra procedere alle modifiche strutturali dei locali di cui agli articoli 28 e 30 il periodo di tempo è protratto a tre anni.
Effettuati nei termini anzidetti gli adempimenti, i titolari degli esercizi di cui al primo comma devono chiedere il rinnovo dell'autorizzazione sanitaria all'autorità competente, secondo le modalità di cui agli articoli 25 e 26 del presente regolamento. L'autorità è tenuta a provvedere secondo quanto stabilito dal precedente art. 73. L'autorità sanitaria, può, ove occorra, prescrivere per il periodo necessario all'adeguamento, obblighi sostitutivi. L'autorità sanitaria, comunque, in casi di necessità e urgenza, può stabilire con proprio decreto un termine più breve per l'adeguamento degli esercizi di cui ai commi precedenti agli obblighi previsti dal presente regolamento, per quanto concerne:

a) la separazione tra i banchi di lavorazione e i banchi di vendita;
b) la separazione della rete di distribuzione interna delle acque potabili;
c) requisiti dei servizi igienici. Sono fatti salvi, in ogni caso, i requisiti minimi previsti per talune lavorazioni, dal decreto del Presidente della Repubblica 19 marzo 1956, n. 303, recante norme generali per l'igiene del lavoro.

Articolo 75

Disposizioni particolari per distributori automatici di alimenti e bevande.

I distributori automatici o semiautomatici di sostanze alimentari attualmente in funzione debbono essere adeguati alle prescrizioni di cui al precedente art. 32 entro un anno dall'entrata in vigore del presente regolamento.

Articolo 76

Etichette - Termine per la nuova disciplina.

Per l'adeguamento ai nuovi oneri di cui agli articoli 62, 64 e 65 è consentita l'utilizzazione in sede di produzione, per la durata di un anno, delle etichette e delle confezioni conformi alla normativa vigente alla data di entrata in vigore del regolamento (1).

(1) Vedi, art. 18, DPR 18 maggio 1982, n. 322.

Articolo 77

Disposizioni particolari per i mezzi di trasporto.

I mezzi di trasporto di cui agli articoli 48, 49 e 50 debbono adeguarsi alle prescrizioni contenute negli articoli stessi entro un anno dall'entrata in vigore del presente regolamento.

Articolo 78

Norma di rinvio.

Il procedimento e le modalità di prelevamento dei campioni previsti nel presente regolamento, si applicano in quanto compatibili, all'esercizio della vigilanza per la repressione delle frodi sulla preparazione e sul commercio di sostanze di uso agrario e di prodotti agrari di cui al regio decreto 1° luglio 1926, n. 1361, di esecuzione del regio decreto 15 ottobre 1925, n. 2033.

Articolo 79

Applicazione del regolamento.

Il presente regolamento entra in vigore il novantesimo giorno successivo a quello della sua pubblicazione nella Gazzetta Ufficiale della Repubblica italiana.

ALLEGATO A

§ 1 - Quantità di campione, da suddividere in cinque aliquote necessaria per l'esecuzione analisi chimiche (*)

Natura del campione	grammi
Cereali	1000
Farine	1000
Paste alimentari.	1000
Paste alimentari speciali	1500
Pane	1000
Pane speciale	2000
Prodotti da forno diversi dal pane	1000
Prodotti dolciari	1000
Olio (di oliva o di semi)	1000
Burro.	1000
Margarina	1000
Grassi idrogenati	1000
Strutto	1000
Grassi emulsionati per panificazione	1000
Cacao	500
Cioccolato	500
Cioccolati farciti e/o ripieni	1500
Latte	1
Latte condensato (1)	750
Latte in polvere (2)	500
Crema di latte o panna	500
Crema per pasticceria e budini	500
Formaggi	1000
Gelati	1000
Vini	5
Birra	2
Acquaviti	1,5
Liquori	1,5
Aperitivi a base di vino	2
Alcool etilico	1
Aceti	2,5
Acque gassate e bevande analcoliche	2,5
Polveri per acqua da tavola	20
Zucchero.	500
Miele	500
Caramelle, confetti e chewing-gum	500
Caffé ed estratti di caffé e surrogati	500
Frutta, ortaggi freschi e surgelati	500
Frutta e vegetali secchi	1000
Marmellata, confettura, mostarda, gelatina, di frutta	1000
Succhi e nettare di frutta	1000
Sciroppi	1000
Conserve di origine vegetale	1000
Carne fresca	1000
Carni conservate – insaccati	1000
Conserve e semiconserve di origine animale	1000
Estratti alimentari e prodotti affini	500

(*) Quantità superiori possono essere prelevate su disposizione dell'autorità che ordina il prelevamento. Deroghe alle quantità indicate in allegato sono previste e possono essere introdotte da norme speciali.

(1) Vedi anche DM 8 novembre 1989, n. 435, con il quale è stato approvato il regolamento concernente i metodi di prelievo ai fini della analisi chimica per il controllo del latte conservato destinato all'alimentazione umana.

§ 2 - Quantità di campione, da suddividere in cinque aliquote, necessaria per l'esecuzione delle analisi chimiche

Natura del campione
Additivi: non meno di 250 grammi
Coloranti: non meno di 250 grammi
In casi particolari l'autorità che ordina il prelevamento può disporre il prelievo di quantità diverse indicando anche le modalità per i prodotti allo stato gassoso.

§ 3 - Norme generali da seguire per il prelievo dei campioni da analizzare

a) Nel caso di sostanze o prodotti omogenei contenuti in un unico recipiente, se ne preleva una quantità rappresentativa della massa, dalla quale si ricava il campione per l'analisi.
b) Nel caso di sostanze o prodotti omogenei contenuti in più recipienti, se ne prelevano quantità parziali da diversi recipienti scelti a caso e rappresentativi della partita; le quantità parziali vengono riunite e mescolate per ricavare il campione per l'analisi.
c) Nel caso di sostanze o prodotti non omogenei contenuti in un unico recipiente e conservati alla rinfusa, se ne prelevano quantità parziali nella parte superiore, centrale e inferiore della massa; l'insieme delle quantità parziali rappresentative della partita, vengono riunite e mescolate per ricavare il campione per l'analisi.
d) Nel caso di sostanze o prodotti non omogenei contenuti in più recipienti, se ne prelevano quantità parziali da diversi recipienti scelti a caso e rappresentativi della partita; le quantità parziali prelevate vengono riunite e mescolate per ricavare il campione per l'analisi.
e) Nel caso di sostanze o prodotti contenuti in confezioni originali chiuse e quando la natura di tale sostanza o prodotto, e il tipo di controllo analitico da effettuare ne consentano l'apertura si prelevano a caso, da un numero di confezioni rappresentative della partita, aliquote di sostanza o prodotto dalle quali, riunite e mescolate, si ricava il campione per l'analisi.
f) Nel caso di sostanze o prodotti contenuti in confezioni originali chiuse, quando la natura delle sostanze o prodotti, e il tipo di controllo analitico da effettuare non ne consentono l'apertura, si preleva a caso, dalla partita, un numero rappresentativo di confezioni per formare il campione per l'analisi. In ogni caso il peso complessivo del campione non deve essere inferiore a quello previsto nell'apposita tabella.
g) Nel caso di latte in confezioni originali chiuse destinate alla vendita al dettaglio se ne prelevano cinque, indipendentemente dal loro volume.

§ 4 - Norme speciali da seguire per il prelievo di campioni di particolari sostanze

Nel caso di sostanze alimentari delle quali si debba controllare il contenuto di umidità, i campioni prelevati debbono essere posti, di regola, in recipienti di vetro a chiusura ermetica, al fine di preservarli dall'assorbimento o dalla perdita di acqua.
Nel confezionamento dei campioni dei prodotti che, per la loro natura, posti in recipienti stagni a chiusura ermetica, si alterano per ammuffimento o putrefazione, si dovranno impiegare sacchetti di carta resistente o altro materiale idoneo.
In questi casi, come pure ogni volta che si debba controllare il contenuto di umidità e per mancanza di recipienti a chiusura ermetica si impieghino sacchetti di carta od altri contenitori non stagni e non a chiusura ermetica si dovrà determinare mediante bilancia sensibile al decigrammo il peso lordo di ogni singolo campione all'atto del prelevamento: peso lordo che dovrà essere annotato sull'involucro del campione medesimo, assieme alla data e ora della pesatura.
Il peso di ciascun campione dovrà essere riportato, inoltre, anche sul verbale di prelevamento e la pesatura dovrà essere esatta al decigrammo per ciascuna aliquota. Il responsabile dello stabilimento, deposito od esercizio presso cui è stato prelevato il campione od il suo rappresentante ha diritto ad assistere alla pesata.

ALLEGATO B

PARTE I
Elenco delle sostanze alimentari confezionate che debbono riportare la data del confezionamento

Sezione I
Prodotti alimentari che debbono recare la data di confezionamento
Riferita a giorno, mese e anno

Latte, bevande a base di latte e simili, crema dessert, da consumarsi crudi o sottoposti a trattamento di pastorizzazione;
Latti fermentati;
Sfarinati riconfezionati;
Paste alimentari fresche con ripieno di carne o ricotta (con indicazione del periodo di durata e delle condizioni di conservazione);
Carni, pollame o selvaggina freschi o congelati;
Prodotti ittici freschi o congelati;
Latte o crema di latte sottoposti a trattamento UHT o sterilizzazione;
Lieviti naturali;
Prodotti d'uovo;
Camomilla (limitatamente all'anno di produzione);
Carni preparate, escluse quelle in scatola sterilizzate;
Semiconserve ittiche;
Pane in cassetta e altri tipi di pane in confezione.

Sezione II
Prodotti alimentari che debbono recare la data di confezionamento
Riferita a mese e anno

Alimentari surgelati;
Succhi di frutta e polvere di frutto;
Estratti alimentari e prodotti affini;
Salse non sterilizzate;
Derivati del latte;
Margarina e grassi idrogenati;
Condimenti per panificazione;
Grassi e oli alimentari confezionati;
Droghe e spezie;
Latte condensato, latte in polvere e prodotti a base di latte sterilizzati.

ALLEGATO C

Parte I - Condizioni di temperatura che debbono essere rispettate durante il trasporto delle sostanze alimentari congelate e surgelate

Sostanze alimentari	Temperatura massima al momento del carico e durante il trasporto	Rialzo termico tollerabile per periodi di breve durata
Gelati alla frutta e succhi di frutta congelati	-10 °C	> + 3 °C
Altri gelati	-15 °C	
Prodotti della pesca congelati o surgelati o surgelati	18 °C	
Altre sostanze alimentari surgelate	18 °C	
Burro o altre sostanze grasse congelate	-10 °C	
Frattaglie, uova sgusciate, pollame e selvaggina congelata	-10 °C	
Carni congelate	-10 °C	
Tutte le altre sostanze alimentari congelate	-10 °C	

Parte II - Elenco delle condizioni di temperatura che debbono essere rispettate durante il trasporto di determinate sostanze alimentari né congelate né surgelate (1)

Sostanze alimentari	Temperature durante il trasporto
Latte crudo trasportato in cisterna o bidoni dalle aziende di produzione ai centri di raccolta ovvero direttamente agli stabilimenti di trattamento termico e confezionamento per il consumo diretto [1]	+ 8 °C [2]
Latte crudo trasportato in cisterna dai centri di raccolta agli stabilimenti di trattamento termico e confezionamento per il consumo diretto [3]	da 0 °C a + 4 °C [4]
Latte pastorizzato trasportato in cisterna da uno stabimento di trattamento termico ad altro stabilimento di trattamento termico e confezionamento per il consumo diretto [3]	da 0 °C a + 4 °C [4]
Latte pastorizzato in confezioni [5]	da 0 °C a + 4 °C
Prodotti lattiero - caseari (latti fermentati, panna o crema di latte, formaggi freschi, ricotta) [5]	da 0 °C a + 4 °C
Burro [5] e burro concentrato (anidro) [6]	da + 1 °C a + 6 °C
Burro anidro liquido	superiore a + 32 °C
Prodotti della pesca freschi da trasportare sempre sotto sotto ghiaccio	da 0 °C a + 4 °C
Carni [5]	da - 1 °C a + 7 °C
Pollame e conigli [5]	da - 1 °C a + 4 °C
Selvaggina [5]	da - 1 °C a + 3 °C
Frattaglie [5]	da - 1 °C a + 3 ° C
Molluschi eduli lamellibranchi, in confezione, compresi quelli sgusciati appartenenti al genere “Chlamys” (canestrelli) e “Pecten” (cappe sante).	+ 6 °C [7]

[1] Per percorsi superiori ai 150 km sono richiesti mezzi isotermici (IN ovvero IR).
[2] Per percorsi superiori a 75 km è tollerata, rispetto al valore prescritto nel presente allegato, un aumento massimo di temperatura di 2 °C.
[3] Per percorsi superiori ai 200 km sono richiesti mezzi isotermici (IN ovvero IR).
[4] Per percorsi superiori ai 200 km è tollerato, rispetto al valore prescritto nel presente allegato, un aumento massimo di temperatura di 2 °C.
[5] Durante il tempo di distribuzione frazionata - da effettuarsi con mezzi aventi caratteristiche tecnico-costruttive idonee per il trasporto in regime di freddo - che comporti ai fini della consegna agli esercizi di vendita numerose operazioni di apertura delle porte dei mezzi stessi, ferme restando in ogni caso le temperature di partenza fissate nel presente allegato, sono tollerati i seguenti valori massimi di temperatura:

latte pastorizzato, in confezioni: + 9 °C
panna o crema di latte pastorizzata, in confezioni: + 9 °C
ricotta: + 9 °C
burro prodotto con crema di latte pastorizzata: + 14 °C
yoghourt od altri latti fermentati, in confezioni: + 14 °C
formaggi freschi (mascarpone e similari, mozzarelle di vacca o di bufala e similari, caprini non stagionati, crescenza, formaggi a prevalente coagulazione lattica od acido-presamica ad elevato tenore di umidità e di pronto consumo, quali robiola, petit suisse, cottagecheese, quark, ecc.) purché prodotti con latte pastorizzato: + 14 °C
carni: + 10 °C
pollame e conigli: + 8 °C
selvaggina: + 8 °C
frattaglie: + 8 °C.

Il valore massimo di temperatura indicato per le carni (bovine, bufalina, suine, ovine e caprine), tuttavia, non è vincolante per il trasporto, in fase di distribuzione o ai depositi frigoriferi, di durata non superiore a due ore di quelle appena macellate in macelli autorizzati e non ancora raffreddate, sempreché il trasporto stesso avvenga con veicoli rispondenti ai requisiti di idoneità igienico-sanitaria prescritti dall’art. 49 del presente regolamento, che risultino almeno isotermici.
[6] Il burro concentrato (anidro) può essere trasportato anche a temperature da + 6 °C a + 18 °C.
[7] La temperatura da osservarsi durante il trasporto è prevista dagli articoli 4 e 5 del decreto ministeriale 4 ottobre 1978 (Pubblicato nella Gazz. Uff. n. 286 del 12 ottobre 1978), recante norme sulle modalità di confezionamento, il periodo e le modalità di conservazione dei molluschi eduli, le specie di molluschi che possono essere venduti sgusciati.
(1) Elenco così sostituito dal DM 1° aprile 1988, n. 178.

ALLEGATO D

Parte I - Scarti in meno consentiti rispetto alle indicazioni apposte sulle confezioni di sostanze alimentari (in peso o volume)

Peso dichiarato (in g o ml)	**Sostanze alimentari**		
	I	**II**	**III**
	Olio di oliva Olio di semi	Torroni Cioccolato alle nocciole Prodotti cavi Frutta candita Prodotti da forno lievitati	Tutti gli altri prodotti non compresi nelle categorie I e II
1 - 250	1%	4%	3%
251 - 1000	0,75%	3%	2%
1000	0,50%	2%	1%
5000	0,25%	-	-

Parte II - Sono ammessi come limiti massimi di scarti in meno rispetto alle indicazioni apposte sulle confezioni prelevate per il controllo e per una sola di esse, i seguenti valori:

Peso dichiarato (in g o ml)	**Sostanze alimentari**		
	I	**II**	**III**
	Olio di oliva Olio di semi	Torroni Cioccolato alle nocciole Prodotti cavi Frutta candita Prodotti da forno lievitati	Tutti gli altri prodotti non compresi nelle categorie I e II
Fino a g o ml 100	5%	12%	10%
Da g o ml 101 a g o ml 300	4%	10%	8%
Da g o ml 301 a g o ml 750	2,50%	7%	5%
Da g o ml 751 a g o ml 1500	1,50%	5%	3%
Oltre g o ml 1501	1%	3%	2%
g o ml 5000 e oltre	1,50	-	-

ALLEGATO E
Modulario

1 - San. Pubbl.

Mod. Sanità Pubblica

Ministero della sanità
LIBRETTO DI IDONEITA' SANITARIA
(Legge 30 aprile 1962, n. 283)

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CORRIGENDA

Corrigendum to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

(Official Journal of the European Union L 139 of 30 April 2004)

Regulation (EC) No 852/2004 should read as follows:

REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the hygiene of foodstuffs

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) The pursuit of a high level of protection of human life and health is one of the fundamental objectives of food law, as laid down in Regulation (EC) No 178/2002 [4]. That Regulation also lays down other common principles and definitions for national and Community food law, including the aim of achieving free movement of food within the Community.

(2) Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs [5] laid down the general rules of hygiene for foodstuffs and the procedures for verification of compliance with these rules.

(3) Experience has shown that these rules and procedures constitute a sound basis for ensuring food safety. In the context of the common agricultural policy, many directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.

(4) With regard to public health, these rules and procedures contain common principles, in particular in relation to the manufacturers 'and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.

(5) These principles constitute a common basis for the hygienic production of all food, including products of animal origin listed in Annex I to the Treaty.

(6) In addition to this common basis, specific hygiene rules are necessary for certain foodstuffs. Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [6] lays down these rules.

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[1] OJ C 365 E, 19.12.2000, p. 43.

[2] OJ C 155, 29.5.2001, p. 39.

[3] Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 267), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 1), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

[5] OJ L 175, 19.7.1993, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

[6] See page 22 of this Official Journal.

(7) The principal objective of the new general and specific hygiene rules is to ensure a high level of consumer protection with regard to food safety.

(8) An integrated approach is necessary to ensure food safety from the place of primary production up to and including placing on the market or export. Every food business operator along the food chain should ensure that food safety is not compromised.

(9) Community rules should not apply either to primary production for private domestic use, or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, they should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation.

(10) Food hazards present at the level of primary production should be identified and adequately controlled to ensure the achievement of the objectives of this Regulation. However, in the case of the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.

(11) The application of hazard analysis and critical control point (HACCP) principles to primary production is not yet generally feasible. However, guides to good practice should encourage the use of appropriate hygiene practices at farm level. Where necessary, specific hygiene rules for primary production should supplement these guides. It is appropriate for the hygiene requirements applicable to primary production and associated operations to differ from those for other operations.

(12) Food safety is a result of several factors: legislation should lay down minimum hygiene requirements; official controls should be in place to check food business operators' compliance and food business operators should establish and operate food safety programmes and procedures based on the HACCP principles.

(13) Successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. To this end, employees should undergo training. The HACCP system is an instrument to help food business operators attain a higher standard of food safety. The HACCP system should not be regarded as a method of self-regulation and should not replace official controls.

(14) While the requirement of establishing procedures based on the HACCP principles should not initially apply to primary production, the feasibility of its extension will be one element of the review that the Commission will carry out following implementation of this Regulation. It is, however, appropriate for Member States to encourage operators at the level of primary production to apply such principles as far as possible.

(15) The HACCP requirements should take account of the principles contained in the *Codex Alimentarius*. They should provide sufficient flexibility to be applicable in all situations, including in small businesses. In particular, it is necessary to recognise that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. Similarly, the requirement of establishing 'critical limits' does not imply that it is necessary to fix a numerical limit in every case. In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.

(16) Flexibility is also appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002.

(17) The setting of objectives such as pathogen reduction targets or performance standards may guide the implementation of hygiene rules. It is therefore necessary to provide procedures for that purpose. Such objectives would supplement existing food law, such as Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food [1], which provides for the establishment of maximum tolerances for specific contaminants, and Regulation (EC) No 178/2002, which prohibits the placing on the market of unsafe food and provides a uniform basis for the use of the precautionary principle.

[1] OJ L 37, 13.2.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003.

(18) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health. This Regulation takes account of international obligations laid down in the WTO Sanitary and Phytosanitary Agreement and the international food safety standards contained in the *Codex Alimentarius*.

(19) The registration of establishments and the cooperation of food business operators are necessary to allow the competent authorities to perform official controls efficiently.

(20) The traceability of food and food ingredients along the food chain is an essential element in ensuring food safety. Regulation (EC) No 178/2002 contains rules to ensure the traceability of food and food ingredients and provides a procedure for the adoption of implementing rules to apply these principles in respect of specific sectors.

(21) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or satisfy rules that are equivalent to Community rules. The present Regulation defines certain specific hygiene requirements for food imported into the Community.

(22) Food exported to third countries from the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002. The present Regulation defines certain specific hygiene requirements for food exported from the Community.

(23) Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.

(24) Since this Regulation replaces Directive 93/43/EEC, the latter should be repealed.

(25) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow the affected industries time to adapt.

(26) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down general rules for food business operators on the hygiene of foodstuffs, taking particular account of the following principles:

(a) primary responsibility for food safety rests with the food business operator;

(b) it is necessary to ensure food safety throughout the food chain, starting with primary production;

(c) it is important, for food that cannot be stored safely at ambient temperatures, particularly frozen food, to maintain the cold chain;

(d) general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;

(e) guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;

(f) it is necessary to establish microbiological criteria and temperature control requirements based on a scientific risk assessment;

(g) it is necessary to ensure that imported foods are of at least the same hygiene standard as food produced in the Community, or are of an equivalent standard.

This Regulation shall apply to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene.

[1] OJ L 184, 17.7.1999, p. 23.

2. This Regulation shall not apply to:

(a) primary production for private domestic use;

(b) the domestic preparation, handling or storage of food for private domestic consumption;

(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;

(d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

3. Member States shall establish, under national law, rules governing the activities referred to in paragraph 2(c). Such national rules shall ensure the achievement of the objectives of this Regulation.

Article 2

Definitions

1. For the purposes of this Regulation:

(a) 'food hygiene', hereinafter called 'hygiene', means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;

(b) 'primary products' means products of primary production including products of the soil, of stock farming, of hunting and fishing;

(c) 'establishment' means any unit of a food business;

(d) 'competent authority' means the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any other authority to which that central authority has delegated that competence; it shall also include, where appropriate, the corresponding authority of a third country;

(e) 'equivalent' means, in respect of different systems, capable of meeting the same objectives;

(f) 'contamination' means the presence or introduction of a hazard;

(g) 'potable water' means water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption [1];

(h) 'clean seawater' means natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food;

(i) 'clean water' means clean seawater and fresh water of a similar quality;

(j) 'wrapping' means the placing of a foodstuff in a wrapper or container in direct contact with the foodstuff concerned, and the wrapper or container itself;

(k) 'packaging' means the placing of one or more wrapped foodstuffs in a second container, and the latter container itself;

(l) 'hermetically sealed container' means a container that is designed and intended to be secure against the entry of hazards;

(m) 'processing' means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;

(n) 'unprocessed products' means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;

(o) 'processed products' means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

2. The definitions laid down in Regulation (EC) No 178/2002 shall also apply.

3. In the Annexes to this Regulation the terms 'where necessary', 'where appropriate', 'adequate' and 'sufficient' shall mean respectively where necessary, where appropriate, adequate or sufficient to achieve the objectives of this Regulation.

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS

Article 3

General obligation

Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the relevant hygiene requirements laid down in this Regulation.

[1] OJ L 330, 5.12.1998, p. 32. Directive as amended by Regulation (EC) No 1882/2003.

Article 4

General and specific hygiene requirements

1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004.

2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004.

3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:

(a) compliance with microbiological criteria for foodstuffs;

(b) procedures necessary to meet targets set to achieve the objectives of this Regulation;

(c) compliance with temperature control requirements for foodstuffs;

(d) maintenance of the cold chain;

(e) sampling and analysis.

4. The criteria, requirements and targets referred to in paragraph 3 shall be adopted in accordance with the procedure referred to in Article 14(2).

Associated sampling and analysis methods shall be laid down in accordance with the same procedure.

5. When this Regulation, Regulation (EC) No 853/2004 and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.

6. Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation.

Article 5

Hazard analysis and critical control points

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

2. The HACCP principles referred to in paragraph 1 consist of the following:

(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;

(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

(d) establishing and implementing effective monitoring procedures at critical control points;

(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;

(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;

and

(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

4. Food business operators shall:

(a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;

(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;

(c) retain any other documents and records for an appropriate period.

5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).

Article 6

Official controls, registration and approval

1. Food business operators shall cooperate with the competent authorities in accordance with other applicable Community legislation or, if it does not exist, with national law.

2. In particular, every food business operator shall notify the appropriate competent authority, in the manner that the latter requires, of each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration of each such establishment.

Food business operators shall also ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment.

3. However, food business operators shall ensure that establishments are approved by the competent authority, following at least one on-site visit, when approval is required:

(a) under the national law of the Member State in which the establishment is located;

(b) under Regulation (EC) No 853/2004;

or

(c) by a decision adopted in accordance with the procedure referred to in Article 14(2).

Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.

CHAPTER III

GUIDES TO GOOD PRACTICE

Article 7

Development, dissemination and use of guides

Member States shall encourage the development of national guides to good practice for hygiene and for the application of HACCP principles in accordance with Article 8. Community guides shall be developed in accordance with Article 9.

The dissemination and use of both national and Community guides shall be encouraged. Nevertheless, food business operators may use these guides on a voluntary basis.

Article 8

National guides

1. When national guides to good practice are developed, they shall be developed and disseminated by food business sectors:

(a) in consultation with representatives of parties whose interests may be substantially affected, such as competent authorities and consumer groups;

(b) having regard to relevant codes of practice of the *Codex Alimentarius*;

and

(c) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.

2. National guides may be developed under the aegis of a national standards institute referred to in Annex II to Directive 98/34/EC [1].

3. Member States shall assess national guides in order to ensure that:

(a) they have been developed in accordance with paragraph 1;

(b) their contents are practicable for the sectors to which they refer;

and

[1] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37). Directive as last amended by the 2003 Act of Accession.

(c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.

4. Member States shall forward to the Commission national guides complying with the requirements of paragraph 3. The Commission shall set up and run a registration system for such guides and make it available to Member States.

5. Guides to good practice drawn up pursuant to Directive 93/43/EEC shall continue to apply after the entry into force of this Regulation, provided that they are compatible with its objectives.

Article 9

Community guides

1 Before Community guides to good practice for hygiene or for the application of the HACCP principles are developed, the Commission shall consult the Committee referred to in Article 14. The objective of this consultation shall be to consider the case for such guides, their scope and subject matter.

2. When Community guides are prepared, the Commission shall ensure that they are developed and disseminated:

(a) by or in consultation with appropriate representatives of European food business sectors, including SMEs, and other interested parties, such as consumer groups;

(b) in collaboration with parties whose interests may be substantially affected, including competent authorities;

(c) having regard to relevant codes of practice of the *Codex Alimentarius*;

and

(d) when they concern primary production and those associated operations listed in Annex I, having regard to the recommendations set out in Part B of Annex I.

3. The Committee referred to in Article 14 shall assess draft Community guides in order to ensure that:

(a) they have been developed in accordance with paragraph 2;

(b) their contents are practicable for the sectors to which they refer throughout the Community;

and

(c) they are suitable as guides to compliance with Articles 3, 4 and 5 in the sectors and for the foodstuffs covered.

4. The Commission shall invite the Committee referred to in Article 14 periodically to review any Community guides prepared in accordance with this Article, in cooperation with the bodies mentioned in paragraph 2.

The aim of this review shall be to ensure that the guides remain practicable and to take account of technological and scientific developments.

5. The titles and references of Community guides prepared in accordance with this Article shall be published in the C series of the *Official Journal of the European Union*.

CHAPTER IV

IMPORTS AND EXPORTS

Article 10

Imports

As regards the hygiene of imported food, the relevant requirements of food law referred to in Article 11 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

Article 11

Exports

As regards the hygiene of exported or re-exported food, the relevant requirements of food law referred to in Article 12 of Regulation (EC) No 178/2002 shall include the requirements laid down in Articles 3 to 6 of this Regulation.

CHAPTER V

FINAL PROVISIONS

Article 12

Implementing measures and transitional arrangements

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 14(2).

Article 13

Amendment and adaptation of Annexes I and II

1. Annexes I and II may be adapted or updated in accordance with the procedure referred to in Article 14(2), taking into account:

(a) the need to revise the recommendations set out in Annex I, Part B, paragraph 2;

(b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5;

(c) technological developments and their practical consequences and consumer expectations with regard to food composition;

(d) scientific advice, particularly new risk assessments;

(e) microbiological and temperature criteria for foodstuffs.

2. Derogations from Annexes I and II may be granted, in particular in order to facilitate the implementation of Article 5 for small businesses, in accordance with the procedure referred to in Article 14(2), taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of this Regulation.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7 of this Article, national measures adapting the requirements laid down in Annex II.

4. (a) The national measures referred to in paragraph 3 shall have the aim of:

(i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food;

or

(ii) accommodating the needs of food businesses situated in regions that are subject to special geographical constraints.

(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. The notification shall:

(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the foodstuffs and establishments concerned;

(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

(d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of the adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 14(1). The Commission may decide, in accordance with the procedure referred to in Article 14(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2.

7. A Member State may adopt national measures adapting the requirements of Annex II only:

(a) in compliance with a decision adopted in accordance with paragraph 6;

or

(b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

Article 14

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 15

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing criteria, requirements or targets in accordance with Article 4(4).

Article 16

Report to the European Parliament and the Council

1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council.

2. The report shall, in particular, review the experience gained from the application of this Regulation and consider whether it would be desirable and practicable to provide for the extension of the requirements of Article 5 to food business operators carrying out primary production and those associated operations listed in Annex I.

3. The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 17

Repeal

1. Directive 93/43/EEC shall be repealed with effect from the date of application of this Regulation.

2. References to the repealed Directive shall be construed as being made to this Regulation.

3. However, decisions adopted pursuant to Articles 3(3) and 10 of Directive 93/43/EEC shall remain in force pending their replacement by decisions adopted in accordance with this Regulation or Regulation (EC) No 178/2002. Pending the setting of the criteria or requirements referred to in Article 4(3)(a) to (e) of this Regulation, Member States may maintain any national rules establishing such criteria or requirements that they had adopted in accordance with Directive 93/43/EEC.

4. Pending the application of new Community legislation laying down rules for official controls on food, Member States shall take all appropriate measures to ensure the fulfilment of the obligations laid down in or under this Regulation.

Article 18

Entry into force

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply 18 months after the date on which all of the following acts have entered into force:

(a) Regulation (EC) No 853/2004;

(b) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [1];

and

(c) Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption [2].

However, it shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
P. M. McDOWELL

[1] See page 83 of this Official Journal.
[2] OJ L 157, 30.4.2004, p. 33.

ANNEX I

PRIMARY PRODUCTION

PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

I. *Scope*

1. This Annex applies to primary production and the following associated operations:

(a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;

(c) the transport of live animals, where this is necessary to achieve the objectives of this Regulation;

and

(c) in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

II. *Hygiene provisions*

2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.

3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:

(a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste;

and

(b) measures relating to animal health and welfare and plant health that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.

4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:

(a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner;

(b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;

(c) as far as possible to ensure the cleanliness of animals going to slaughter and, where necessary, production animals;

(d) to use potable water, or clean water, whenever necessary to prevent contamination;

(e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;

(f) as far as possible to prevent animals and pests from causing contamination;

(g) to store and handle waste and hazardous substances so as to prevent contamination;

(h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority;

(i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health;

and

(j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.

5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:

(a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;

(b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;

(c) to use potable water, or clean water, whenever necessary to prevent contamination;

(d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;

(e) as far as possible to prevent animals and pests from causing contamination;

(f) to store and handle wastes and hazardous substances so as to prevent contamination;

(g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health;

and

(h) to use plant protection products and biocides correctly, as required by the relevant legislation.

6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

III. *Record-keeping*

7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.

8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:

(a) the nature and origin of feed fed to the animals;

(b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;

(c) the occurrence of diseases that may affect the safety of products of animal origin;

(d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health;

and

(e) any relevant reports on checks carried out on animals or products of animal origin.

9. Food business operators producing or harvesting plant products are, in particular, to keep records on:

(a) any use of plant protection products and biocides;

(b) any occurrence of pests or diseases that may affect the safety of products of plant origin;

and

(c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.

10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE

1. National and Community guides referred to in Articles 7 to 9 of this Regulation should contain guidance on good hygiene practice for the control of hazards in primary production and associated operations.

2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. Examples of such hazards and measures may include:

(a) the control of contamination such as mycotoxins, heavy metals and radioactive material;

(b) the use of water, organic waste and fertilisers;

(c) the correct and appropriate use of plant protection products and biocides and their traceability;

(d) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;

(e) the preparation, storage, use and traceability of feed;

(f) the proper disposal of dead animals, waste and litter;

(g) protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;

(h) procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;

(i) measures relating to the cleanliness of slaughter and production animals;

(j) measures relating to record-keeping.

ANNEX II

GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES)

INTRODUCTION

Chapters V to XII apply to all stages of production, processing and distribution of food and the remaining Chapters apply as follows:

— Chapter I applies to all food premises, except premises to which Chapter III applies

— Chapter II applies to all rooms where food is prepared, treated or processed, except dining areas and premises to which Chapter III applies

— Chapter III applies to those premises listed in the heading to the Chapter

— Chapter IV applies to all transportation.

CHAPTER I

General requirements for food premises (other than those specified in chapter iii)

1. Food premises are to be kept clean and maintained in good repair and condition.

2. The layout, design, construction, siting and size of food premises are to:

   (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;

   (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;

   (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control;

   and

   (d) where necessary, provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.

3. An adequate number of flush lavatories are to be available and connected to an effective drainage system. Lavatories are not to open directly into rooms in which food is handled.

4. An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands and for hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.

5. There is to be suitable and sufficient means of natural or mechanical ventilation. Mechanical airflow from a contaminated area to a clean area is to be avoided. Ventilation systems are to be so constructed as to enable filters and other parts requiring cleaning or replacement to be readily accessible.

6. Sanitary conveniences are to have adequate natural or mechanical ventilation.

7. Food premises are to have adequate natural and/or artificial lighting.

8. Drainage facilities are to be adequate for the purpose intended. They are to be designed and constructed to avoid the risk of contamination. Where drainage channels are fully or partially open, they are to be so designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled.

9. Where necessary, adequate changing facilities for personnel are to be provided.

10. Cleaning agents and disinfectants are not to be stored in areas where food is handled.

CHAPTER II

Specific requirements in rooms where foodstuffs are prepared, treated or processed (excluding dining areas and those premises specified in chapter III)

1. In rooms where food is prepared, treated or processed (excluding dining areas and those premises specified in Chapter III, but including rooms contained in means of transport) the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations. In particular:

   (a) floor surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate. Where appropriate, floors are to allow adequate surface drainage;

   (b) wall surfaces are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of impervious, non-absorbent, washable and non-toxic materials and require a smooth surface up to a height appropriate for the operations unless food business operators can satisfy the competent authority that other materials used are appropriate;

   (c) ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures are to be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles;

   (d) windows and other openings are to be constructed to prevent the accumulation of dirt. Those which can be opened to the outside environment are, where necessary, to be fitted with insect-proof screens which can be easily removed for cleaning. Where open windows would result in contamination, windows are to remain closed and fixed during production;

   (e) doors are to be easy to clean and, where necessary, to disinfect. This will require the use of smooth and non-absorbent surfaces unless food business operators can satisfy the competent authority that other materials used are appropriate;

   and

   (f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.

2. Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.

3. Adequate provision is to be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water consistent with the requirements of Chapter VII and be kept clean and, where necessary, disinfected.

CHAPTER III

Requirements for movable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles), premises used primarily as a private dwelling-house but where foods are regularly prepared for placing on the market and vending machines

1. Premises and vending machines are, so far as is reasonably practicable, to be so sited, designed, constructed and kept clean and maintained in good repair and condition as to avoid the risk of contamination, in particular by animals and pests.

2. In particular, where necessary:

(a) appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities);

(b) surfaces in contact with food are to be in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate;

(c) adequate provision is to be made for the cleaning and, where necessary, disinfecting of working utensils and equipment;

(d) where foodstuffs are cleaned as part of the food business' operations, adequate provision is to be made for this to be undertaken hygienically;

(e) an adequate supply of hot and/or cold potable water is to be available;

(f) adequate arrangements and/or facilities for the hygienic storage and disposal of hazardous and/or inedible substances and waste (whether liquid or solid) are to be available;

(g) adequate facilities and/or arrangements for maintaining and monitoring suitable food temperature conditions are to be available;

(h) foodstuffs are to be so placed as to avoid the risk of contamination so far as is reasonably practicable.

CHAPTER IV

Transport

1. Conveyances and/or containers used for transporting foodstuffs are to be kept clean and maintained in good repair and condition to protect foodstuffs from contamination and are, where necessary, to be designed and constructed to permit adequate cleaning and/or disinfection.

2. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination.

3. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.

4. Bulk foodstuffs in liquid, granulate or powder form are to be transported in receptacles and/or containers/tankers reserved for the transport of foodstuffs. Such containers are to be marked in a clearly visible and indelible fashion, in one or more Community languages, to show that they are used for the transport of foodstuffs, or are to be marked 'for foodstuffs only'.

5. Where conveyances and/or containers have been used for transporting anything other than foodstuffs or for transporting different foodstuffs, there is to be effective cleaning between loads to avoid the risk of contamination.

6. Foodstuffs in conveyances and/or containers are to be so placed and protected as to minimise the risk of contamination.

7. Where necessary, conveyances and/or containers used for transporting foodstuffs are to be capable of maintaining foodstuffs at appropriate temperatures and allow those temperatures to be monitored.

CHAPTER V

Equipment requirements

1. All articles, fittings and equipment with which food comes into contact are to:

   (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;

   (b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;

   (c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected;

   and

   (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.

2. Where necessary, equipment is to be fitted with any appropriate control device to guarantee fulfilment of this Regulation's objectives.

3. Where chemical additives have to be used to prevent corrosion of equipment and containers, they are to be used in accordance with good practice.

CHAPTER VI

Food waste

1. Food waste, non-edible by-products and other refuse are to be removed from rooms where food is present as quickly as possible, so as to avoid their accumulation.

2. Food waste, non-edible by-products and other refuse are to be deposited in closable containers, unless food business operators can demonstrate to the competent authority that other types of containers or evacuation systems used are appropriate. These containers are to be of an appropriate construction, kept in sound condition, be easy to clean and, where necessary, to disinfect.

3. Adequate provision is to be made for the storage and disposal of food waste, non-edible by-products and other refuse. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and, where necessary, free of animals and pests.

4. All waste is to be eliminated in a hygienic and environmentally friendly way in accordance with Community legislation applicable to that effect, and is not to constitute a direct or indirect source of contamination.

CHAPTER VII

Water supply

1. (a) There is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated;

   (b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply.

2. Where non-potable water is used, for example for fire control, steam production, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with, or allow reflux into, potable water systems.

3. Recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.

4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.

5. Steam used directly in contact with food is not to contain any substance that presents a hazard to health or is likely to contaminate the food.

6. Where heat treatment is applied to foodstuffs in hermetically sealed containers it is to be ensured that water used to cool the containers after heat treatment is not a source of contamination for the foodstuff.

CHAPTER VIII

Personal hygiene

1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.

2. No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

CHAPTER IX

Provisions applicable to foodstuffs

1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption.

2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.

3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.

4. Adequate procedures are to be in place to control pests. Adequate procedures are also to be in place to prevent domestic animals from having access to places where food is prepared, handled or stored (or, where the competent authority so permits in special cases, to prevent such access from resulting in contamination).

5. Raw materials, ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins are not to be kept at temperatures that might result in a risk to health. The cold chain is not to be interrupted. However, limited periods outside temperature control are permitted, to accommodate the practicalities of handling during preparation, transport, storage, display and service of food, provided that it does not result in a risk to health. Food businesses manufacturing, handling and wrapping processed foodstuffs are to have suitable rooms, large enough for the separate storage of raw materials from processed material and sufficient separate refrigerated storage.

6. Where foodstuffs are to be held or served at chilled temperatures they are to be cooled as quickly as possible following the heat-processing stage, or final preparation stage if no heat process is applied, to a temperature which does not result in a risk to health.

7. The thawing of foodstuffs is to be undertaken in such a way as to minimise the risk of growth of pathogenic micro-organisms or the formation of toxins in the foods. During thawing, foods are to be subjected to temperatures that would not result in a risk to health. Where run-off liquid from the thawing process may present a risk to health it is to be adequately drained. Following thawing, food is to be handled in such a manner as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins.

8. Hazardous and/or inedible substances, including animal feed, are to be adequately labelled and stored in separate and secure containers.

CHAPTER X

Provisions applicable to the wrapping and packaging of foodstuffs

1. Material used for wrapping and packaging are not to be a source of contamination.

2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.

3. Wrapping and packaging operations are to be carried out so as to avoid contamination of the products. Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness is to be assured.

4. Wrapping and packaging material re-used for foodstuffs is to be easy to clean and, where necessary, to disinfect.

CHAPTER XI

Heat treatment

The following requirements apply only to food placed on the market in hermetically sealed containers:

1. any heat treatment process used to process an unprocessed product or to process further a processed product is:

   (a) to raise every party of the product treated to a given temperature for a given period of time;

   and

   (b) to prevent the product from becoming contaminated during the process;

2. to ensure that the process employed achieves the desired objectives, food business operators are to check regularly the main relevant parameters (particularly temperature, pressure, sealing and microbiology), including by the use of automatic devices;

3. the process used should conform to an internationally recognised standard (for example, pasteurisation, ultra high temperature or sterilisation).

CHAPTER XII

Training

Food business operators are to ensure:

1. that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;

2. that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles;

and

3. compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.

Corrigendum to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin

(Official Journal of the European Union L 139 of 30 April 2004)

Regulation (EC) No 853/2004 should read as follows:

REGULATION (EC) No 853/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific hygiene rules for food of animal origin

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Pursuant to Regulation (EC) No 852/2004 [4], the European Parliament and the Council laid down general rules for food business operators on the hygiene of foodstuffs.

(2) Certain foodstuffs may present specific hazards to human health, requiring the setting of specific hygiene rules. This is particularly the case for food of animal origin, in which microbiological and chemical hazards have frequently been reported.

(3) In the context of the common agricultural policy, many Directives have been adopted to establish specific health rules for the production and placing on the market of the products listed in Annex I to the Treaty. These health rules have reduced trade barriers for the products concerned, contributing to the creation of the internal market while ensuring a high level of protection of public health.

(4) With regard to public health, these rules contain common principles, in particular in relation to the manufacturers 'and competent authorities' responsibilities, structural, operational and hygiene requirements for establishments, procedures for the approval of establishments, requirements for storage and transport and health marks.

(5) These principles constitute a common basis for the hygienic production of food of animal origin, permitting the simplification of the existing directives.

(6) It is desirable to achieve further simplification by applying the same rules wherever appropriate to all products of animal origin.

(7) The requirement in Regulation (EC) No 852/2004 whereby food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations must put in place, implement and maintain procedures based on hazard analysis and critical control point (HACCP) principles also permits simplification.

(8) Taken together, these elements justify a recasting of the specific hygiene rules contained in existing directives.

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(1) OJ C 365 E, 19.12.2000, p. 58.

(2) OJ C 155, 29.5.2001, p. 39.

(3) Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 288), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 23), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

(4) See page 3 of this Official Journal.

(9) The principal objectives of the recasting are to secure a high level of consumer protection with regard to food safety, in particular by making food business operators throughout the Community subject to the same rules, and to ensure the proper functioning of the internal market in products of animal origin, thus contributing to the achievement of the objectives of the common agricultural policy.

(10) It is necessary to maintain and, where required to ensure consumer protection, to tighten detailed hygiene rules for products of animal origin.

(11) Community rules should not apply either to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption. Moreover, where small quantities of primary products or of certain types of meat are supplied directly by the food business operator producing them to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer.

(12) The requirements of Regulation (EC) No 852/2004 are generally sufficient to ensure food safety in establishments carrying out retail activities involving the direct sale or supply of food of animal origin to the final consumer. This Regulation should generally apply to wholesale activities (that is, when a retail establishment carries out operations with a view to supplying food of animal origin to another establishment). Nevertheless, with the exception of the specific temperature requirements laid down in this Regulation, the requirements of Regulation (EC) No 852/2004 should suffice for wholesale activities consisting only of storage or transport.

(13) Member States should have some discretion to extend or to limit the application of the requirements of this Regulation to retail under national law. However, they may limit their application only if they consider that the requirements of Regulation (EC) No 852/2004 are sufficient to achieve food hygiene objectives and when the supply of food of animal origin from a retail establishment to another establishment is a marginal, localised and restricted activity. Such supply should therefore be only a small part of the establishment's business; the establishments supplied should be situated in its immediate vicinity; and the supply should concern only certain types of products or establishments.

(14) In accordance with Article 10 of the Treaty, Member States are to take all appropriate measures to ensure that food business operators comply with the obligations laid down in this Regulation.

(15) The traceability of food is an essential element in ensuring food safety. In addition to complying with the general rules of Regulation (EC) No 178/2002 [1], food business operators responsible for establishments that are subject to approval in accordance with this Regulation should ensure that all products of animal origin that they place on the market bear either a health mark or an identification mark.

(16) Food imported into the Community is to comply with the general requirements laid down in Regulation (EC) No 178/2002 or to satisfy rules that are equivalent to Community rules. This Regulation defines specific hygiene requirements for food of animal origin imported into the Community.

(17) The adoption of this Regulation should not reduce the level of protection provided by the additional guarantees agreed for Finland and Sweden on their accession to the Community and confirmed by Commission Decisions 94/968/EC [2], 95/50/EC [3], 95/160/EC [4], 95/161/E [5] and 95/168/EC [6], and Council Decisions 95/409/EC [7], 95/410/EC [8] and 95/411/EC [9]. It should establish a procedure for the granting, for a transitional period, of guarantees to any Member State that has an approved national control programme which, for the food of animal origin concerned, is equivalent to those approved for Finland and Sweden. Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents [10] provides for a similar procedure in respect of live animals and hatching eggs.

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[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1). Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

[2] OJ L 371, 31.12.1994, p. 36.

[3] OJ L 53, 9.3.1995, p. 31.

[4] OJ L 105 9.5.1995, p. 40.

[5] OJ L 105, 9.5.1995, p. 44.

[6] OJ L 109, 16.5.1995, p. 44.

[7] OJ L 243, 11.10.1995, p. 21.

[8] OJ L 243, 11.10.1995, p. 25.

[9] OJ L 243, 11.10.1995, p. 29.

[10] OJ L 325, 12.12.2003, p. 1.

(18) It is appropriate for the structural and hygiene requirements laid down in this Regulation to apply to all types of establishments, including small businesses and mobile slaughterhouses.

(19) Flexibility is appropriate to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food and in relation to structural requirements for establishments. Flexibility is particularly important for regions that are subject to special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty. However, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will normally be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. It should provide, where necessary to resolve disagreements, for discussion within the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002 and for the Commission to coordinate the process and take appropriate measures.

(20) The definition of mechanically separated meat (MSM) should be a generic one covering all methods of mechanical separation. Rapid technological developments in this area mean that a flexible definition is appropriate. The technical requirements for MSM should differ, however, depending on a risk assessment of the product resulting from different methods.

(21) There are interactions between food business operators, including the animal feed sector, and connections between animal health, animal welfare and public health considerations at all stages of production, processing and distribution. This requires adequate communication between the different stakeholders along the food chain from primary production to retail.

(22) In order to ensure proper inspection of hunted wild game placed on the Community market, bodies of hunted animals and their viscera should be presented for official post-mortem inspection at a game-handling establishment. However, to preserve certain hunting traditions without prejudicing food safety, it is appropriate to provide for training for hunters who place wild game on the market for human consumption. This should enable hunters to undertake an initial examination of wild game on the spot. In these circumstances, it is not necessary to require trained hunters to deliver all viscera to the game-handling establishment for post-mortem examination, if they carry out this initial examination and identify no anomalies or hazards. However, Member States should be allowed to establish stricter rules within their territories to take account of specific risks.

(23) This Regulation should establish criteria for raw milk pending the adoption of new requirements for its placing on the market. These criteria should be trigger values, implying that, in the event of any overshooting, food business operators are to take corrective action and to notify the competent authority. The criteria should not be maximum figures beyond which raw milk cannot be placed on the market. This implies that, in certain circumstances, raw milk not fully meeting the criteria can safely be used for human consumption, if appropriate measures are taken. As regards raw milk and raw cream intended for direct human consumption, it is appropriate to enable each Member State to maintain or establish appropriate health measures to ensure the achievement of the objectives of this Regulation on its territory.

(24) It is appropriate for the criterion for raw milk used to manufacture dairy products to be three times as high as the criterion for raw milk collected from the farm. The criterion for milk used to manufacture processed dairy products is an absolute value, whereas for raw milk collected from the farm it is an average. Compliance with the temperature requirements laid down in this Regulation will not halt all bacterial growth during transport and storage.

(25) The present recasting means that the existing hygiene rules can be repealed. Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives on food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption [1] achieves this.

(26) In addition, the rules of this Regulation on eggs replace those of Council Decision 94/371/EC of 20 June 1994 laying down specific public health conditions for the putting on the market of certain types of eggs [2], which the repeal of Annex II to Council Directive 92/118/EEC [3] renders void.

(27) Scientific advice should underpin Community legislation on food hygiene. To this end, the European Food Safety Authority should be consulted whenever necessary.

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[1] OJ L 157, 30.4.2004, p. 33.

[2] OJ L 168, 2.7.1994, p. 34.

[3] Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC (OJ L 62, 15.3.1993, p. 49). Directive as last amended by Commission Regulation (EC) No 445/2004 (OJ L 72, 11.3.2004, p. 60).

(28) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee on the Food Chain and Animal Health.

(29) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow the industries affected time to adapt.

(30) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down specific rules on the hygiene of food of animal origin for food business operators. These rules supplement those laid down by Regulation (EC) No 852/2004. They shall apply to unprocessed and processed products of animal origin.

2. Unless expressly indicated to the contrary, this Regulation shall not apply to food containing both products of plant origin and processed products of animal origin. However, processed products of animal origin used to prepare such food shall be obtained and handled in accordance with the requirements of this Regulation.

3. This Regulation shall not apply in relation to:

(a) primary production for private domestic use;

(b) the domestic preparation, handling or storage of food for private domestic consumption;

(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer;

(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;

(e) hunters who supply small quantities of wild game or wild game meat directly to the final consumer or to local retail establishments directly supplying the final consumer.

4. Member States shall establish, according to national law, rules governing the activities and persons referred to in paragraph 3(c), (d) and (e). Such national rules shall ensure the achievement of the objectives of this Regulation.

5. (a) Unless expressly indicated to the contrary, this Regulation shall not apply to retail.

(b) However, this Regulation shall apply to retail when operations are carried out with a view to the supply of food of animal origin to another establishment, unless:

(i) the operations consist only of storage or transport, in which case the specific temperature requirements laid down in Annex III shall nevertheless apply;

or

(ii) the supply of food of animal origin from the retail establishment is to other retail establishments only and, in accordance with national law, is a marginal, localised and restricted activity.

(c) Member States may adopt national measures to apply the requirements of this Regulation to retail establishments situated on their territory to which it would not apply pursuant to subparagraphs (a) or (b).

6. This Regulation shall apply without prejudice to:

(a) relevant animal and public health rules, including more stringent rules laid down for the prevention, control and eradication of certain transmissible spongiform encephalopathies;

(b) animal welfare requirements;

and

(c) requirements concerning the identification of animals and the traceability of products of animal origin.

[1] OJ L 184, 17.7.1999, p. 23.

Article 2

Definitions

The following definitions shall apply for the purposes of this Regulation:

1. the definitions laid down in Regulation (EC) No 178/2002;

2. the definitions laid down in Regulation (EC) No 852/2004;

3. the definitions laid down in Annex I;

and

4. any technical definitions contained in Annexes II and III.

CHAPTER II

FOOD BUSINESS OPERATORS' OBLIGATIONS

Article 3

General obligations

1. Food business operators shall comply with the relevant provisions of Annexes II and III.

2. Food business operators shall not use any substance other than potable water — or, when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water — to remove surface contamination from products of animal origin, unless use of the substance has been approved in accordance with the procedure referred to in Article 12(2). Food business operators shall also comply with any conditions for use that may be adopted under the same procedure. The use of an approved substance shall not affect the food business operator's duty to comply with the requirements of this Regulation.

Article 4

Registration and approval of establishments

1. Food business operators shall place products of animal origin manufactured in the Community on the market only if they have been prepared and handled exclusively in establishments:

(a) that meet the relevant requirements of Regulation (EC) No 852/2004, those of Annexes II and III of this Regulation and other relevant requirements of food law;

and

(b) that the competent authority has registered or, where required in accordance with paragraph 2, approved.

2. Without prejudice to Article 6(3) of Regulation (EC) No 852/2004, establishments handling those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them in accordance with paragraph 3 of this Article, with the exception of establishments carrying out only:

(a) primary production;

(b) transport operations;

(c) the storage of products not requiring temperature-controlled storage conditions;

or

(d) retail operations other than those to which this Regulation applies pursuant to Article 1(5)(b).

3. An establishment subject to approval in accordance with paragraph 2 shall not operate unless the competent authority has, in accordance with Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption [1]:

(a) granted the establishment approval to operate following an on-site visit;

or

(b) provided the establishment with conditional approval.

4. Food business operators shall cooperate with the competent authorities in accordance with Regulation (EC) No 854/2004. In particular, food business operators shall ensure that an establishment ceases to operate if the competent authority withdraws its approval or, in the case of conditional approval, fails to prolong it or to grant full approval.

5. This Article shall not prevent an establishment from placing food on the market between the date of application of this Regulation and the first subsequent inspection by the competent authority, if the establishment:

(a) is subject to approval in accordance with paragraph 2 and placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation;

or

(b) is of a type in respect of which there was no requirement for approval before the application of this Regulation.

[1] See page 83 of this Official Journal.

Article 5

Health and identification marking

1. Food business operators shall not place on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) unless it has either:

(a) a health mark applied in accordance with Regulation (EC) No 854/2004;

or

(b) when that Regulation does not provide for the application of a health mark, an identification mark applied in accordance with Annex II, Section I, of this Regulation.

2. Food business operators may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with this Regulation in establishments meeting the requirements of Article 4.

3. Food business operators may not remove a health mark applied in accordance with Regulation (EC) No 854/2004 from meat unless they cut or process it or work upon it in another manner.

Article 6

Products of animal origin from outside the Community

1. Food business operators importing products of animal origin from third countries shall ensure that importation takes place only if:

(a) the third country of dispatch appears on a list, drawn up in accordance with Article 11 of Regulation (EC) No 854/2004, of third countries from which imports of that product are permitted;

(b) (i) the establishment from which that product was dispatched, and in which it was obtained or prepared, appears on a list, drawn up in accordance with Article 12 of Regulation (EC) No 854/2004, of establishments from which imports of that product are permitted, when applicable,

(ii) in the case of fresh meat, minced meat, meat preparations, meat products and MSM, the product was manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with Article 12 of Regulation (EC) No 854/2004 or in approved Community establishments,

and

(iii) in the case of live bivalve molluscs, echinoderms, tunicates and marine gastropods, the production area appears on a list drawn up in accordance with Article 13 of that Regulation, when applicable;

(c) the product satisfies:

(i) the requirements of this Regulation, including the requirements of Article 5 on health and identification marking;

(ii) the requirements of Regulation (EC) No 852/2004;

and

(iii) any import conditions laid down in accordance with Community legislation governing import controls for products of animal origin,

and

(d) the requirements of Article 14 of Regulation (EC) No 854/2004 concerning certificates and documents are satisfied, when applicable.

2. By way of derogation from paragraph 1, the importation of fishery products may also take place in accordance with the special provisions laid down in Article 15 of Regulation (EC) No 854/2004.

3. Food business operators importing products of animal origin shall ensure that:

(a) products are made available for control upon importation in accordance with Directive 97/78/EC [1];

(b) importation complies with the requirements of Directive 2002/99/EC [2];

and

(c) operations under their control that take place after importation are carried out in accordance with the requirements of Annex III.

4. Food business operators importing food containing both products of plant origin and processed products of animal origin shall ensure that the processed products of animal origin contained in such food satisfy the requirements of paragraphs 1 to 3. They must be able to demonstrate that they have done so (for example, through appropriate documentation or certification, which need not be in the format specified in paragraph 1(d)).

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[1] Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9). Directive amended by the 2003 Act of Accession.

[2] Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11).

CHAPTER III

TRADE

Article 7

Documents

1. When required in accordance with Annex II or III, food business operators shall ensure that certificates or other documents accompany consignments of products of animal origin.

2. In accordance with the procedure referred to in Article 12(2):

(a) model documents may be established;

and

(b) provision may be made for the use of electronic documents.

Article 8

Special guarantees

1. Food business operators intending to place the following food of animal origin on the market in Sweden or Finland shall comply with the rules set out in paragraph 2 in respect of salmonella:

(a) meat from bovine and porcine animals, including minced meat but excluding meat preparations and MSM;

(b) meat from poultry of the following species: domestic fowl, turkeys, guinea-fowl, ducks and geese, including minced meat but excluding meat preparations and MSM;

and

(c) eggs.

2. (a) In the case of meat from bovine and porcine animals and meat from poultry, samples of consignments shall have been taken in the dispatching establishment and been subjected to a microbiological test with negative results in accordance with Community legislation.

(b) In the case of eggs, packing centres shall provide a guarantee that consignments originate from flocks that have been subjected to a microbiological test with negative results in accordance with Community legislation.

(c) In the case of meat from bovine and porcine animals, the test provided for in subparagraph (a) need not be carried out for consignments intended for an establishment for the purposes of pasteurisation, sterilisation or treatment having a similar effect. In the case of eggs, the test provided for in subparagraph (b) need not be carried out for consignments intended for the manufacture of processed products by a process that guarantees the elimination of salmonella.

(d) The tests provided for in subparagraphs (a) and (b) need not be carried out for foodstuffs originating in an establishment that is subject to a control programme recognised, in respect of the food of animal origin concerned and in accordance with the procedure referred to in Article 12(2), as equivalent to that approved for Sweden and Finland.

(e) In the case of meat from bovine and porcine animals and meat from poultry, a trade document or certificate conforming to a model laid down by Community legislation shall accompany the food and state that:

(i) the checks referred to in subparagraph (a) have been carried out with negative results;

or

(ii) the meat is intended for one of the purposes referred to in subparagraph (c);

or

(iii) the meat comes from an establishment covered by subparagraph (d).

(f) In the case of eggs, a certificate stating that the tests referred to in subparagraph (b) have been carried out with negative results, or that the eggs are destined to be used in the manner referred to in subparagraph (c), must accompany consignments.

3. In accordance with the procedure referred to in Article 12(2):

(a) the requirements of paragraphs 1 and 2 may be updated to take account in particular of changes to Member States' control programmes or the adoption of microbiological criteria in accordance with Regulation (EC) No 852/2004;

and

(b) the rules laid down in paragraph 2 in respect of any of the foodstuffs referred to in paragraph 1 may be extended, in whole or in part, to any Member State, or any region of a Member State, that has a control programme recognised as equivalent to that approved for Sweden and Finland in respect of the food of animal origin concerned.

4. For the purposes of this Article, 'control programme' means a control programme approved in accordance with Regulation (EC) No 2160/2003.

CHAPTER IV

FINAL PROVISIONS

Article 9

Implementing measures and transitional measures

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 12(2).

Article 10

Amendment and adaptation of Annexes II and III

1. Annexes II and III may be adapted or updated in accordance with the procedure referred to in Article 12(2), taking into account:

(a) the development of guides to good practice;

(b) the experience gained from the implementation of HACCP-based systems pursuant to Article 5 of Regulation (EC) No 852/2004;

(c) the technological developments and their practical consequences and consumer expectations with regard to food composition;

(d) scientific advice, particularly new risk assessments;

(e) microbiological and temperature criteria for foodstuffs;

(f) changes in patterns of consumption.

2. Exemptions from Annex II and III may be granted in accordance with the procedure referred to in Article 12(2), provided that they do not affect the achievement of the objectives of this Regulation.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 8, national measures adapting the requirements laid down in Annex III.

4. (a) The national measures referred to in paragraph 3 shall have the aim of:

(i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;

or

(ii) accommodating the needs of food businesses situated in regions that are subject to special geographic constraints.

(b) In other cases, they shall apply only to the construction, layout and equipment of establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:

(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the foodstuffs and establishments concerned;

(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

(d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. In the case of adaptations arising from paragraph 4(b), this period shall, at the request of any Member State, be extended to four months. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 12(1). The Commission may decide, in accordance with the procedure referred to in Article 12(2), whether the envisaged measures may be implemented, subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraph 1 or 2 of this Article.

7. A Member State may adopt national measures adapting the requirements of Annex III only:

(a) in compliance with a decision adopted in accordance with paragraph 6;

(b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6;

or

(c) in accordance with paragraph 8.

8. A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:

(a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption;

or

(b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.

Article 11

Specific decisions

Without prejudice to the generality of Article 9 and Article 10(1), implementing measures may be laid down, or amendments to Annex II or III adopted, in accordance with the procedure referred to in Article 12(2):

1. to lay down rules for the transport of meat while it is warm;

2. to specify, in respect of MSM, which calcium content is not significantly higher than that of minced meat;

3. to lay down other treatments that may be applied in a processing establishment to live bivalve molluscs from class B or C production areas that have not been submitted to purification or relaying;

4. to specify recognised testing methods for marine biotoxins;

5. to lay down additional health standards for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:

   (a) limit values and analysis methods for other marine biotoxins;

   (b) virus testing procedures and virological standards;

   and

   (c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards;

6. to lay down health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;

7. to extend Annex III, Section VII, Chapter IX, to live bivalve molluscs other than pectinidae;

8. to specify criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D;

9. to lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products;

10. to permit the use for the manufacture of certain dairy products of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards its plate count and somatic cell count;

11. without prejudice to Directive 96/23/EC [1], to fix a maximum permitted value for the combined total of residues of antibiotic substances in raw milk;

    and

12. to approve equivalent processes for the production of gelatine or collagen.

Article 12

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

[1] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

Article 13

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter falling within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing to extend Annex III, Section III, to other animal species.

Article 14

Report to the European Parliament and to the Council

1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council reviewing the experience gained from the implementation of this Regulation.

2. The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 15

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply 18 months after the date on which all of the following acts have entered into force:

(a) Regulation (EC) No 852/2004;

(b) Regulation (EC) No 854/2004;

and

(c) Directive 2004/41/EC.

However, it shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
M. McDOWELL

ANNEX I

DEFINITIONS

For the purpose of this Regulation:

1. MEAT

1.1. 'Meat' means edible parts of the animals referred to in points 1.2 to 1.8, including blood.

1.2. 'Domestic ungulates' means domestic bovine (including *Bubalus* and Bison species), porcine, ovine and caprine animals, and domestic solipeds.

1.3. 'Poultry' means farmed birds, including birds that are not considered as domestic but which are farmed as domestic animals, with the exception of ratites.

1.4. 'Lagomorphs' means rabbits, hares and rodents.

1.5. 'Wild game' means:

— wild ungulates and lagomorphs, as well as other land mammals that are hunted for human consumption and are considered to be wild game under the applicable law in the Member State concerned, including mammals living in enclosed territory under conditions of freedom similar to those of wild game;

and

— wild birds that are hunted for human consumption.

1.6. 'Farmed game' means farmed ratites and farmed land mammals other than those referred to in point 1.2.

1.7. 'Small wild game' means wild game birds and lagomorphs living freely in the wild.

1.8. 'Large wild game' means wild land mammals living freely in the wild that do not fall within the definition of small wild game.

1.9. 'Carcase' means the body of an animal after slaughter and dressing.

1.10. 'Fresh meat' means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere.

1.11. 'Offal' means fresh meat other than that of the carcase, including viscera and blood.

1.12. 'Viscera' means the organs of the thoracic, abdominal and pelvic cavities, as well as the trachea and oesophagus and, in birds, the crop.

1.13. 'Minced meat' means boned meat that has been minced into fragments and contains less than 1 % salt.

1.14. 'Mechanically separated meat' or 'MSM' means the product obtained by removing meat from flesh-bearing bones after boning or from poultry carcases, using mechanical means resulting in the loss or modification of the muscle fibre structure.

1.15. 'Meat preparations' means fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.

1.16. 'Slaughterhouse' means an establishment used for slaughtering and dressing animals, the meat of which is intended for human consumption.

1.17. 'Cutting plant' means an establishment used for boning and/or cutting up meat.

1.18. 'Game-handling establishment' means any establishment in which game and game meat obtained after hunting are prepared for placing on the market.

2. LIVE BIVALVE MOLLUSCS

2.1. 'Bivalve molluscs' means filter-feeding lamellibranch molluscs.

2.2. 'Marine biotoxins' means poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins.

2.3. 'Conditioning' means the storage of live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packaging.

2.4. 'Gatherer' means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market.

2.5. 'Production area' means any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken.

2.6. 'Relaying area' means any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs.

2.7. 'Dispatch centre' means any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption.

2.8. 'Purification centre' means an establishment with tanks fed by clean seawater in which live bivalve molluscs are placed for the time necessary to reduce contamination to make them fit for human consumption.

2.9. 'Relaying' means the transfer of live bivalve molluscs to sea, lagoon or estuarine areas for the time necessary to reduce contamination to make them fit for human consumption. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening.

3. FISHERY PRODUCTS

3.1. 'Fishery products' means all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals.

3.2. 'Factory vessel' means any vessel on board which fishery products undergo one or more of the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing.

3.3. 'Freezer vessel' means any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging.

3.4. 'Mechanically separated fishery product' means any product obtained by removing flesh from fishery products using mechanical means resulting in the loss or modification of the flesh structure.

3.5. 'Fresh fishery products' means unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling.

3.6. 'Prepared fishery products' means unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting, and chopping.

4. MILK

4.1. 'Raw milk' means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect.

4.2. 'Milk production holding' means an establishment where one or more farmed animals are kept to produce milk with a view to placing it on the market as food.

5. EGGS

5.1. 'Eggs' means eggs in shell — other than broken, incubated or cooked eggs — that are produced by farmed birds and are fit for direct human consumption or for the preparation of egg products.

5.2. 'Liquid egg' means unprocessed egg contents after removal of the shell.

5.3. 'Cracked eggs' means eggs with damaged shell and intact membranes.

5.4. 'Packing centre' means an establishment where eggs are graded by quality and weight.

6. FROGS' LEGS AND SNAILS

6.1. 'Frogs' legs' means the posterior part of the body divided by a transverse cut behind the front limbs, eviscerated and skinned, of the species RNA (family Ranidae).

6.2. 'Snails' means terrestrial gastropods of the species *Helix pomatiaLinné, Helix aspersaMuller, Helix lucorum* and species of the family Achatinidae.

7. PROCESSED PRODUCTS

7.1. 'Meat products' means processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat.

7.2. 'Dairy products' means processed products resulting from the processing of raw milk or from the further processing of such processed products.

7.3. 'Egg products' means processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products.

7.4. 'Processed fishery products' means processed products resulting from the processing of fishery products or from the further processing of such processed products.

7.5. 'Rendered animal fat' means fat derived from rendering meat, including bones, and intended for human consumption.

7.6. 'Greaves' means the protein-containing residue of rendering, after partial separation of fat and water.

7.7. 'Gelatine' means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals.

7.8. 'Collagen' means the protein-based product derived from animal bones, hides, skins and tendons manufactured in accordance with the relevant requirements of this Regulation.

7.9. 'Treated stomachs, bladders and intestines' means stomachs, bladders and intestines that have been submitted to a treatment such as salting, heating or drying after they have been obtained and after cleaning.

8. OTHER DEFINITIONS

8.1. 'Products of animal origin' means:

— food of animal origin, including honey and blood;

— live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption;

and

— other animals destined to be prepared with a view to being supplied live to the final consumer.

8.2. 'Wholesale market' means a food business that includes several separate units which share common installations and sections where foodstuffs are sold to food business operators.

ANNEX II

REQUIREMENTS CONCERNING SEVERAL PRODUCTS OF ANIMAL ORIGIN

SECTION I: IDENTIFICATION MARKING

When required in accordance with Article 5 or 6, and subject to the provisions of Annex III, food business operators must ensure that products of animal origin have an identification mark applied in compliance with the following provisions.

A. APPLICATION OF THE IDENTIFICATION MARK

1. The identification mark must be applied before the product leaves the establishment.

2. However, a new mark need not be applied to a product unless its packaging and/or wrapping is removed or it is further processed in another establishment, in which case the new mark must indicate the approval number of the establishment where these operations take place.

3. An identification mark is not necessary for eggs in respect of which Regulation (EC) No 1907/90 [1] lays down requirements concerning labelling or marking.

4. Food business operators must, in accordance with Article 18 of Regulation (EC) No 178/2002, have in place systems and procedures to identify food business operators from whom they have received and to whom they have delivered products of animal origin.

B. FORM OF THE IDENTIFICATION MARK

5. The mark must be legible and indelible, and the characters easily decipherable. It must be clearly displayed for the competent authorities.

6. The mark must indicate the name of the country in which the establishment is located, which may be written out in full or shown as a two-letter code in accordance with the relevant ISO standard.

   In the case of Member States, however, these codes are AT, BE, DE, DK, ES, FI, FR, GR, IE, IT, LU, NL, PT, SE and UK.

   Food business operators may continue to use stocks and equipment that they ordered before the entry into force of this Regulation until they are exhausted or require replacement.

7. The mark must indicate the approval number of the establishment. If an establishment manufactures both food to which this Regulation applies and food to which it does not, the food business operator may apply the same identification mark to both types of food.

8. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK or EY.

C. METHOD OF MARKING

9. The mark may, depending on the presentation of different products of animal origin, be applied directly to the product, the wrapping or the packaging, or be printed on a label affixed to the product, the wrapping or the packaging. The mark may also be an irremovable tag made of a resistant material.

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[1] Council Regulation (EEC) No 1907/90 of 26 June 1990 on certain marketing standards for eggs (OJ L 173, 6.7.1990, p. 5). Regulation as last amended by Regulation (EC) No 2052/2003 (OJ L 305, 22.11.2003, p. 1).

10. In the case of packaging containing cut meat or offal, the mark must be applied to a label fixed to the packaging, or printed on the packaging, in such a way that it is destroyed when the packaging is opened. This is not necessary, however, if the process of opening destroys the packaging. When wrapping provides the same protection as packaging, the label may be affixed to the wrapping.

11. For products of animal origin that are placed in transport containers or large packages and are intended for further handling, processing, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container or packaging.

12. In the case of liquid, granulate and powdered products of animal origin carried in bulk, and fishery products carried in bulk, an identification mark is not necessary if accompanying documentation contains the information specified in points 6, 7 and, where appropriate, 8.

13. When products of animal origin are placed in a package destined for direct supply to the final consumer, it is sufficient to apply the mark to the exterior of that package only.

14. When the mark is applied directly to products of animal origin, the colours used must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs.

SECTION II: OBJECTIVES OF HACCP-BASED PROCEDURES

1. Food business operators operating slaughterhouses must ensure that the procedures that they have put in place in accordance with the general requirements of Article 5 of Regulation (EC) No 852/2004 meet the requirements that the hazard analysis shows to be necessary and the specific requirements listed in point 2.

2. The procedures must guarantee that each animal or, where appropriate, each lot of animals accepted onto the slaughterhouse premises:

(a) is properly identified;

(b) is accompanied by the relevant information from the holding of provenance referred to in Section III;

(c) does not come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits;

(d) is clean;

(e) is healthy, as far as the food business operator can judge;

and

(f) is in a satisfactory state as regards welfare on arrival at the slaughterhouse.

3. In the event of failure to comply with any of the requirements listed under point 2, the food business operator must notify the official veterinarian and take appropriate measures.

SECTION III: FOOD CHAIN INFORMATION

Food business operators operating slaughterhouses must, as appropriate, request, receive, check and act upon food chain information as set out in this Section in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse.

1. Slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have requested and been provided with relevant food safety information contained in the records kept at the holding of provenance in accordance with Regulation (EC) No 852/2004.

2. Slaughterhouse operators must be provided with the information no less than 24 hours before the arrival of animals at the slaughterhouse, except in the circumstances mentioned in point 7.

3. The relevant food safety information referred to in point 1 is to cover, in particular:

(a) the status of the holding of provenance or the regional animal health status;

(b) the animals' health status;

(c) veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods;

(d) the occurrence of diseases that may affect the safety of meat;

(e) the results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including samples taken in the framework of the monitoring and control of zoonoses and residues;

(f) relevant reports about previous *ante-* and *post-mortem* inspections of animals from the same holding of provenance including, in particular, reports from the official veterinarian;

(g) production data, when this might indicate the presence of disease;

and

(h) the name and address of the private veterinarian normally attending the holding of provenance.

4. (a) However, it is not necessary for the slaughterhouse operator to be provided with:

(i) the information referred to in point 3(a), (b), (f) and (h), if the operator is already aware of this information (for example, through a standing arrangement or a quality assurance scheme);

or

(ii) the information referred to in point 3(a), (b), (f) and (g), if the producer declares that there is no relevant information to report.

(b) The information need not be provided as a verbatim extract from the records of the holding of provenance. It may be provided through electronic data exchange or in the form of a standardised declaration signed by the producer.

5. Food business operators deciding to accept animals onto the slaughterhouse premises after evaluating the relevant food chain information must make it available to the official veterinarian without delay and, except in the circumstances mentioned in point 7, no less than 24 hours before the arrival of the animal or lot. The food business operator must notify the official veterinarian of any information that gives rise to health concerns before *ante-mortem* inspection of the animal concerned.

6. If any animal arrives at the slaughterhouse without food chain information, the operator must immediately notify the official veterinarian. Slaughter of the animal may not take place until the official veterinarian so permits.

7. If the competent authority so permits, food chain information may accompany the animals to which it relates to the slaughterhouse, rather than arriving at least 24 hours in advance, in the case of:

(a) porcine animals, poultry or farmed game that have undergone *ante-mortem* inspection at the holding of provenance, if a certificate that the veterinarian has signed stating that he or she examined the animals at the holding and found them to be healthy accompanies them;

(b) domestic solipeds;

(c) animals that have undergone emergency slaughter, if a declaration, that the veterinarian has signed recording the favourable outcome of the ante-mortem inspection accompanies them;

and

(d) animals that are not delivered directly from the holding of provenance to the slaughterhouse.

Slaughterhouse operators must evaluate the relevant information. If they accept the animals for slaughter, they must give the documents mentioned in subparagraphs (a) and (c) to the official veterinarian. Slaughter or dressing of the animals may not take place until the official veterinarian so permits.

8. Food business operators must check passports accompanying domestic solipeds to ensure that the animal is intended for slaughter for human consumption. If they accept the animal for slaughter, they must give the passport to the official veterinarian.

ANNEX III

SPECIFIC REQUIREMENTS

SECTION I: MEAT OF DOMESTIC UNGULATES

CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE

Food business operators transporting live animals to slaughterhouses must ensure compliance with the following requirements.

1. During collection and transport, animals must be handled carefully without causing unnecessary distress.

2. Animals showing symptoms of disease or originating in herds known to be contaminated with agents of public health importance may only be transported to the slaughterhouse when the competent authority so permits.

CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which domestic ungulates are slaughtered meet the following requirements.

1. (a) Slaughterhouses must have adequate and hygienic lairage facilities or, climate permitting, waiting pens that are easy to clean and disinfect. These facilities must be equipped for watering the animals and, if necessary, feeding them. The drainage of the wastewater must not compromise food safety.

   (b) They must also have separate lockable facilities or, climate permitting, pens for sick or suspect animals with separate draining and sited in such a way as to avoid contamination of other animals, unless the competent authority considers that such facilities are unnecessary.

   (c) The size of the lairage facilities must ensure that the welfare of the animals is respected. Their layout must facilitate ante-mortem inspections, including the identification of the animals or groups of animals.

2. To avoid contaminating meat, they must:

   (a) have a sufficient number of rooms, appropriate to the operations being carried out;

   (b) have a separate room for the emptying and cleaning of stomachs and intestines, unless the competent authority authorises the separation in time of these operations within a specific slaughterhouse on a case-by-case basis;

   (c) ensure separation in space or time of the following operations:

      (i) stunning and bleeding;

      (ii) in the case of porcine animals, scalding, depilation, scraping and singeing;

      (iii) evisceration and further dressing;

      (iv) handling clean guts and tripe;

      (v) preparation and cleaning of other offal, particularly the handling of skinned heads if it does not take place at the slaughter line;

      (vi) packaging offal;

      and

      (vii) dispatching meat;

(d) have installations that prevent contact between the meat and the floors, walls and fixtures;

and

(e) have slaughter lines (where operated) that are designed to allow constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.

5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock. However, slaughterhouses need not have these places and facilities if the competent authority so permits and official authorised places and facilities exist nearby.

7. They must have lockable facilities reserved for the slaughter of sick and suspect animals. This is not essential if this slaughter takes place in other establishments authorised by the competent authority for this purpose, or at the end of the normal slaughter period.

8. If manure or digestive tract content is stored in the slaughterhouse, there must be a special area or place for that purpose.

9. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS

Food business operators must ensure that cutting plants handling meat of domestic ungulates:

1. are constructed so as to avoid contamination of meat, in particular by:

(a) allowing constant progress of the operations;

or

(b) ensuring separation between the different production batches;

2. have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;

3. have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;

4. have equipment for washing hands with taps designed to prevent the spread of contamination, for use by staff engaged in handling exposed meat;

and

5. have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

CHAPTER IV: SLAUGHTER HYGIENE

Food business operators operating slaughterhouses in which domestic ungulates are slaughtered must ensure compliance with the following requirements.

1. After arrival in the slaughterhouse, the slaughter of the animals must not be unduly delayed. However, where required for welfare reasons, animals must be given a resting period before slaughter.

2. (a) Meat from animals other than those referred to in subparagraphs (b) and (c) must not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse.

   (b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:

      (i) animals that have undergone emergency slaughter outside the slaughterhouse in accordance with Chapter VI;

      (ii) animals slaughtered at the place of production in accordance with Section III;

      and

      (iii) wild game, in compliance with Section IV, Chapter II.

   (c) Meat from animals that undergo slaughter following an accident in a slaughterhouse may be used for human consumption if, on inspection, no serious lesions other than those due to the accident are found.

3. The animals or, where appropriate, each batch of animals sent for slaughter must be identified so that their origin can be traced.

4. Animals must be clean.

5. Slaughterhouse operators must follow the instructions of the veterinarian appointed by the competent authority in accordance with Regulation (EC) No 854/2004 to ensure that ante-mortem inspection of every animal to be slaughtered is carried out under suitable conditions.

6. Animals brought into the slaughter hall must be slaughtered without undue delay.

7. Stunning, bleeding, skinning, evisceration and other dressing must be carried out without undue delay and in a manner that avoids contaminating the meat. In particular:

   (a) the trachea and oesophagus must remain intact during bleeding, except in the case of slaughter according to a religious custom;

   (b) during the removal of hides and fleece:

      (i) contact between the outside of the skin and the carcase must be prevented;

      and

      (ii) operators and equipment coming into contact with the outer surface of hides and fleece must not touch the meat;

   (c) measures must be taken to prevent the spillage of digestive tract content during and after evisceration and to ensure that evisceration is completed as soon as possible after stunning;

   and

   (d) removal of the udder must not result in contamination of the carcase with milk or colostrum.

8. Complete skinning of the carcase and other parts of the body intended for human consumption must be carried out, except for porcine animals and the heads and feet of ovine and caprine animals and calves. Heads and feet must be handled so as to avoid contamination of other meat.

9. When not skinned, porcine animals must have their bristles removed immediately. The risk of contamination of the meat with scalding water must be minimised. Only approved additives may be used for this operation. Porcine animals must be thoroughly rinsed afterwards with potable water.

10. The carcases must not contain visible faecal contamination. Any visible contamination must be removed without delay by trimming or alternative means having an equivalent effect.

11. Carcases and offal must not come into contact with floors, walls or work stands.

12. Slaughterhouse operators must follow the instructions of the competent authority to ensure that post-mortem inspection of all slaughtered animals is carried out under suitable conditions in accordance with Regulation (EC) No 854/2004.

13. Until post-mortem inspection is completed, parts of a slaughtered animal subject to such inspection must:

(a) remain identifiable as belonging to a given carcase;

and

(b) come into contact with no other carcase, offal or viscera, including those that have already undergone post-mortem inspection.

However, provided that it shows no pathological lesion, the penis may be discarded immediately.

14. Both kidneys must be removed from their fatty covering. In the case of bovine and porcine animals, and solipeds, the peri-renal capsule must also be removed.

15. If the blood or other offal of several animals is collected in the same container before completion of post-mortem inspection, the entire contents must be declared unfit for human consumption if the carcase of one or more of the animals concerned has been declared unfit for human consumption.

16. After post-mortem inspection:

(a) the tonsils of bovine animals and solipeds must be removed hygienically;

(b) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;

(c) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption;

and

(d) viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely and as soon as possible, unless the competent authority authorises otherwise.

17. After completion of slaughter and post-mortem inspection, the meat must be stored in accordance with the requirements laid down in Chapter VII.

18. When destined for further handling:

(a) stomachs must be scalded or cleaned;

(b) intestines must be emptied and cleaned;

and

(c) heads and feet must be skinned or scalded and depilated.

19. Where establishments are approved for the slaughter of different animal species or for the handling of carcases of farmed game and wild game, precautions must be taken to prevent cross-contamination by separation either in time or in space of operations carried out on the different species. Separate facilities for the reception and storage of unskinned carcases of farmed game slaughtered at the farm and for wild game must be available.

20. If the slaughterhouse does not have lockable facilities reserved for the slaughter of sick or suspect animals, the facilities used to slaughter such animals must be cleaned, washed and disinfected under official supervision before the slaughter of other animals is resumed.

CHAPTER V: HYGIENE DURING CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of domestic ungulates takes place in accordance with the following requirements.

1. Carcases of domestic ungulates may be cut into half-carcases or quarters, and half carcases into no more than three wholesale cuts, in slaughterhouses. Further cutting and boning must be carried out in a cutting plant.

2. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:

   (a) meat intended for cutting is brought into the workrooms progressively as needed;

   (b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the meat is maintained at not more than 3 °C for offal and 7 °C for other meat, by means of an ambient temperature of not more than 12 °C or an alternative system having an equivalent effect;

   and

   (c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

3. However, meat may be boned and cut before it reaches the temperature referred to in point 2(b) in accordance with Chapter VII, point 3.

4. Meat may also be boned and cut prior to reaching the temperature referred to in point 2(b) when the cutting room is on the same site as the slaughter premises. In this case, the meat must be transferred to the cutting room either directly from the slaughter premises or after a waiting period in a chilling or refrigerating room. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 2(b).

CHAPTER VI: EMERGENCY SLAUGHTER OUTSIDE THE SLAUGHTERHOUSE

Food business operators must ensure that meat from domestic ungulates that have undergone emergency slaughter outside the slaughterhouse may be used for human consumption only if it complies with all the following requirements.

1. An otherwise healthy animal must have suffered an accident that prevented its transport to the slaughterhouse for welfare reasons.

2. A veterinarian must carry out an ante-mortem inspection of the animal.

3. The slaughtered and bled animal must be transported to the slaughterhouse hygienically and without undue delay. Removal of the stomach and intestines, but no other dressing, may take place on the spot, under the supervision of the veterinarian. Any viscera removed must accompany the slaughtered animal to the slaughterhouse and be identified as belonging to that animal.

4. If more than two hours elapse between slaughter and arrival at the slaughterhouse, the animal must be refrigerated. Where climatic conditions so permit, active chilling is not necessary.

5. A declaration by the food business operator who reared the animal, stating the identity of the animal and indicating any veterinary products or other treatments administered to the animal, dates of administration and withdrawal periods, must accompany the slaughtered animal to the slaughterhouse.

6. A declaration issued by the veterinarian recording the favourable outcome of the ante-mortem inspection, the date and time of, and reason for, emergency slaughter, and the nature of any treatment administered by the veterinarian to the animal, must accompany the slaughtered animal to the slaughterhouse.

7. The slaughtered animal must be fit for human consumption following post-mortem inspection carried out in the slaughterhouse in accordance with Regulation (EC) No 854/2004, including any additional tests required in the case of emergency slaughter.

8. Food business operators must follow any instructions that the official veterinarian may give after post-mortem inspection concerning the use of the meat.

9. Food business operators may not place meat from animals having undergone emergency slaughter on the market unless it bears a special health mark which cannot be confused either with the health mark provided for in Regulation (EC) No 854/2004 or with the identification mark provided for in Annex II, Section I to this Regulation. Such meat may be placed on the market only in the Member State where slaughter takes place and in accordance with national law.

CHAPTER VII: STORAGE AND TRANSPORT

Food business operators must ensure that the storage and transport of meat of domestic ungulates takes place in accordance with the following requirements.

1. (a) Unless other specific provisions provide otherwise, post-mortem inspection must be followed immediately by chilling in the slaughterhouse to ensure a temperature throughout the meat of not more than 3 °C for offal and 7 °C for other meat along a chilling curve that ensures a continuous decrease of the temperature. However, meat may be cut and boned during chilling in accordance with Chapter V, point 4.

   (b) During the chilling operations, there must be adequate ventilation to prevent condensation on the surface of the meat.

2. Meat must attain the temperature specified in point 1 and remain at that temperature during storage.

3. Meat must attain the temperature specified in point 1 before transport, and remain at that temperature during transport. However, transport may also take place if the competent authority so authorises to enable the production of specific products, provided that:

   (a) such transport takes place in accordance with the requirements that the competent authority specifies in respect of transport from one given establishment to another;

   and

   (b) the meat leaves the slaughterhouse, or a cutting room on the same site as the slaughter premises, immediately and transport takes no more than two hours.

4. Meat intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.

5. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

SECTION II: MEAT FROM POULTRY AND LAGOMORPHS

CHAPTER I: TRANSPORT OF LIVE ANIMALS TO THE SLAUGHTERHOUSE

Food business operators transporting live animals to slaughterhouses must ensure compliance with the following requirements.

1. During collection and transport, animals must be handled carefully without causing unnecessary distress.

2. Animals showing symptoms of disease or originating in flocks known to be contaminated with agents of public-health importance may only be transported to the slaughterhouse when permitted by the competent authority.

3. Crates for delivering animals to the slaughterhouse and modules, where used, must be made of non-corrodible material and be easy to clean and disinfect. Immediately after emptying and, if necessary, before re-use, all equipment used for collecting and delivering live animals must be cleaned, washed and disinfected.

CHAPTER II: REQUIREMENTS FOR SLAUGHTERHOUSES

Food business operators must ensure that the construction, layout and equipment of slaughterhouses in which poultry or lagomorphs are slaughtered meet the following requirements.

1. They must have a room or covered space for the reception of the animals and for their inspection before slaughter.

2. To avoid contaminating meat, they must:

(a) have a sufficient number of rooms, appropriate to the operations being carried out;

(b) have a separate room for evisceration and further dressing, including the addition of seasonings to whole poultry carcases, unless the competent authority authorises separation in time of these operations within a specific slaughterhouse on a case-by-case basis;

(c) ensure separation in space or time of the following operations:

(i) stunning and bleeding;

(ii) plucking or skinning, and any scalding;

and

(iii) dispatching meat;

(d) have installations that prevent contact between the meat and the floors, walls and fixtures;

and

(e) have slaughter lines (where operated) that are designed to allow a constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.

3. They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

4. The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination.

5. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption.

6. There must be a separate place with appropriate facilities for the cleaning, washing and disinfection of:

(a) transport equipment such as crates;

and

(b) means of transport.

These places and facilities are not compulsory for (b) if officially authorised places and facilities exist nearby.

7. They must have an adequately equipped lockable facility or, where needed, room for the exclusive use of the veterinary service.

CHAPTER III: REQUIREMENTS FOR CUTTING PLANTS

1. Food business operators must ensure that cutting plants handling meat from poultry or lagomorphs:

(a) are constructed so as to avoid contamination of meat, in particular by:

(i) allowing constant progress of the operations;

or

(ii) ensuring separation between the different production batches;

(b) have rooms for the separate storage of packaged and exposed meat, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat;

(c) have cutting rooms equipped to ensure compliance with the requirements laid down in Chapter V;

(d) have equipment for washing hands used by staff handling exposed meat with taps designed to prevent the spread of contamination;

and

(e) have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

2. If the following operations are undertaken in a cutting plant:

(a) the evisceration of geese and ducks reared for the production of 'foie gras', which have been stunned, bled and plucked on the fattening farm;

or

(b) the evisceration of delayed eviscerated poultry,

food business operators must ensure that separate rooms are available for that purpose.

CHAPTER IV: SLAUGHTER HYGIENE

Food business operators operating slaughterhouses in which poultry or lagomorphs are slaughtered must ensure compliance with the following requirements.

1. (a) Meat from animals other than those referred to in (b) must not be used for human consumption if they die otherwise than by being slaughtered in the slaughterhouse.

(b) Only live animals intended for slaughter may be brought into the slaughter premises, with the exception of:

(i) delayed eviscerated poultry, geese and ducks reared for the production of 'foie gras' and birds that are not considered as domestic but which are farmed as domestic animals, if slaughtered at the farm in accordance with Chapter VI;

(ii) farmed game slaughtered at the place of production in accordance with Section III;

and

(iii) small wild game in accordance with Section IV, Chapter III.

2. Slaughterhouse operators must follow the instructions of the competent authority to ensure that ante-mortem inspection is carried out under suitable conditions.

3. Where establishments are approved for the slaughter of different animal species or for the handling of farmed ratites and small wild game, precautions must be taken to prevent cross contamination by separation either in time or in space of the operations carried out on the different species. Separate facilities for the reception and storage of carcases of farmed ratites slaughtered at the farm and for small wild game must be available.

4. Animals brought into the slaughter room must be slaughtered without undue delay.

5. Stunning, bleeding, skinning or plucking, evisceration and other dressing must be carried out without undue delay in such a way that contamination of the meat is avoided. In particular, measures must be taken to prevent the spillage of digestive tract contents during evisceration.

6. Slaughterhouse operators must follow the instructions of the competent authority to ensure that the post-mortem inspection is carried out under suitable conditions, and in particular that slaughtered animals can be inspected properly.

7. After post-mortem inspection:

   (a) parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment;

   (b) meat detained or declared unfit for human consumption and inedible by-products must not come into contact with meat declared fit for human consumption;

   and

   (c) viscera or parts of viscera remaining in the carcase, except for the kidneys, must be removed entirely, if possible, and as soon as possible, unless otherwise authorised by the competent authority.

8. After inspection and evisceration, slaughtered animals must be cleaned and chilled to not more than 4 °C as soon as possible, unless the meat is cut while warm.

9. When carcases are subjected to an immersion chilling process, account must be taken of the following.

   (a) Every precaution must be taken to avoid contamination of carcases, taking into account parameters such as carcase weight, water temperature, volume and direction of water flow and chilling time.

   (b) Equipment must be entirely emptied, cleaned and disinfected whenever this is necessary and at least once a day.

10. Sick or suspect animals, and animals slaughtered in application of disease eradication or control programmes, must not be slaughtered in the establishment except when permitted by the competent authority. In that event, slaughter must be performed under official supervision and steps taken to prevent contamination; the premises must be cleaned and disinfected before being used again.

CHAPTER V: HYGIENE DURING AND AFTER CUTTING AND BONING

Food business operators must ensure that cutting and boning of meat of poultry and lagomorphs takes place in accordance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that:

   (a) meat intended for cutting is brought into the workrooms progressively as needed;

(b) during cutting, boning, trimming, slicing, dicing, wrapping and packaging, the temperature of the meat is maintained at not more than 4 °C by means of an ambient temperature of 12 °C or an alternative system having an equivalent effect;

and

(c) where the premises are approved for the cutting of meat of different animal species, precautions are taken to avoid cross-contamination, where necessary by separation of the operations on the different species in either space or time.

2. However, meat may be boned and cut prior to reaching the temperature referred to in point 1(b) when the cutting room is on the same site as the slaughter premises, provided that it is transferred to the cutting room either:

(a) directly from the slaughter premises;

or

(b) after a waiting period in a chilling or refrigerating room.

3. As soon as it is cut and, where appropriate, packaged, the meat must be chilled to the temperature referred to in point 1(b).

4. Exposed meat must be stored and transported separately from packaged meat, unless stored or transported at different times or in such a way that the packaging material and the manner of storage or transport cannot be a source of contamination for the meat.

CHAPTER VI: SLAUGHTER ON THE FARM

Food business operators may slaughter poultry referred to in Chapter IV, point 1(b)(i), on the farm only with the authorisation of the competent authority and in compliance with the following requirements.

1. The farm must undergo regular veterinary inspection.

2. The food business operator must inform the competent authority in advance of the date and time of slaughter.

3. The holding must have facilities for concentrating the birds to allow an ante-mortem inspection of the group to be made.

4. The holding must have premises suitable for the hygienic slaughter and further handling of the birds.

5. Animal welfare requirements must be complied with.

6. The slaughtered birds must be accompanied to the slaughterhouse by a declaration by the food business operator who reared the animal indicating any veterinary products or other treatments administered to the animal, dates of administration and withdrawal periods, and the date and time of slaughter.

7. The slaughtered animal must be accompanied to the slaughterhouse by a certificate issued by the official veterinarian or approved veterinarian in accordance with Regulation (EC) No 854/2004.

8. In the case of poultry reared for the production of 'foie gras', the uneviscerated birds must be transported immediately and, if necessary, refrigerated to a slaughterhouse or cutting plant. They must be eviscerated within 24 hours of slaughter under the supervision of the competent authority.

9. Delayed eviscerated poultry obtained at the farm of production may be kept for up to 15 days at a temperature of not more than 4 °C. It must then be eviscerated in a slaughterhouse or in a cutting plant located in the same Member State as the farm of production.

SECTION III: MEAT OF FARMED GAME

1. The provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game mammals (Cervidae and Suidae), unless the competent authority considers them inappropriate.

2. The provisions of Section II apply to the production and placing on the market of meat from ratites. However, those of Section I apply where the competent authority considers them appropriate. Appropriate facilities must be provided, adapted to the size of the animals.

3. Notwithstanding points 1 and 2, food business operators may slaughter farmed ratites and farmed ungulates referred to in point 1 at the place of origin with the authorisation of the competent authority if:

(a) the animals cannot be transported, to avoid any risk for the handler or to protect the welfare of the animals;

(b) the herd undergoes regular veterinary inspection;

(c) the owner of the animals submits a request;

(d) the competent authority is informed in advance of the date and time of slaughter of the animals;

(e) the holding has procedures for concentrating the animals to allow an ante-mortem inspection of the group to be made;

(f) the holding has facilities suitable for the slaughter, bleeding and, where ratites are to be plucked, plucking of the animals;

(g) animal welfare requirements are complied with;

(h) slaughtered and bled animals are transported to the slaughterhouse hygienically and without undue delay. If transport takes more than two hours, the animals are, if necessary, refrigerated. Evisceration may take place on the spot, under the supervision of the veterinarian;

(i) a declaration by the food business operator who reared the animals, stating their identity and indicating any veterinary products or other treatments administered, dates of administration and withdrawal periods, accompanies the slaughtered animals to the slaughterhouse;

and

(j) during transport to the approved establishment, a certificate issued and signed by the official veterinarian or approved veterinarian, attesting to a favourable result of the ante-mortem inspection, correct slaughter and bleeding and the date and time of slaughter, accompanies the slaughtered animals.

4. Food business operators may also slaughter bison on the farm in accordance with point 3 in exceptional circumstances.

SECTION IV: WILD GAME MEAT

CHAPTER I: TRAINING OF HUNTERS IN HEALTH AND HYGIENE

1. Persons who hunt wild game with a view to placing it on the market for human consumption must have sufficient knowledge of the pathology of wild game, and of the production and handling of wild game and wild game meat after hunting, to undertake an initial examination of wild game on the spot.

2. It is however enough if at least one person of a hunting team has the knowledge referred to in point 1. References in this Section to a 'trained person' are references to that person.

3. The trained person could also be the gamekeeper or the game manager if he or she is part of the hunting team or located in the immediate vicinity of where hunting is taking place. In the latter case, the hunter must present the wild game to the gamekeeper or game manager and inform them of any abnormal behaviour observed before killing.

4. Training must be provided to the satisfaction of the competent authority to enable hunters to become trained persons. It should cover at least the following subjects:

   (a) the normal anatomy, physiology and behaviour of wild game;

   (b) abnormal behaviour and pathological changes in wild game due to diseases, environmental contamination or other factors which may affect human health after consumption;

   (c) the hygiene rules and proper techniques for the handling, transportation, evisceration, etc. of wild game animals after killing;

   and

   (d) legislation and administrative provisions on the animal and public health and hygiene conditions governing the placing on the market of wild game.

5. The competent authority should encourage hunters' organisations to provide such training.

CHAPTER II: HANDLING OF LARGE WILD GAME

1. After killing, large wild game must have their stomachs and intestines removed as soon as possible and, if necessary, be bled.

2. The trained person must carry out an examination of the body, and of any viscera removed, to identify any characteristics that may indicate that the meat presents a health risk. The examination must take place as soon as possible after killing.

3. Meat of large wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 2. The viscera must accompany the body as specified in point 4. The viscera must be identifiable as belonging to a given animal.

4. (a) If no abnormal characteristics are found during the examination referred to in point 2, no abnormal behaviour was observed before killing, and there is no suspicion of environmental contamination, the trained person must attach to the animal body a numbered declaration stating this. This declaration must also indicate the date, time and place of killing. In this case, the head and the viscera need not accompany the body, except in the case of species susceptible to Trichinosis (porcine animals, solipeds and others), whose head (except for tusks) and diaphragm must accompany the body. However, hunters must comply with any additional requirements imposed in the Member State where hunting takes place, in particular to permit the monitoring of certain residues and substances in accordance with Directive 96/23/EC;

   (b) In other circumstances, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and intestines must accompany the body. The trained person who carried out the examination must inform the competent authority of the abnormal characteristics, abnormal behaviour or suspicion of environmental contamination that prevented him or her from making a declaration in accordance with (a);

   (c) If no trained person is available to carry out the examination referred to in point 2 in a particular case, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and the intestines must accompany the body.

5. Chilling must begin within a reasonable period of time after killing and achieve a temperature throughout the meat of not more than 7 °C. Where climatic conditions so permit, active chilling is not necessary.

6. During transport to the game-handling establishment, heaping must be avoided.

7. Large wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.

8. In addition, unskinned large wild game may be skinned and placed on the market only if:

(a) before skinning, it is stored and handled separately from other food and not frozen;

and

(b) after skinning, it undergoes a final inspection in accordance with Regulation (EC) No 854/2004.

9. The rules laid down in Section I, Chapter V, apply to the cutting and boning of large wild game.

CHAPTER III: HANDLING OF SMALL WILD GAME

1. The trained person must carry out an examination to identify any characteristics that may indicate that the meat presents a health risk. The examination must take place as soon as possible after killing.

2. If abnormal characteristics are found during the examination, abnormal behaviour was observed before killing, or environmental contamination is suspected, the trained person must inform the competent authority.

3. Meat of small wild game may be placed on the market only if the body is transported to a game-handling establishment as soon as possible after the examination referred to in point 1.

4. Chilling must begin within a reasonable period of time of killing and achieve a temperature throughout the meat of not more than 4 °C. Where climatic conditions so permit, active chilling is not necessary.

5. Evisceration must be carried out, or completed, without undue delay upon arrival at the game -handling establishment, unless the competent authority permits otherwise.

6. Small wild game delivered to a game-handling establishment must be presented to the competent authority for inspection.

7. The rules laid down in Section II, Chapter V, apply to the cutting and boning of small wild game.

SECTION V: MINCED MEAT, MEAT PREPARATIONS AND MECHANICALLY SEPARATED MEAT (MSM)

CHAPTER I: REQUIREMENTS FOR PRODUCTION ESTABLISHMENTS

Food business operators operating establishments producing minced meat, meat preparations or MSM must ensure that they:

1. are constructed so as to avoid contamination of meat and products, in particular by:

(a) allowing constant progress of the operations;

or

(b) ensuring separation between the different production batches;

2. have rooms for the separate storage of packaged and exposed meat and products, unless stored at different times or in such a way that the packaging material and the manner of storage cannot be a source of contamination for the meat or products;

3. have rooms equipped to ensure compliance with the temperature requirements laid down in Chapter III;

4. have equipment for washing hands used by staff handling exposed meat and products with taps designed to prevent the spread of contamination;

and

5. have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.

CHAPTER II: REQUIREMENTS FOR RAW MATERIAL

Food business operators producing minced meat, meat preparations or MSM must ensure that the raw materials used satisfy the following requirements.

1. The raw material used to prepare minced meat must meet the following requirements.

   (a) It must comply with the requirements for fresh meat;

   (b) It must derive from skeletal muscle, including adherent fatty tissues;

   (c) It must not derive from:

      (i) scrap cuttings and scrap trimmings (other than whole muscle cuttings);

      (ii) MSM;

      (iii) meat containing bone fragments or skin;

      or

      (iv) meat of the head with the exception of the masseters, the non-muscular part of the *linea alba*, the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed).

2. The following raw material may be used to prepare meat preparations:

   (a) fresh meat;

   (b) meat meeting the requirements of point 1;

   and

   (c) if the meat preparation is clearly not intended to be consumed without first undergoing heat treatment:

      (i) meat derived from the mincing or fragmentation of meat meeting the requirements of point 1 other than point 1(c)(i);

      and

      (ii) MSM meeting the requirements of Chapter III, point 3(d).

3. The raw material used to produce MSM must meet the following requirements.

   (a) It must comply with the requirements for fresh meat;

   (b) The following material must not be used to produce MSM:

      (i) for poultry, the feet, neckskin and head;

      and

      (ii) for other animals, the bones of the head, feet, tails, femur, tibia, fibula, humerus, radius and ulna.

CHAPTER III: HYGIENE DURING AND AFTER PRODUCTION

Food business operators producing minced meat, meat preparations or MSM must ensure compliance with the following requirements.

1. The work on meat must be organised in such a way as to prevent or minimise contamination. To this end, food business operators must ensure in particular that the meat used is:

   (a) at a temperature of not more than 4 °C for poultry, 3 °C for offal and 7 °C for other meat;

   and

   (b) brought into the preparation room progressively as needed.

2. The following requirements apply to the production of minced meat and meat preparations.

   (a) Unless the competent authority authorises boning immediately before mincing, frozen or deep-frozen meat used for the preparation of minced meat or meat preparations must be boned before freezing. It may be stored only for a limited period.

   (b) When prepared from chilled meat, minced meat must be prepared:

      (i) in the case of poultry, within no more than three days of their slaughter;

      (ii) in the case of animal other than poultry, within no more than six days of their slaughter;

      or

      (iii) within no more than 15 days from the slaughter of the animals in the case of boned, vacuum-packed beef and veal.

   (c) Immediately after production, minced meat and meat preparations must be wrapped or packaged and be:

      (i) chilled to an internal temperature of not more than 2 °C for minced meat and 4 °C for meat preparations;

      or

      (ii) frozen to an internal temperature of not more than -18 °C.

   These temperature conditions must be maintained during storage and transport.

3. The following requirements apply to the production and use of MSM produced using techniques that do not alter the structure of the bones used in the production of MSM and the calcium content of which is not significantly higher than that of minced meat.

   (a) Raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcases must be no more than three days old.

   (b) Mechanical separation must take place immediately after deboning.

   (c) If not used immediately after being obtained, MSM must be wrapped or packaged and then chilled to a temperature of not more than 2 °C or frozen to an internal temperature of not more than −18 °C. These temperature requirements must be maintained during storage and transport.

(d) If the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat adopted in accordance with Regulation (EC) No 852/2004 it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment and in meat products.

(e) MSM not shown to comply with the criteria referred to in (d) may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.

4. The following requirements apply to the production and use of MSM produced using techniques other than those mentioned in point 3.

(a) Raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcases must be no more than three days old.

(b) If mechanical separation does not take place immediately after deboning the flesh-bearing bones must be stored and transported at a temperature of not more than 2 °C or, if frozen, at a temperature of not more than -18 °C.

(c) Flesh-bearing bones obtained from frozen carcases must not be refrozen.

(d) If not used within one hour of being obtained, MSM must be chilled immediately to a temperature of not more than 2 °C.

(e) If, after chilling, MSM is not processed within 24 hours, it must be frozen within 12 hours of production and reach an internal temperature of not more than −18 °C within six hours.

(f) Frozen MSM must be wrapped or packaged before storage or transport, must not be stored for more than three months and must be maintained at a temperature of not more than −18 °C during storage and transport.

(g) MSM may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.

5. Minced meat, meat preparations and MSM must not be re-frozen after thawing.

CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC [1], food business operators must ensure compliance with the requirement of point 2 if, and to the extent that, national rules in the Member State in the territory of which the product is placed on the market so require.

2. Packages intended for supply to the final consumer containing minced meat from poultry or solipeds or meat preparations containing MSM must bear a notice indicating that such products should be cooked before consumption.

SECTION VI: MEAT PRODUCTS

1. Food business operators must ensure that the following items are not used in the preparation of meat products:

(a) genital organs of either female or male animals, except testicles;

(b) urinary organs, except the kidneys and the bladder;

(c) the cartilage of the larynx, the trachea and the extra-lobular bronchi;

[1] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15).

(d) eyes and eyelids;

(e) the external auditory meatus;

(f) horn tissue;

and

(g) in poultry, the head — except the comb and the ears, the wattles and caruncles — the oesophagus, the crop, the intestines and the genital organs.

2. All meat, including minced meat and meat preparations, used to produce meat product must meet the requirements for fresh meat. However, minced meat and meat preparations used to produce meat products need not satisfy other specific requirements of Section V.

SECTION VII: LIVE BIVALVE MOLLUSCS

1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, tunicates and marine gastropods.

2. Chapters I to VIII apply to animals harvested from production areas that the competent authority has classified in accordance with Regulation (EC) No 854/2004. Chapter IX applies to pectinidae harvested outside those areas.

3. Chapters V, VI, VIII and IX, and point 3 of Chapter VII, apply to retail.

4. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:

(a) In the case of operations that take place before live bivalve molluscs arrive at a dispatch or purification centre, they supplement the requirements of Annex I to that Regulation.

(b) In the case of other operations, they supplement the requirements of Annex II to that Regulation.

CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.

2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in points 3 to 7 have been complied with.

3. Whenever a food business operator moves a batch of live bivalve molluscs between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a registration document must accompany the batch.

4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.

(a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:

(i) the gatherer's identity and address;

(ii) the date of harvesting;

(iii) the location of the production area described in as precise detail as is practicable or by a code number;

(iv) the health status of the production area;

(v) the shellfish species and quantity;

and

(vi) the destination of the batch.

(b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:

(i) the location of the relaying area;

and

(ii) the duration of relaying.

(c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:

(i) the address of the purification centre;

(ii) the duration of purification;

and

(iii) the dates on which the batch entered and left the purification centre.

5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.

6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).

7. However, if:

(a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs;

and

(b) a single competent authority supervises all the establishments concerned,

registration documents are not necessary if that competent authority so permits.

CHAPTER II: HYGIENE REQUIREMENTS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS

A. REQUIREMENTS FOR PRODUCTION AREAS

1. Gatherers may only harvest live bivalve molluscs from production areas with fixed locations and boundaries that the competent authority has classified — where appropriate, in cooperation with food business operators — as being of class A, B or C in accordance with Regulation (EC) No 854/2004.

2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption only if they meet the requirements of Chapter V.

3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.

4. Food business operators may place live bivalve molluscs collected from class C production areas on the market for human consumption only after relaying over a long period in accordance with Part C of this Chapter.

5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of Chapter V. However, live bivalve molluscs from such areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic micro-organisms (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:

   (a) sterilisation in hermetically sealed containers;

   and

   (b) heat treatments involving:

      (i) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90 °C and maintenance of this minimum temperature for a period of not less than 90 seconds;

      (ii) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160 °C and the pressure is between 2 and 5 kg/cm^2, followed by shelling and freezing of the flesh to a core temperature of – 20 °C;

      and

      (iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.

6. Food business operators must not produce live bivalve molluscs in, or harvest them from, areas that the competent authority has not classified, or which are unsuitable for health reasons. Food business operators must take account of any relevant information concerning areas' suitability for production and harvesting, including information obtained from own-checks and the competent authority. They must use this information, particularly information on environmental and weather conditions, to determine the appropriate treatment to apply to harvested batches.

B. REQUIREMENTS FOR HARVESTING AND HANDLING FOLLOWING HARVESTING

Food business operators harvesting live bivalve molluscs, or handling them immediately after harvesting, must ensure compliance with the following requirements.

1. Harvesting techniques and further handling must not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes significantly affecting their suitability for treatment by purification, processing or relaying. Food business operators must in particular:

   (a) adequately protect live bivalve molluscs from crushing, abrasion or vibration;

   (b) not expose live bivalve molluscs to extreme temperatures;

   (c) not re-immerse live bivalve molluscs in water that could cause additional contamination;

   and

   (d) if carrying out conditioning in natural sites, use only areas that the competent authority has classified as being of class A.

2. Means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.

C. REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS

Food business operators relaying live bivalve molluscs must ensure compliance with the following requirements.

1. Food business operators may use only those areas that the competent authority has approved for relaying live bivalve molluscs. Buoys, poles or other fixed means must clearly identify the boundaries of the sites. There must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to minimise any risk of the spread of contamination.

2. Conditions for relaying must ensure optimal conditions for purification. In particular, food business operators must:

(a) use techniques for handling live bivalve molluscs intended for relaying that permit the resumption of filter-feeding activity after immersion in natural waters;

(b) not relay live bivalve molluscs at a density that prevents purification;

(c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature, which period must be of at least two months' duration unless the competent authority agrees to a shorter period on the basis of the food business operator's risk analysis;

and

(d) ensure sufficient separation of sites within a relaying area to prevent mixing of batches; the 'all in, all out' system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed.

3. Food business operators managing relaying areas must keep permanent records of the source of live bivalve molluscs, relaying periods, relaying areas used and the subsequent destination of the batch after relaying, for inspection by the competent authority.

CHAPTER III: STRUCTURAL REQUIREMENTS FOR DISPATCH AND PURIFICATION CENTRES

1. The location of premises on land must not be subject to flooding by ordinary high tides or run-off from surrounding areas.

2. Tanks and water storage containers must meet the following requirements:

(a) Internal surfaces must be smooth, durable, impermeable and easy to clean.

(b) They must be constructed so as to allow complete draining of water.

(c) Any water intake must be situated in a position that avoids contamination of the water supply.

3. In addition, in purification centres, purification tanks must be suitable for the volume and type of products to be purified.

CHAPTER IV: HYGIENE REQUIREMENTS FOR PURIFICATION AND DISPATCH CENTRES

A. REQUIREMENTS FOR PURIFICATION CENTRES

Food business operators purifying live bivalve molluscs must ensure compliance with the following requirements.

1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using clean water.

2. Operation of the purification system must allow live bivalve molluscs rapidly to resume and to maintain filter-feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.

3. The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre. The live bivalve molluscs must be continuously purified for a period sufficient to achieve compliance with allow the health standards of Chapter V and microbiological criteria adopted in accordance with Regulation (EC) No 852/2004.

4. Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of the treatment must be based on the time required by the batch needing the longest period of purification.

5. Containers used to hold live bivalve molluscs in purification systems must have a construction that allows clean seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.

6. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.

7. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

B. REQUIREMENTS FOR DISPATCH CENTRES

Food business operators operating dispatch centres must ensure compliance with the following requirements.

1. Handling of live bivalve molluscs, particularly conditioning, calibration, wrapping and packing, must not cause contamination of the product or affect the viability of the molluscs.

2. Before dispatch, the shells of live bivalve molluscs must be washed thoroughly with clean water.

3. Live bivalve molluscs must come from:

(a) a class A production area;

(b) a relaying area;

(c) a purification centre;

or

(d) another dispatch centre.

4. The requirements laid down in points 1 and 2 also apply to dispatch centres situated on board vessels. Molluscs handled in such centres must come from a class A production area or a relaying area.

CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion and normal amounts of intravalvular liquid.

2. They must not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:

   (a) for paralytic shellfish poison (PSP), 800 micrograms per kilogram;

   (b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;

   (c) for okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;

   (d) for yessotoxins, 1 milligram of yessotoxin equivalent per kilogram;

   and

   (e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

CHAPTER VI: WRAPPING AND PACKAGING OF LIVE BIVALVE MOLLUSCS

1. Oysters must be wrapped or packaged with the concave shell downwards.

2. Individual consumer-size packages of live bivalve molluscs must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.

CHAPTER VII: IDENTIFICATION MARKING AND LABELLING

1. The label, including the identification mark, must be waterproof.

2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:

   (a) the species of bivalve mollusc (common name and scientific name);

   and

   (b) the date of packaging, comprising at least the day and the month.

   By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry 'these animals must be alive when sold'.

3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer-size packages for at least 60 days after splitting up the contents.

CHAPTER VIII: OTHER REQUIREMENTS

1. Food business operators storing and transporting live bivalve molluscs must ensure that they are kept at a temperature that does not adversely affect food safety or their viability.

2. Live bivalve molluscs must not be re-immersed in, or sprayed with, water after they have been packaged for retail sale and left the dispatch centre.

CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae outside classified production areas or handling such pectinidae must comply with the following requirements.

1. Pectinidae may not be placed on the market unless they are harvested and handled in accordance with Chapter II, Part B, and meet the standards laid down in Chapter V, as proved by a system of own-checks.

2. In addition, where data from official monitoring programmes enable the competent authority to classify fishing grounds — where appropriate, in cooperation with food business operators — the provisions of Chapter II, Part A, apply by analogy to pectinidae.

3. Pectinidae may not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae, food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV.

4. Food business operators handling pectinidae must comply:

   (a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area where the pectinidae were harvested;

   or

   (b) as regards packaged pectinidae, and wrapped pectinidae if the wrapping provides protection equivalent to that of packaging, with the requirements of Chapter VII concerning identification marking and labelling.

SECTION VIII: FISHERY PRODUCTS

1. This Section does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods when placed on the market live. With the exception of Chapters I and II, it applies to such animals when not placed on the market live, in which case they must have been obtained in accordance with Section VII.

2. Chapter III, Parts A, C and D, Chapter IV and Chapter V apply to retail.

3. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:

   (a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of Annex I to that Regulation.

   (b) In the case of other establishments, including vessels, they supplement the requirements of Annex II to that Regulation.

4. In relation to fishery products:

   (a) primary production covers the farming, fishing and collection of live fishery products with a view to their being placed on the market;

   and

   (b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include:

      1. the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land;

      and

      2. the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination.

CHAPTER I: REQUIREMENTS FOR VESSELS

Food business operators must ensure that:

1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, comply with the structural and equipment requirements laid down in Part I;

   and

2. operations carried out on board vessels take place in accordance with the rules laid down in Part II.

I. STRUCTURAL AND EQUIPMENT REQUIREMENTS

A. **Requirements for all vessels**

1. Vessels must be designed and constructed so as not to cause contamination of the products with bilge-water, sewage, smoke, fuel, oil, grease or other objectionable substances.

2. Surfaces with which fishery products come into contact must be of suitable corrosion-resistant material that is smooth and easy to clean. Surface coatings must be durable and non-toxic.

3. Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.

4. When vessels have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water supply.

B. **Requirements for vessels designed and equipped to preserve fresh fishery products for more than 24 hours**

1. Vessels designed and equipped to preserve fishery products for more than 24 hours must be equipped with holds, tanks or containers for the storage of fishery products at the temperatures laid down in Chapter VII.

2. Holds must be separated from the engine compartments and from the crew quarters by partitions which are sufficient to prevent any contamination of the stored fishery products. Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory conditions of hygiene and, where necessary, ensure that melt water does not remain in contact with the products.

3. In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fish and clean seawater reaches not more than 3 °C six hours after loading and not more than 0 °C after 16 hours and allow the monitoring and, where necessary, recording of temperatures.

C. **Requirements for freezer vessels**

Freezer vessels must:

1. have freezing equipment with sufficient capacity to lower the temperature rapidly so as to achieve a core temperature of not more than -18 °C;

2. have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at not more than -18 °C. Storage holds must be equipped with a temperature-recording device in a place where it can be easily read. The temperature sensor of the reader must be situated in the area where the temperature in the hold is the highest;

and

3. meet the requirements for vessels designed and equipped to preserve fishery products for more than 24 hours laid down in part B, point 2.

D. **Requirements for factory vessels**

1. Factory vessels must have at least:

(a) a receiving area reserved for taking fishery products on board, designed to allow each successive catch to be separated. This area must be easy to clean and designed so as to protect the products from the sun or the elements and from any source of contamination;

(b) a hygienic system for conveying fishery products from the receiving area to the work area;

(c) work areas that are large enough for the hygienic preparation and processing of fishery products, easy to clean and disinfect and designed and arranged in such a way as to prevent any contamination of the products;

(d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste-processing unit operates on board, a separate hold must be designated for the storage of such waste;

(e) a place for storing packaging materials that is separate from the product preparation and processing areas;

(f) special equipment for disposing waste or fishery products that are unfit for human consumption directly into the sea or, where circumstances so require, into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to its sanitation, separate areas must be allocated for that purpose;

(g) a water intake situated in a position that avoids contamination of the water supply;

and

(h) hand-washing equipment for use by the staff engaged in handling exposed fishery products with taps designed to prevent the spread of contamination.

2. However, factory vessels on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of point 1 if no other form of handling or processing takes place on board such vessels.

3. Factory vessels that freeze fishery products must have equipment meeting the requirements for freezer vessels laid down in part C, points 1 and 2.

II. HYGIENE REQUIREMENTS

1. When in use, the parts of vessels or containers set aside for the storage of fishery products must be kept clean and maintained in good repair and condition. In particular, they must not be contaminated by fuel or bilge water.

2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat. When they are washed, the water used must be either potable water or, where appropriate, clean water.

3. Fishery products must be handled and stored so as to prevent bruising. Handlers may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products suffers no damage.

4. Fishery products other than those kept alive must undergo chilling as soon as possible after loading. However, when chilling is not possible, fishery products must be landed as soon as possible.

5. Ice used to chill fishery products must be made from potable water or clean water.

6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly with potable water or clean water. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen.

7. Where freezing in brine of whole fish intended for canning is practised, a temperature of not more than – 9 °C must be achieved for the product. The brine must not be a source of contamination for the fish.

CHAPTER II: REQUIREMENTS DURING AND AFTER LANDING

1. Food business operators responsible for the unloading and landing of fishery products must:

(a) ensure that unloading and landing equipment that comes into contact with fishery products is constructed of material that is easy to clean and disinfect and maintained in a good state of repair and cleanliness;

and

(b) avoid contamination of fishery products during unloading and landing, in particular by:

(i) carrying out unloading and landing operations rapidly;

(ii) placing fishery products without delay in a protected environment at the temperature specified in Chapter VII;

and

(iii) not using equipment and practices that cause unnecessary damage to the edible parts of the fishery products.

2. Food business operators responsible for auction and wholesale markets or parts thereof where fishery products are displayed for sale must ensure compliance with the following requirements.

(a) (i) There must be lockable facilities for the refrigerated storage of detained fishery products and separate lockable facilities for the storage of fishery products declared unfit for human consumption.

(ii) If the competent authority so requires, there must be an adequately equipped lockable facility or, where needed, room for the exclusive use of the competent authority.

(b) At the time of display or storage of fishery products:

(i) the premises must not be used for other purposes;

(ii) vehicles emitting exhaust fumes likely to impair the quality of fishery products must not have access to the premises;

(iii) persons having access to the premises must not introduce other animals;

and

(iv) the premises must be well lit to facilitate official controls.

3. When chilling was not possible on board the vessel, fresh fishery products, other than those kept alive, must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.

4. Food business operators must cooperate with relevant competent authorities so as to permit them to carry out official controls in accordance with Regulation (EC) No 854/2004, in particular as regards any notification procedures for the landing of fishery products that the competent authority of the Member State the flag of which the vessel is flying or the competent authority of the Member State where the fishery products are landed might consider necessary.

CHAPTER III: REQUIREMENTS FOR ESTABLISHMENTS, INCLUDING VESSELS, HANDLING FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling fishery products.

A. REQUIREMENTS FOR FRESH FISHERY PRODUCTS

1. Where chilled, unpackaged products are not distributed, dispatched, prepared or processed immediately after reaching an establishment on land, they must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary. Packaged fresh fishery products must be chilled to a temperature approaching that of melting ice.

2. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly with potable water or, on board vessels, clean water immediately after these operations.

3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.

4. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products.

5. Whole and gutted fresh fishery products may be transported and stored in cooled water on board vessels. They may also continue to be transported in cooled water after landing, and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or sorting.

B. REQUIREMENTS FOR FROZEN PRODUCTS

Establishments on land that freeze fishery products must have equipment that satisfies the requirements laid down for freezer vessels in Section VIII, Chapter I, part I. C, points 1 and 2.

C. REQUIREMENTS FOR MECHANICALLY SEPARATED FISHERY PRODUCTS

Food business operators manufacturing mechanically separated fishery products must ensure compliance with the following requirements.

1. The raw materials used must satisfy the following requirements.

   (a) Only whole fish and bones after filleting may be used to produce mechanically separated fishery products;

   (b) All raw materials must be free from guts.

2. The manufacturing process must satisfy the following requirements:

   (a) Mechanical separation must take place without undue delay after filleting.

   (b) If whole fish are used, they must be gutted and washed beforehand.

   (c) After production, mechanically separated fishery products must be frozen as quickly as possible or incorporated in a product intended for freezing or a stabilising treatment.

D. REQUIREMENTS CONCERNING PARASITES

1. The following fishery products must be frozen at a temperature of not more than – 20 °C in all parts of the product for not less than 24 hours; this treatment must be applied to the raw product or the finished product:

   (a) fishery products to be consumed raw or almost raw;

   (b) fishery products from the following species, if they are to undergo a cold smoking process in which the internal temperature of the fishery product is not more than 60 °C:

      (i) herring;

      (ii) mackerel;

      (iii) sprat;

      (iv) (wild) Atlantic and Pacific salmon;

      and

   (c) marinated and/or salted fishery products, if the processing is insufficient to destroy nematode larvae.

2. Food business operators need not carry out the treatment required under point 1 if:

   (a) epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites;

      and

   (b) the competent authority so authorises.

3. A document from the manufacturer, stating the type of process they have undergone, must accompany fishery products referred to in point 1 when placed on the market, except when supplied to the final consumer.

CHAPTER IV: REQUIREMENTS FOR PROCESSED FISHERY PRODUCTS

Food business operators cooking crustaceans and molluscs must ensure compliance with the following requirements.

1. Rapid cooling must follow cooking. Water used for this purpose must be potable water or, on board vessels, clean water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.

2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.

3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature laid down in Chapter VII.

CHAPTER V: HEALTH STANDARDS FOR FISHERY PRODUCTS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter.

A. ORGANOLEPTIC PROPERTIES OF FISHERY PRODUCTS

Food business operators must carry out an organoleptic examination of fishery products. In particular, this examination must ensure that fishery products comply with any freshness criteria.

B. HISTAMINE

Food business operators must ensure that the limits with regard to histamine are not exceeded.

C. TOTAL VOLATILE NITROGEN

Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to TVB-N or TMA-N have been exceeded.

D. PARASITES

Food business operators must ensure that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before being placed on the market. They must not place fishery products that are obviously contaminated with parasites on the market for human consumption.

E. TOXINS HARMFUL TO HUMAN HEALTH

1. Fishery products derived from poisonous fish of the following families must not be placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*.

2. Fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII and comply with the standards laid down in Chapter V, point 2, of that section.

CHAPTER VI: WRAPPING AND PACKAGING OF FISHERY PRODUCTS

1. Receptacles in which fresh fishery products are kept under ice must be water-resistant and ensure that melt-water does not remain in contact with the products.

2. Frozen blocks prepared on board vessels must be adequately wrapped before landing.

3. When fishery products are wrapped on board fishing vessels, food business operators must ensure that wrapping material:

(a) is not a source of contamination;

(b) is stored in such a manner that it is not exposed to a risk of contamination;

(c) intended for re-use is easy to clean and, where necessary, to disinfect.

CHAPTER VII: STORAGE OF FISHERY PRODUCTS

Food business operators storing fishery products must ensure compliance with the following requirements.

1. Fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice.

2. Frozen fishery products must be kept at a temperature of not more than –18 °C in all parts of the product; however, whole frozen fish in brine intended for the manufacture of canned food may be kept at a temperature of not more than –9 °C.

3. Fishery products kept alive must be kept at a temperature and in a manner that does not adversely affect food safety or their viability.

CHAPTER VIII: TRANSPORT OF FISHERY PRODUCTS

Food business operators transporting fishery products must ensure compliance with the following requirements.

1. During transport, fishery products must be maintained at the required temperature. In particular:

   (a) fresh fishery products, thawed unprocessed fishery products, and cooked and chilled products from crustaceans and molluscs, must be maintained at a temperature approaching that of melting ice;

   (b) frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned food, must be maintained during transport at an even temperature of not more than –18 °C in all parts of the product, possibly with short upward fluctuations of not more than 3 °C.

2. Food business operators need not comply with point 1(b) when frozen fishery products are transported from a cold store to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing, if the journey is short and the competent authority so permits.

3. If fishery products are kept under ice, melt water must not remain in contact with the products.

4. Fishery products to be placed on the market live must be transported in such a way as not adversely to affect food safety or their viability.

SECTION IX: RAW MILK AND DAIRY PRODUCTS

CHAPTER I: RAW MILK — PRIMARY PRODUCTION

Food business operators producing or, as appropriate, collecting raw milk must ensure compliance with the requirements laid down in this Chapter.

I. HEALTH REQUIREMENTS FOR RAW MILK PRODUCTION

1. Raw milk must come from animals:

   (a) that do not show any symptoms of infectious diseases communicable to humans through milk;

   (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;

   (c) that do not have any udder wound likely to affect the milk;

   (d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;

   and

   (e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

2. (a) In particular, as regards brucellosis, raw milk must come from:

   (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC [1], is free or officially free of brucellosis;

[1] Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64). Directive as last amended by the 2003 Act of Accession.

(ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC [1];

or

(iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.

(b) As regards tuberculosis, raw milk must come from:

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis;

or

(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.

(c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.

3. However, raw milk from animals that do not meet the requirements of point 2 may be used with the authorisation of the competent authority:

(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the phosphatase test;

(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:

(i) for the manufacture of cheese with a maturation period of at least two months;

or

(ii) after having undergone heat treatment such as to show a negative reaction to the phosphatase test;

and

(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.

4. Raw milk from any animal not complying with the requirements of points 1 to 3 — in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC — must not be used for human consumption.

5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk.

II. HYGIENE ON MILK PRODUCTION HOLDINGS

A. **Requirements for premises and equipment**

1. Milking equipment, and premises where milk is stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk.

[1] Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

2. Premises for the storage of milk must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.

3. Surfaces of equipment that are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.

4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of raw milk must be cleaned and disinfected in an appropriate manner before re-use.

B. **Hygiene during milking, collection and transport**

1. Milking must be carried out hygienically, ensuring in particular:

(a) that, before milking starts, the teats, udder and adjacent parts are clean;

(b) that milk from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk presenting such abnormalities is not used for human consumption;

(c) that milk from animals showing clinical signs of udder disease is not used for human consumption otherwise than in accordance with the instructions of a veterinarian;

(d) the identification of animals undergoing medical treatment likely to transfer residues to the milk, and that milk obtained from such animals before the end of the prescribed withdrawal period is not used for human consumption;

and

(e) that teat dips or sprays are used only if the competent authority has approved them and in a manner that does not produce unacceptable residue levels in the milk.

2. Immediately after milking, milk must be held in a clean place designed and equipped to avoid contamination. It must be cooled immediately to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily.

3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk must not be more than 10 °C.

4. Food business operators need not comply with the temperature requirements laid down in points 2 and 3 if the milk meets the criteria provided for in Part III and either:

(a) the milk is processed within two hours of milking;

or

(b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.

C. **Staff hygiene**

1. Persons performing milking and/or handling raw milk must wear suitable clean clothes.

2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk to wash their hands and arms.

III. CRITERIA FOR RAW MILK

1. The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products.

2. A representative number of samples of raw milk collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4.

The checks may be carried out by, or on behalf of:

(a) the food business operator producing the milk;

(b) the food business operator collecting or processing the milk;

(c) a group of food business operators;

or

(d) in the context of a national or regional control scheme.

3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria:

(i) for raw cows' milk:

Plate count at 30 °C (per ml)	≤ 100 000 (*)
Somatic cell count (per ml)	≤ 400 000 (**)

(*) Rolling geometric average over a two-month period, with at least two samples per month.
(**) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

(ii) for raw milk from other species:

Plate count at 30 °C (per ml)	≤ 1 500 000 (*)

(*) Rolling geometric average over a two-month period, with at least two samples per month.

(b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion:

Plate count at 30 °C (per ml)	≤ 500 000 (*)

(*) Rolling geometric average over a two-month period, with at least two samples per month.

4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures to ensure that raw milk is not placed on the market if either:

(a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90 [1], exceeds the levels authorised under that Regulation;

or

(b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.

[1] Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 546/2004 (OJ L 87, 25.3.2004, p. 13).

5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER II: REQUIREMENTS CONCERNING DAIRY PRODUCTS

I. TEMPERATURE REQUIREMENTS

1. Food business operators must ensure that, upon acceptance at a processing establishment, milk is quickly cooled to not more than 6 °C and kept at that temperature until processed.

2. However, food business operators may keep milk at a higher temperature if:

(a) processing begins immediately after milking, or within four hours of acceptance at the processing establishment;

or

(b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy products.

II. REQUIREMENTS FOR HEAT TREATMENT

1. When raw milk or dairy products undergo heat treatment, food business operators must ensure that this satisfies the requirements of Regulation (EC) No 852/2004, Annex II, Chapter XI.

2. When considering whether to subject raw milk to heat treatment, food business operators must:

(a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 854/2004;

and

(b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No 854/2004.

III. CRITERIA FOR RAW COWS' MILK

1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before processing:

(a) raw cows' milk used to prepare dairy products has a plate count at 30 °C of less than 300 000 per ml;

and

(b) processed cows' milk used to prepare dairy products has a plate count at 30 °C of less than 100 000 per ml.

2. When milk fails to meet the criteria laid down in point 1, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER III: WRAPPING AND PACKAGING

Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products takes place, by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check.

CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:

   (a) in the case of raw milk intended for direct human consumption, the words 'raw milk';

   (b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words 'made with raw milk'.

2. The requirements of point 1 apply to products destined for retail trade. The term 'labelling' includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

CHAPTER V: IDENTIFICATION MARKING

By way of derogation from the requirements of Annex II, Section I:

1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;

2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment.

SECTION X: EGGS AND EGG PRODUCTS

CHAPTER I: EGGS

1. At the producer's premises, and until sale to the consumer, eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine.

2. Eggs must be stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties.

3. Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.

CHAPTER II: EGG PRODUCTS

I. REQUIREMENTS FOR ESTABLISHMENTS

Food business operators must ensure that establishments for the manufacture of egg products are constructed, laid out and equipped so as to ensure separation of the following operations:

1. washing, drying and disinfecting dirty eggs, where carried out;

2. breaking eggs, collecting their contents and removing parts of shells and membranes;

   and

3. operations other than those referred to in points 1 and 2.

II. RAW MATERIALS FOR THE MANUFACTURE OF EGG PRODUCTS

Food business operators must ensure that raw materials used to manufacture egg products comply with the following requirements.

1. The shells of eggs used in the manufacture of egg products must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of egg products if the establishment of production or a packing centre delivers them directly to a processing establishment, where they must be broken as soon as possible.

2. Liquid egg obtained in an establishment approved for that purpose may be used as raw material. Liquid egg must be obtained in accordance with the requirements of points 1, 2, 3, 4 and 7 of Part III.

III. SPECIAL HYGIENE REQUIREMENTS FOR THE MANUFACTURE OF EGG PRODUCTS

Food business operators must ensure that all operations are carried out in such a way as to avoid any contamination during production, handling and storage of egg products, in particular by ensuring compliance with the following requirements.

1. Eggs must not be broken unless they are clean and dry.

2. Eggs must be broken in a manner that minimises contamination, in particular by ensuring adequate separation from other operations. Cracked eggs must be processed as soon as possible.

3. Eggs other than those of hens, turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected before processing of hens', turkeys' and guinea fowls' eggs is resumed.

4. Egg contents may not be obtained by the centrifuging or crushing of eggs, nor may centrifuging be used to obtain the remains of egg whites from empty shells for human consumption.

5. After breaking, each particle of the egg product must undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level. A batch that has been insufficiently processed may immediately undergo processing again in the same establishment, if this processing renders it fit for human consumption. When a batch is found to be unfit for human consumption, it must be denatured so as to ensure that it is not used for human consumption.

6. Processing is not required for egg white intended for the manufacture of dried or crystallised albumin destined subsequently to undergo heat treatment.

7. If processing is not carried out immediately after breaking, liquid egg must be stored either frozen or at a temperature of not more than 4 °C. The storage period before processing at 4 °C must not exceed 48 hours. However, these requirements do not apply to products to be de-sugared, if de-sugaring process is performed as soon as possible.

8. Products that have not been stabilised so as to be kept at room temperature must be cooled to not more than 4 °C. Products for freezing must be frozen immediately after processing.

IV. ANALYTICAL SPECIFICATIONS

1. The concentration of 3-OH-butyric acid must not exceed 10 mg/kg in the dry matter of the unmodified egg product.

2. The lactic acid content of raw material used to manufacture egg products must not exceed 1 g/kg of dry matter. However, for fermented products, this value must be the one recorded before the fermentation process.

3. The quantity of eggshell remains, egg membranes and any other particles in the processed egg product must not exceed 100 mg/kg of egg product.

V. LABELLING AND IDENTIFICATION MARKING

1. In addition to the general requirements for identification marking laid down in Annex II, Section I, consignments of egg products, destined not for retail but for use as an ingredient in the manufacture of another product, must have a label giving the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

2. In the case of liquid eggs, the label referred to in point 1 must also bear the words: 'non-pasteurised egg products - to be treated at place of destination' and indicate the date and hour of breaking.

SECTION XI: FROGS' LEGS AND SNAILS

Food business operators preparing frogs' legs or snails for human consumption must ensure compliance with the following requirements.

1. Frogs and snails must be killed in an establishment constructed, laid out and equipped for that purpose.

2. Establishment in which frogs' legs are prepared must have a room reserved for the storage and washing of live frogs, and for their slaughter and bleeding. This room must be physically separate from the preparation room.

3. Frogs and snails that die otherwise than by being killed in the establishment must not be prepared for human consumption.

4. Frogs and snails must be subjected to an organoleptic examination carried out by sampling. If that examination indicates that they might present a hazard, they must not be used for human consumption.

5. Immediately following preparation, frogs' legs must be washed fully with running potable water and immediately chilled to a temperature approaching that of melting ice, frozen or processed.

6. After killing, snails' hepato-pancreas must, if it might present a hazard, be removed and not be used for human consumption.

SECTION XII: RENDERED ANIMAL FATS AND GREAVES

CHAPTER I: REQUIREMENTS APPLICABLE TO ESTABLISHMENTS COLLECTING OR PROCESSING RAW MATERIALS

Food business operators must ensure that establishments collecting or processing raw materials for the production of rendered animal fats and greaves comply with the following requirements.

1. Centres for the collection of raw materials and further transport to processing establishments must be equipped with facilities for the storage of raw materials at a temperature of not more than 7 °C.

2. Each processing establishment must have:

   (a) refrigeration facilities;

   (b) a dispatch room, unless the establishment dispatches rendered animal fat only in tankers;

   and

   (c) if appropriate, suitable equipment for the preparation of products consisting of rendered animal fats mixed with other foodstuffs and/or seasonings.

3. However, the refrigeration facilities required under points 1 and 2(a) are not necessary if the arrangements for the supply of raw materials ensure that they are never stored or transported without active refrigeration otherwise than as provided for in Chapter II, point 1(d).

CHAPTER II: HYGIENE REQUIREMENTS FOR THE PREPARATION OF RENDERED ANIMAL FAT AND GREAVES

Food business operators preparing rendered animal fats and greaves must ensure compliance with the following requirements.

1. Raw materials must:

   (a) derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;

(b) consist of adipose tissues or bones, which are reasonably free from blood and impurities;

(c) come from establishments registered or approved pursuant to Regulation (EC) No 852/2003 or in accordance with this Regulation;

and

(d) be transported, and stored until rendering, in hygienic conditions and at an internal temperature of not more than 7 °C. However, raw materials may be stored and transported without active refrigeration if rendered within 12 hours after the day on which they were obtained.

2. During rendering the use of solvents is prohibited.

3. When the fat for refining meets the standards laid down in point 4, rendered animal fat prepared in accordance with points 1 and 2 may be refined in the same establishment or in another establishment with a view to improving its physico-chemical quality.

4. Rendered animal fat, depending on type, must meet the following standards:

	Ruminants			**Porcine animals**			**Other animal fat**	
	Edible tallow		Tallow for refining	Edible fat		Lard and other fat for refining	Edible	For refining
	Premier jus (1)	Other		Lard (2)	Other			
FFA (m/m % oleic acid) maximum	0,75	1,25	3,0	0,75	1,25	2,0	1,25	3,0
Peroxide maximum	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	4 meq/kg	6 meq/kg	4 meq/kg	10 meq/kg
Total insoluble impurities	Maximum 0,15 %			Maximum 0,5 %				
Odour, taste, colour	Normal							

(1) Rendered animal fat obtained by low-temperature rendering of fresh fat from the heart, caul, kidneys and mesentery of bovine animals, and fat from cutting rooms.
(2) Rendered animal fat obtained from the adipose tissues of porcine animals.

5. Greaves intended for human consumption must be stored in accordance with the following temperature requirements.

(a) When greaves are rendered at a temperature of not more than 70 °C, they must be stored:

(i) at a temperature of not more than 7 °C for a period not exceeding 24 hours;

or

(ii) at a temperature of not more than −18 °C.

(b) When greaves are rendered at a temperature of more than 70 °C and have a moisture content of 10 % (m/m) or more, they must be stored:

(i) at a temperature of not more than 7 °C for a period not exceeding 48 hours or a time/temperature ratio giving an equivalent guarantee;

or

(ii) at a temperature of not more than −18 °C.

(c) When greaves are rendered at a temperature of more than 70 °C and have a moisture content of less than 10 % (m/m), there are no specific requirements.

SECTION XIII: TREATED STOMACHS, BLADDERS AND INTESTINES

Food business operators treating stomachs, bladders and intestines must ensure compliance with the following requirements.

1. Animal intestines, bladders and stomachs may be placed on the market only if:

(a) they derive from animals which have been slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;

(b) they are salted, heated or dried;

and

(c) after the treatment referred to in (b), effective measures are taken to prevent re-contamination.

2. Treated stomachs, bladders and intestines that cannot be kept at ambient temperature must be stored chilled using facilities intended for that purpose until their dispatch. In particular, products that are not salted or dried must be kept at a temperature of not more than 3 °C.

SECTION XIV: GELATINE

1. Food business operators manufacturing gelatine must ensure compliance with the requirements of this section.

2. For the purpose of this section, 'tanning' means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

1. For the production of gelatine intended for use in food, the following raw materials may be used:

(a) bones;

(b) hides and skins of farmed ruminant animals;

(c) pig skins;

(d) poultry skin;

(e) tendons and sinews;

(f) wild game hides and skins;

and

(g) fish skin and bones.

2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.

3. Raw materials listed in point 1(a) to (e) must derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante-mortem and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.

4. Raw materials must come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.

5. Collection centres and tanneries may also supply raw material for the production of gelatine intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.

   (a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.

   (b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

   (c) If raw material not in conformity with this chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this chapter throughout the period of receipt, storage, processing and dispatch.

CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS

1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the gelatine-processing establishment.

2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF GELATINE

1. The production process for gelatine must ensure that:

   (a) all ruminant bone material derived from animals born, reared or slaughtered in countries or regions classified as having a low incidence of BSE in accordance with Community legislation is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 % and pH < 1,5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (pH > 12,5) for a period of at least 20 days with a sterilisation step of 138 to 140 °C during four seconds or by any approved equivalent process;

   and

   (b) other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.

2. If a food business operator manufacturing gelatine complies with the requirements applying to gelatine intended for human consumption in respect of all the gelatine that it produces, it may produce and store gelatine not intended for human consumption in the same establishment.

CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that gelatine complies with the residue limits set out in the following table.

Residue	**Limit**
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	10 ppm

SECTION XV: COLLAGEN

1. Food business operators manufacturing collagen must ensure compliance with the requirements of this section.

2. For the purpose of this section, 'tanning' means the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents.

CHAPTER I: REQUIREMENTS FOR RAW MATERIALS

1. For the production of collagen intended for use in food, the following raw materials may be used:

   (a) hides and skins of farmed ruminant animals;

   (b) pig skins and bones;

   (c) poultry skin and bones;

   (d) tendons;

   (e) wild game hides and skins;

   and

   (f) fish skin and bones.

2. The use of hides and skins is prohibited if they have undergone any tanning process, regardless of whether this process was completed.

3. Raw materials listed in point 1(a) to (d) must derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante-and post-mortem inspection or, in the case of hides and skins from wild game, found fit for human consumption.

4. Raw materials must come from establishments registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation.

5. Collection centres and tanneries may also supply raw material for the production of collagen intended for human consumption if the competent authority specifically authorises them for this purpose and they fulfil the following requirements.

   (a) They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.

   (b) The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

   (c) If raw material not in conformity with this chapter is stored and/or processed in these premises, it must be segregated from raw material in conformity with this chapter throughout the period of receipt, storage, processing and dispatch.

CHAPTER II: TRANSPORT AND STORAGE OF RAW MATERIALS

1. In place of the identification mark provided for in Annex II, Section I, a document indicating the establishment of origin and containing the information set out in the Appendix to this Annex must accompany raw materials during transport, when delivered to a collection centre or tannery and when delivered to the collagen-processing establishment.

2. Raw materials must be transported and stored chilled or frozen unless they are processed within 24 hours after their departure. However, degreased and dried bones or ossein, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.

CHAPTER III: REQUIREMENTS FOR THE MANUFACTURE OF COLLAGEN

1. Collagen must be produced by a process that ensures that the raw material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion or by an approved equivalent process.

2. After having been subjected to the process referred to in point 1, collagen may undergo a drying process.

3. If a food business operator manufacturing collagen complies with the requirements applying to collagen intended for human consumption in respect of all the collagen that it produces, it may produce and store collagen not intended for human consumption in the same establishment.

CHAPTER IV: REQUIREMENTS FOR FINISHED PRODUCTS

Food business operators must ensure that collagen complies with the residue limits set out in the following table.

Residue	**Limit**
As	1 ppm
Pb	5 ppm
Cd	0,5 ppm
Hg	0,15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO_2 (Reith Williams)	50 ppm
H_2O_2 (European Pharmacopoeia 1986 (V_2O_2))	10 ppm

CHAPTER V: LABELLING

Wrapping and packaging containing collagen must bear the words ‘collagen fit for human consumption’ and indicate the date of preparation.

Appendix to ANNEX III

MODEL DOCUMENT TO ACCOMPANY RAW MATERIAL DESTINED FOR THE PRODUCTION OF GELATINE OR COLLAGEN

I. Identification of raw material

Type of products: .....

Date of manufacture: .....

Type of packaging: .....

Number of packages: .....

Guaranteed storage period: .....

Net weight (kg): .....

II. Origin of raw material

Address(es) and registration number(s) of the approved production establishment(s):

.....

III. Destination of raw material

The raw material will be sent:

from: .....

(place of loading)

to: .....

(country and place of destination)

by the following means of transport: .....

Name and address of consignor: .....

Name and address of consignee: .....

Corrigendum to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

(Official Journal of the European Union L 139 of 30 April 2004)

Regulation (EC) No 854/2004 should read as follows:

REGULATION (EC) No 854/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Regulation (EC) No 852/2004 of the European Parliament and of the Council [4] lays down general hygiene rules applying to all foodstuffs and Regulation (EC) No 853/2004 of the European Parliament and of the Council [5] lays down specific hygiene rules for products of animal origin.

(2) Specific rules for official controls on products of animal origin are necessary to take account of specific aspects associated with such products.

(3) The scope of the specific control rules should mirror the scope of the specific hygiene rules for food business operators laid down in Regulation (EC) No 853/2004. However, Member States should also carry out appropriate official controls to enforce national rules established in accordance with Article 1(4) of that Regulation. They may do so by extending the principles of this Regulation to such national rules.

(4) Official controls on products of animal origin should cover all aspects that are important for protecting public health and, where appropriate, animal health and animal welfare. They should be based on the most recent relevant information available and it should therefore be possible to adapt them as relevant new information becomes available.

(5) Community legislation on food safety should have a sound scientific basis. To that end, the European Food Safety Authority should be consulted whenever necessary.

(6) The nature and intensity of the official controls should be based on an assessment of public health risks, animal health and welfare, where appropriate, the type and throughput of the processes carried out and the food business operator concerned.

(7) It is appropriate to provide for the adaptation of certain specific control rules, through the transparent procedure provided for in Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004, to provide flexibility in order to accommodate the specific needs of establishments which use traditional methods, have a low throughput or are located in regions that are subject to special geographical constraints. The procedure should also allow pilot projects to take place in order to try out new approaches to hygiene controls on meat. However, such flexibility should not compromise food hygiene objectives.

(8) Official controls on the production of meat are necessary to verify that food business operators comply with hygiene rules and respect criteria and targets laid down in Community legislation. These official controls should comprise audits of food business operators 'activities and inspections, including checks on food business operators' own controls.

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(1) OJ C 262 E, 29.10.2002, p. 449.

(2) OJ C 95, 23.4.2003, p. 22.

(3) Opinion of the European Parliament of 5 June 2003 (not yet published in the Official Journal), Council Common Position of 27 October 2003 (OJ C 48 E, 24.2.2004, p. 82), Position of the European Parliament of 30 March 2004 (not yet published in the Official Journal) and Council Decision of 16 April 2004.

(4) Page 3 of this Official Journal.

(5) Page 22 of this Official Journal.

(9) In view of their specific expertise, it is appropriate for official veterinarians to carry out audits and inspections of slaughterhouses, game handling establishments and certain cutting plants. Member States should have discretion to decide which are the most appropriate staff for audits and inspections of other types of establishments.

(10) Official controls on the production of live bivalve molluscs and on fishery products are necessary to check for compliance with the criteria and targets laid down in Community legislation. Official controls on the production of live bivalve molluscs should in particular target relaying and production areas for bivalve molluscs and the end product.

(11) Official controls on the production of raw milk are necessary to check for compliance with criteria and targets laid down in Community legislation. Such official controls should in particular target milk production holdings and raw milk upon collection.

(12) The requirements of this Regulation should not apply until all parts of the new legislation on food hygiene have entered into force. It is also appropriate to provide for at least 18 months to elapse between entry into force and the application of the new rules, to allow competent authorities and the industries affected time to adapt.

(13) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation lays down specific rules for the organisation of official controls on products of animal origin.

2. It shall apply only in respect of activities and persons to which Regulation (EC) No 853/2004 applies.

3. The performance of official controls pursuant to this Regulation shall be without prejudice to food business operators' primary legal responsibility for ensuring food safety, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety [2], and any civil or criminal liability arising from the breach of their obligations.

Article 2

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'official control' means any form of control that the competent authority performs for the verification of compliance with food law, including animal health and animal welfare rules;

(b) 'verification' means checking, by examination and the provision of objective evidence, whether specified requirements have been fulfilled;

(c) 'competent authority' means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence;

(d) 'audit' means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

(e) 'inspection' means the examination of establishments, of animals and food, and the processing thereof, of food businesses, and their management and production systems, including documents, finished product testing and feeding practices, and of the origin and destination of production inputs and outputs, in order to verify compliance with the legal requirements in all cases;

(f) 'official veterinarian' means a veterinarian qualified, in accordance with this Regulation, to act in such a capacity and appointed by the competent authority;

(g) 'approved veterinarian' means a veterinarian designated by the competent authority to carry out specific official controls on holdings on its behalf;

(h) 'official auxiliary' means a person qualified, in accordance with this Regulation, to act in such a capacity, appointed by the competent authority and working under the authority and responsibility of an official veterinarian;

and

[1] OJ L 184, 17.7.1999, p. 23.

[2] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(i) 'health mark' means a mark indicating that, when it was applied, official controls had been carried out in accordance with this Regulation.

2. The definitions laid down in the following Regulations shall also apply as appropriate:

(a) Regulation (EC) No 178/2002;

(b) the definitions of 'animal by-products', 'TSEs' (transmissible spongiform encephalopathies) and 'specified risk material' laid down in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption [1];

(c) Regulation (EC) No 852/2004, except for the definition of 'competent authority';

and

(d) Regulation (EC) No 853/2004.

CHAPTER II

OFFICIAL CONTROLS IN RELATION TO COMMUNITY ESTABLISHMENTS

Article 3

Approval of establishments

1. (a) When Community legislation requires the approval of establishments, the competent authority shall make an on-site visit. It shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it meets the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 and other relevant requirements of food law.

(b) The competent authority may grant conditional approval if it appears from the on-site visit that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new on-site visit carried out within three months of the granting of conditional approval that the establishment meets the other requirements referred to in (a). If clear progress has been made but the establishment still does not meet all of these requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

2. In the case of factory and freezer vessels flying the flag of Member States, the maximum periods of three and six months applying to the conditional approval of other establishments may be extended, if necessary. However, conditional approval shall not exceed a total of 12 months. Inspections of such vessels shall take place as specified in Annex III.

3. The competent authority shall give each approved establishment, including those with conditional approval, an approval number, to which codes may be added to indicate the types of products of animal origin manufactured. For wholesale markets, secondary numbers indicating units or groups of units selling or manufacturing products of animal origin may be added to the approval number.

4. (a) The competent authority shall keep the approval of establishments under review when carrying out official controls in accordance with Articles 4 to 8.

(b) If the competent authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval. However, the competent authority may suspend an establishment's approval if the food business operator can guarantee that it will resolve deficiencies within a reasonable time.

(c) In the case of wholesale markets, the competent authority may withdraw or suspend approval in respect of certain units or groups of units.

5. Paragraphs 1, 2 and 3 shall apply both:

(a) to establishments that begin placing products of animal origin on the market on or after the date of application of this Regulation;

and

(b) to establishments already placing products of animal origin on the market but in respect of which there was previously no requirement for approval. In the latter case, the competent authority's on-site visit required under paragraph 1 shall take place as soon as possible.

Paragraph 4 shall also apply to approved establishments that placed products of animal origin on the market in accordance with Community legislation immediately prior to the application of this Regulation.

6. Member States shall maintain up-to-date lists of approved establishments, with their respective approval numbers and other relevant information, and make them available to other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 19(2).

[1] OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 813/2003 (OJ L 117, 13.5.2003, p. 22).

Article 4

General principles for official controls in respect of all products of animal origin falling within the scope of this Regulation

1. Member States shall ensure that food business operators offer all assistance needed to ensure that official controls carried out by the competent authority can be performed effectively

They shall in particular:

— give access to all buildings, premises, installations or other infrastructures;

— make available any documentation and record required under the present regulation or considered necessary by the competent authority for judging the situation.

2. The competent authority shall carry out official controls to verify food business operators' compliance with the requirements of:

(a) Regulation (EC) No 852/2004;

(b) Regulation (EC) No 853/2004;

and

(c) Regulation (EC) No 1774/2002.

3. The official controls referred to in paragraph 1 shall include:

(a) audits of good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures;

(b) the official controls specified in Articles 5 to 8;

and

(c) any particular auditing tasks specified in the Annexes.

4. Audits of good hygiene practices shall verify that food business operators apply procedures continuously and properly concerning at least:

(a) checks on food-chain information;

(b) the design and maintenance of premises and equipment;

(c) pre-operational, operational and post-operational hygiene;

(d) personal hygiene;

(e) training in hygiene and in work procedures;

(f) pest control;

(g) water quality;

(h) temperature control;

and

(i) controls on food entering and leaving the establishment and any accompanying documentation.

5. Audits of HACCP-based procedures shall verify that food business operators apply such procedures continuously and properly, having particular regard to ensuring that the procedures provide the guarantees specified in Section II of Annex II to Regulation (EC) No 853/2004. They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin:

(a) comply with microbiological criteria laid down under Community legislation;

(b) comply with Community legislation on residues, contaminants and prohibited substances;

and

(c) do not contain physical hazards, such as foreign bodies.

When, in accordance with Article 5 of Regulation (EC) No 852/2004, a food business operator uses procedures set out in guides to the application of HACCP principles rather than establishing its own specific procedures, the audit shall cover the correct use of these guides.

6. Verification of compliance with the requirements of Regulation (EC) No 853/2004 concerning the application of identification marks shall take place in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements.

7. In the case of slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market, an official veterinarian shall carry out the auditing tasks referred to in paragraphs 3 and 4.

8. When carrying out auditing tasks, the competent authority shall take special care:

(a) to determine whether staff and staff activities in the establishment at all stages of the production process comply with the relevant requirements of the Regulations referred to in paragraph 1(a) and (b). To support the audit, the competent authority may carry out performance tests, in order to ascertain that staff performance meets specified parameters;

(b) to verify the food business operator's relevant records;

(c) to take samples for laboratory analysis whenever necessary;

and

(d) to document elements taken into account and the findings of the audit.

9. The nature and intensity of auditing tasks in respect of individual establishments shall depend upon the assessed risk. To this end, the competent authority shall regularly assess:

(a) public and, where appropriate, animal health risks;

(b) in the case of slaughterhouses, animal welfare aspects;

(c) the type and throughput of the processes carried out;

and

(d) the food business operator's past record as regards compliance with food law.

Article 5

Fresh meat

Member States shall ensure that official controls with respect to fresh meat take place in accordance with Annex I.

1. The official veterinarian shall carry out inspection tasks in slaughterhouses, game handling establishments and cutting plants placing fresh meat on the market in accordance with the general requirements of Section I, Chapter II, of Annex I, and with the specific requirements of Section IV, in particular as regards:

   (a) food chain information;

   (b) *ante-mortem* inspection;

   (c) animal welfare;

   (d) post-mortem inspection;

   (e) specified risk material and other animal by-products;

   and

   (f) laboratory testing.

2. The health marking of carcases of domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, as well as half-carcases, quarters and cuts produced by cutting half-carcases into three wholesale cuts, shall be carried out in slaughterhouses and game-handling establishments in accordance with Section I, Chapter III, of Annex I. Health marks shall be applied by, or under the responsibility of, the official veterinarian when official controls have not identified any deficiencies that would make the meat unfit for human consumption.

3. After carrying out the controls mentioned in points 1 and 2, the official veterinarian shall take appropriate measures as set out in Annex I, Section II, in particular as regards:

   (a) the communication of inspection results;

   (b) decisions concerning food chain information;

   (c) decisions concerning live animals;

   (d) decisions concerning animal welfare;

   and

   (e) decisions concerning meat.

4. Official auxiliaries may assist the official veterinarian with official controls carried out in accordance with Sections I and II of Annex I as specified in Section III, Chapter I. In that case, they shall work as part of an independent team.

5. (a) Member States shall ensure that they have sufficient official staff to carry out the official controls required under Annex I with the frequency specified in Section III, Chapter II.

   (b) A risk-based approach shall be followed to assess the number of official staff that need to be present on the slaughter line in any given slaughterhouse. The number of official staff involved shall be decided by the competent authority and shall be such that all the requirements of this Regulation can be met.

6. (a) Member States may allow slaughterhouse staff to assist with official controls by carrying out certain specific tasks, under the supervision of the official veterinarian, in relation to the production of meat from poultry and lagomorphs in accordance with Annex I, Section III, Chapter III, part A. If they do so, they shall ensure that staff carrying out such tasks:

      (i) are qualified and undergo training in accordance with those provisions;

      (ii) act independently from production staff;

      and

      (iii) report any deficiency to the official veterinarian.

(b) Member States may also allow slaughterhouse staff to carry out specific sampling and testing tasks in accordance with Annex I, Section III, Chapter III, Part B.

7. Member States shall ensure that official veterinarians and official auxiliaries are qualified and undergo training in accordance with Annex I, Section III, Chapter IV.

Article 6

Live bivalve molluscs

Member States shall ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as described in Annex II.

Article 7

Fishery products

Member States shall ensure that official controls with respect to fishery products take place in accordance with Annex III.

Article 8

Raw milk and dairy products

Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV.

Article 9

Action in the case of non-compliance

1. When the competent authority identifies non-compliance with the Regulations referred to in Article 4(2)(a) and (b), it shall take action to ensure that the food business operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the food business operator's past record with regard to non-compliance.

2. Such action shall include, where appropriate, the following measures:

(a) the imposition of sanitation procedures or any other corrective action deemed necessary to ensure the safety of products of animal origin or compliance with the relevant legal requirements;

(b) the restriction or prohibition of the placing on the market, import or export of products of animal origin;

(c) monitoring or, if necessary, ordering the recall, withdrawal and/or destruction of products of animal origin;

(d) authorisation to use products of animal origin for purposes other than those for which they were originally intended;

(e) the suspension of operations or closure of all or part of the food business concerned for an appropriate period of time;

(f) the suspension or withdrawal of the establishment's approval;

(g) in the case of consignments from third countries, seizure followed by destruction or re-dispatch;

(h) any other measure that the competent authority deems appropriate.

3. The competent authority shall provide the food business operator concerned, or a representative, with:

(a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision;

and

(b) information on rights of appeal against such decisions and of the applicable procedure and time limits.

Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

CHAPTER III

PROCEDURES CONCERNING IMPORTS

Article 10

General principles and conditions

To ensure the uniform application of the principles and conditions laid down in Article 11 of Regulation (EC) No 178/2002 the procedures laid down in this c+hapter shall apply.

Article 11

Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted

1. Products of animal origin shall be imported only from a third country or a part of third country that appears on a list drawn up and updated in accordance with the procedure referred to in Article 19(2).

2. A third country shall appear on such lists only if a Community control in that country has taken place and demonstrates that the competent authority provides appropriate guarantees as specified in paragraph 4. However, a third country may appear on such lists without a Community control having taken place there if:

(a) the risk determined in accordance with Article 18(18) does not warrant it;

and

(b) it is determined, when deciding to add a particular third country to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

3. Lists drawn up in accordance with this Article may be combined with other lists drawn up for public and animal health purposes.

4. When lists are drawn up or updated, particular account shall be taken of the following criteria:

(a) the legislation of the third country on:

(i) products of animal origin,

(ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;

and

(iii) the preparation and use of feedingstuffs, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;

(b) the organisation of the third countries' competent authorities, their powers and independence, the supervision to which they are subject and the authority that they have effectively to enforce the applicable legislation;

(c) the training of staff in the performance of official controls;

(d) the resources, including diagnostic facilities available to competent authorities;

(e) the existence and operation of documented control procedures and control systems based on priorities;

(f) where applicable, the situation regarding animal health and procedures for notifying the Commission and relevant international bodies of outbreaks of animal diseases;

(g) the extent and operation of official controls on imports of animals and products of animal origin;

(h) the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements;

(i) the hygiene conditions of production, manufacture, handling, storage and dispatch actually applied to products of animal origin destined for the Community;

(j) any experience of marketing of the product from the third country and the results of any import controls carried out;

(k) the results of Community controls carried out in the third country, in particular the results of the assessment of the competent authorities, and the action that competent authorities have taken in the light of any recommendations addressed to them following a Community control;

(l) the existence, implementation and communication of an approved zoonoses control programme;

and

(m) the existence, implementation and communication of an approved residue control programme.

5. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 12

List of establishments from which imports of specified products of animal origin are permitted

1. Products of animal origin may be imported into the Community only if they have been dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and updated in accordance with this Article, except:

(a) when, on a case-by-case basis, it is decided, in accordance with the procedure referred to in Article 19(2), that the guarantees that a specified third country provides in respect of imports of specified products of animal origin are such that the procedure provided for in this Article is unnecessary to ensure compliance with the requirements of paragraph 2;

and

(b) in the cases specified in Annex V.

In addition, fresh meat, minced meat, meat preparations, meat products and mechanically separated meat (MSM) may be imported into the Community only if they have been manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with this Article or in approved Community establishments.

2. An establishment may be placed on such a list only if the competent authority of the third country of origin guarantees that:

(a) that establishment, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, complies with relevant Community requirements, in particular those of Regulation (EC) No 853/2004, or with requirements that were determined to be equivalent to such requirements when deciding to add that third country to the relevant list in accordance with Article 11;

(b) an official inspection service in that third country supervises the establishments and makes available to the Commission, where necessary, all relevant information on establishments furnishing raw materials;

and

(c) it has real powers to stop the establishments from exporting to the Community in the event that the establishments fail to meet the requirements referred to under (a).

3. The competent authorities of third countries appearing on lists drawn up and updated in accordance with Article 11 shall guarantee that lists of the establishments referred to in paragraph 1 are drawn up, kept up-to-date and communicated to the Commission.

4. (a) The Commission shall provide the contact points that Member States have designated for this purpose with regular notifications concerning new or updated lists that it has received from the competent authorities of third countries concerned in accordance with paragraph 3.

(b) If no Member State objects to the new or updated list within 20 working days of the Commission's notification, imports shall be authorised from establishments appearing on the list 10 working days after the day on which the Commission makes it available to the public.

(c) The Commission shall, whenever at least one Member State makes written comments, or whenever it considers that the modification of a list is necessary in the light of relevant information such as Community inspection reports or a notification under the rapid alert system, inform all Member States and include the point on agenda of the next meeting of the relevant section of the Standing Committee on the Food Chain and Animal Health for decision, where appropriate, in accordance with the procedure referred to in Article 19(2).

5. The Commission shall arrange for up-to-date versions of all lists to be available to the public.

Article 13

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

1. Notwithstanding Article 12(1)(b), live bivalve molluscs, echinoderms, tunicates and marine gastropods shall come from production areas in third countries that appear on lists drawn up and updated in accordance with Article 12.

2. The requirement of paragraph 1 shall not apply to pectinidae harvested outside classified production areas. However, official controls with respect to pectinidae shall take place in accordance with Annex II, Chapter III.

3. (a) Before the lists referred to in paragraph 1 are drawn up, particular account shall be taken of the guarantees that the competent authority of the third country can give concerning compliance with the requirements of this Regulation on the classification and control of production zones.

(b) An on-the-spot Community inspection visit shall take place before such lists are drawn up unless:

(i) the risk determined in accordance with Article 18(18) does not warrant it;

and

(ii) it is determined, when deciding to add a particular production area to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

4. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 14

Documents

1. A document meeting the requirements set out in Annex VI shall accompany consignments of products of animal origin when they are imported into the Community.

2. The document shall certify that the products satisfy:

(a) the requirements laid down for such products according to Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 or provisions that are equivalent to those requirements;

and

(b) any special import conditions established in accordance with Article 18(19).

3. Documents may include details required in accordance with other Community legislation on public and animal health matters.

4. Exemptions from paragraph 1 may be granted in accordance with the procedure referred to in Article 19(2) when it is possible to obtain the guarantees referred to in paragraph 2 of this Article in another manner.

Article 15

Special provisions for fishery products

1. The procedures laid down in this Chapter do not apply to fresh fishery products landed in the Community directly from a fishing vessel flying the flag of a third country.

Official controls with respect to such fishery products shall take place in accordance with Annex III.

2. (a) Fishery products imported from a factory or freezer vessel flying the flag of a third country shall come from vessels that appear on a list drawn up and updated in accordance with the procedure set out in Article 12(4).

(b) However, by way of exemption from Article 12(2)(b), a vessel may also be included on such lists:

(i) on the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and from the competent authority of another third country to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, on condition that:

— that third country appears on the list of third countries, drawn up in accordance with Article 11, from which imports of fisheries products are permitted,

— all fishery products from the vessel concerned that are destined for placing on the market in the Community are landed directly in that third country,

— the competent authority of that third country has inspected the vessel and has declared that it complies with Community requirements,

and

— the competent authority of that third country has declared that it will regularly inspect the vessel to ensure that it continues to comply with Community requirements;

or

(ii) on the basis of a joint communication from the competent authority of the third country the flag of which the vessel is flying and from the competent authority of a Member State, to which the former competent authority has delegated responsibility for the inspection of the vessel concerned, on condition that:

— all fishery products from the vessel concerned that are destined for placing on the market in the Community are landed directly in that Member State,

— the competent authority of that Member State has inspected the vessel and has declared that it complies with Community requirements,

and

— the competent authority of that Member State has declared that it will regularly inspect the vessel to ensure that it continues to comply with Community requirements.

(c) The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

3. When fishery products are imported directly from a fishing or freezer vessel, a document signed by the captain may replace the document required under Article 14.

4. Detailed rules for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 19(2).

CHAPTER IV

FINAL PROVISIONS

Article 16

Implementing measures and transitional measures

Implementing measures and transitional arrangements may be laid down in accordance with the procedure referred to in Article 19(2).

Article 17

Amendment and adaptation of the Annexes

1. Annexes I, II, III, IV, V and VI may be amended or supplemented to take account of scientific and technical progress in accordance with the procedure referred to in Article 19(2).

2. Exemptions from Annexes I, II, III, IV, V and VI may be granted in accordance with the procedure referred to in Article 19(2), provided that they do not affect the achievement of the objectives of this Regulation.

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7, national measures adapting the requirements laid down in Annex I.

4. The national measures referred to in paragraph 3 shall:

(a) have the aim of:

(i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;

(ii) accommodating the needs of food businesses with a low throughput or that are situated in regions that are subject to special geographic constraints;

or

(iii) permitting pilot projects to take place in order to try out new approaches to hygiene controls on meat;

(b) concern in particular the following elements of Annex I:

(i) food chain information;

(ii) the presence of the competent authority in establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:

(a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the establishments concerned;

(c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;

and

(d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 19(1). The Commission may decide, in accordance with the procedure referred to in Article 19(2), whether the envisaged measures may be implemented subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraphs 1 or 2 of this Article.

7. A Member State may adopt national measures adapting the requirements of Annex I only:

(a) in compliance with a decision adopted in accordance with paragraph 6;

(b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

8. When a Member State adopts national measures implementing a pilot project to try out new approaches to hygiene controls on meat in accordance with paragraphs 3 to 7, the Member State shall communicate the results to the Commission as soon as they are available. The Commission shall then consider proposing general measures in accordance with paragraph 1.

Article 18

Specific decisions

Without prejudice to the generality of Article 16 and Article 17(1), implementing measures may be laid down, or amendments to Annexes I, II, III, IV, V or VI adopted, in accordance with the procedure referred to in Article 19(2), to specify:

1. tests to assess the performance of food business operators and their staff;

2. the method of communicating inspection results;

3. criteria to determine when, on the basis of a risk analysis, the official veterinarian need not be present in slaughterhouses and game handling establishments throughout ante-mortem and post-mortem inspection;

4. rules concerning the content of tests for official veterinarians and official auxiliaries;

5. microbiological criteria for process control in relation to hygiene in establishments;

6. alternative procedures, serological or other laboratory tests that provide guarantees at least equivalent to specific post-mortem inspection procedures described in Annex I, Section IV, and may therefore replace them, if the competent authority so decides;

7. circumstances in which certain of the specific post-mortem inspection procedures described in Annex I, Section IV, are not necessary, having regard to the holding, region or country of origin and to the principles of risk analysis,

8. rules for laboratory testing;

9. the cold treatment to be applied to meat in relation to cysticercosis and trichinosis;

10. conditions under which holdings and regions can be certified as officially free of cysticercus or trichinae;

11. methods to be applied when examining for the conditions referred to in Annex I, Section IV, Chapter IX;

12. for fattening pigs, criteria for controlled housing conditions and integrated production systems;

13. criteria for the classification of production and relaying areas for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:

(a) limit values and analysis methods for marine biotoxins,

(b) virus testing procedures and virological standards,

and

(c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the criteria;

14. organoleptic criteria for the evaluation of the freshness of fishery products;

15. analytical limits, methods of analysis and sampling plans for the official controls on fishery products required under Annex III, including with regard to parasites and environmental contaminants;

16. the method by which the Commission will make lists of third countries and establishments in third countries available to the public pursuant to Articles 11, 12, 13 and 15;

17. models for documents and criteria for the use of electronic documents;

18. criteria for determining the risk that particular products of animal origin imported into the Community present;

19. special import conditions for particular products of animal origin, taking account of the associated risks, information that relevant third countries have provided and, where necessary, the results of Community controls carried out in such third countries. These special import conditions may be established for a single product of animal origin or for group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries;

and

20. the conditions governing imports of products of animal origin from a third country or a region of a third country pursuant to the implementation of an equivalence agreement, or to a satisfactory audit, recognising that measures applied in that third country or region offer guarantees equivalent to those applied in the Community, if the third country supplies objective proof in this respect.

Article 19

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 20

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on matters falling within the scope of this Regulation whenever necessary and, in particular:

1. before proposing to modify the specific requirements concerning post-mortem inspection procedures laid down in Section IV of Annex I;

2. before proposing to modify the rules of Annex I, Section IV, Chapter IX, on meat from animals in which post-mortem inspection has revealed lesions indicating infection with brucellosis or tuberculosis;

and

3. before proposing implementing measures on the matters referred to in Article 18(5) to (15).

Article 21

Report to the European Parliament and to the Council

1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council reviewing the experience gained from the application of this Regulation.

2. The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 22

Entry into force

This Regulation shall enter into force on the 20th day after that of its publication in the *Official Journal of the European Union*.

It shall apply 18 months after the date on which all of the following acts have entered into force:

(a) Regulation (EC) No 852/2004;

(b) Regulation (EC) No 853/2004

and

(c) Directive 2004/41/EC of the European Parliament and of the Council of 29 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption [1].

However, it shall apply no earlier than 1 January 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
M. McDOWELL

[1] OJ L 157, 30.4.2004, p. 33.

ANNEX I

FRESH MEAT

SECTION I: TASKS OF THE OFFICIAL VETERINARIAN

CHAPTER I: AUDITING TASKS

1. In addition to the general requirements of Article 4(4) concerning audits of good hygiene practices, the official veterinarian is to verify continuous compliance with food business operators' own procedures concerning any collection, transport, storage, handling, processing and use or disposal of animal by-products, including specified risk material, for which the food business operator is responsible.

2. In addition to the general requirements of Article 4(5) concerning audits of HACCP-based principles, the official veterinarian is to check that the operators' procedures guarantee, to the extent possible, that meat:

   (a) does not contain patho-physiological abnormalities or changes;

   (b) does not bear faecal or other contamination;

   and

   (c) does not contain specified risk material, except as provided for under Community legislation, and has been produced in accordance with Community legislation on TSEs.

CHAPTER II: INSPECTION TASKS

When carrying out inspection tasks in accordance with this Chapter, the official veterinarian is to take account of the results of the auditing tasks carried out in accordance with Article 4 and Chapter I of this Annex. Where appropriate he or she is to target inspection tasks accordingly.

A. **Food chain information**

1. The official veterinarian is to check and analyse relevant information from the records of the holding of provenance of animals intended for slaughter and to take account of the documented results of this check and analysis when carrying out ante- and post-mortem inspection.

2. When carrying out inspection tasks, the official veterinarian is to take account of official certificates accompanying animals, and any declarations made by veterinarians carrying out controls at the level of primary production, including official veterinarians and approved veterinarians.

3. When food business operators in the food chain take additional measures to guarantee food safety by implementing integrated systems, private control systems, independent third party certification or by other means, and when these measures are documented and animals covered by these schemes clearly identifiable, the official veterinarian may take this into account when carrying out inspection tasks and reviewing the HACCP-based procedures.

B. **Ante-mortem inspection**

1. Subject to paragraphs 4 and 5:

   (a) the official veterinarian is to carry out an ante-mortem inspection of all animals before slaughter;

   (b) that inspection must take place within 24 hours of arrival at the slaughterhouse and less than 24 hours before slaughter.

   In addition, the official veterinarian may require inspection at any other time.

2. Ante-mortem inspection must in particular determine whether, as regards the particular animal inspected, there is any sign:

   (a) that welfare has been compromised;

   or

   (b) of any condition which might adversely affect human or animal health, paying particular attention to the detection of zoonotic diseases and diseases on List A or, where appropriate, List B of the Office International des Epizooties (World organisation for animal health, OIE).

3. In addition to routine ante-mortem inspection, the official veterinarian is to carry out a clinical inspection of all animals that the food business operator or an official auxiliary may have put aside.

4. In the case of emergency slaughter outside the slaughterhouse and of hunted wild game, the official veterinarian at the slaughterhouse or game handling establishment is to examine the declaration accompanying the body of the animal issued by the veterinarian or the trained person in accordance with Regulation (EC) No 853/2004.

5. Where provided for in Section III, Chapter II, or in Section IV, ante-mortem inspection may be carried out at the holding of provenance. In such cases, the official veterinarian at the slaughterhouse need carry out ante-mortem inspection only when and to the extent specified.

C. **Animal welfare**

The official veterinarian is to verify compliance with relevant Community and national rules on animal welfare, such as rules concerning the protection of animals at the time of slaughter and during transport.

D. **Post-mortem inspection**

1. Carcases and accompanying offal are to be subjected without delay after slaughter to post-mortem inspection. All external surfaces are to be viewed. Minimal handling of the carcase and offal or special technical facilities may be required for that purpose. Particular attention is to be paid to the detection of zoonotic diseases and diseases on OIE List A and, where appropriate, OIE List B. The speed of the slaughter line and the number of inspection staff present are to be such as to allow for proper inspection.

2. Additional examinations are to take place, such as palpation and incision of parts of the carcase and offal and laboratory tests, whenever considered necessary:

   (a) to reach a definitive diagnosis;

   or

   (b) to detect the presence of:

      (i) an animal disease,

      (ii) residues or contaminants in excess of the levels laid down under Community legislation,

      (iii) non-compliance with microbiological criteria,

      or

      (iv) other factors that might require the meat to be declared unfit for human consumption or restrictions to be placed on its use,

   particularly in the case of animals having undergone emergency slaughter.

3. The official veterinarian is to require carcases of domestic solipeds, bovine animals over six months old, and domestic swine over four weeks old to be submitted for post-mortem inspection split lengthways into half carcases down the spinal column. If the inspection so necessitates, the official veterinarian may also require any head or any carcase to be split lengthways. However, to take account of particular eating habits, technological developments or specific sanitary situations, the competent authority may authorise the submission for inspection of carcases of domestic solipeds, bovine animals over six months old, and domestic swine over four weeks old, not split in half.

4. During the inspection, precautions must be taken to ensure that contamination of the meat by actions such as palpation, cutting or incision is kept to a minimum.

5. In the event of an emergency slaughter, the carcase shall be subjected to post-mortem examination as soon as possible in accordance with paragraphs 1 to 4 before it is released for human consumption.

E. **Specified risk material and other animal by-products**

In accordance with specific Community rules on specified risk material and other animal by-products, the official veterinarian is to check the removal, separation and, where appropriate, marking of such products. The official veterinarian is to ensure that the food business operator takes all necessary measures to avoid contaminating meat with specified risk material during slaughter (including stunning) and removal of specified risk material.

F. **Laboratory testing**

1. The official veterinarian is to ensure that sampling takes place and that samples are appropriately identified and handled and sent to the appropriate laboratory within the framework of:

   (a) the monitoring and control of zoonoses and zoonotic agents;

   (b) specific laboratory testing for the diagnosis of TSEs in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council ([1]);

   (c) the detection of unauthorised substances or products and the control of regulated substances, in particular within the framework of the National Residue Plans referred to in Council Directive 96/23/EC ([2]);

   and

   (d) the detection of OIE List A and, where appropriate, OIE List B diseases.

2. The official veterinarian is also to ensure that any other necessary laboratory testing takes place.

CHAPTER III: HEALTH MARKING

1. The official veterinarian is to supervise health marking and the marks used.

2. The official veterinarian is to ensure, in particular, that:

   (a) the health mark is applied only to animals (domestic ungulates, farmed game mammals other than lagomorphs, and large wild game) having undergone ante-mortem and post-mortem inspection in accordance with this Regulation and when there are no grounds for declaring the meat unfit for human consumption. However, the health mark may be applied before the results of any examination for trichinosis is available, if the official veterinarian is satisfied that meat from the animal concerned will be placed on the market only if the results are satisfactory;

   and

   (b) health-marking takes place on the external surface of the carcase, by stamping the mark in ink or hot branding, and in such a manner that, if carcases are cut into half carcases or quarters, or half carcases are cut into three pieces, each piece bears a health mark.

3. The health mark must be an oval mark at least 6,5 cm wide by 4,5 cm high bearing the following information in perfectly legible characters:

   (a) the mark must indicate name of the country in which the establishment is located, which may be written out in full in capitals or shown as a two-letter code in accordance with the relevant ISO standard.

   In the case of Member States, however, these codes are AT, BE, DE, DK, ES, FI, FR, GR, IE, IT, LU, NL, PT, SE and UK;

([1]) OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 2245/2003 (OJ L 333, 20.12.2003, p. 28).
([2]) OJ L 125, 23.5.1996, p. 10. Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

(b) the mark must indicate the approval number of the slaughterhouse;

and

(c) when applied in a slaughterhouse within the Community, the mark must include the abbreviation CE, EC, EF, EG, EK or EY.

4. Letters must be at least 0,8 cm high and figures at least 1 cm high. The dimensions and characters of the mark may be reduced for health marking of lamb, kids and piglets.

5. The colours used for health marking must be authorised in accordance with Community rules on the use of colouring substances in foodstuffs.

6. The health mark may also include an indication of the official veterinarian who carried out the health inspection of the meat. Competent authorities and food business operators may continue to use equipment that they ordered before entry into force of this Regulation until it is exhausted or requires replacement.

7. Meat from animals having undergone emergency slaughter outside the slaughterhouse must bear a special health mark, which cannot be confused either with the health mark provided for in this Chapter or with the identification mark provided for in Annex II, Section I, to Regulation (EC) No 853/2004.

8. Meat from unskinned wild game cannot bear a health mark unless, after skinning in a game handling establishment, it has undergone post-mortem inspection and been declared fit for human consumption.

9. This Chapter is to apply without prejudice to animal health rules on health marking.

SECTION II: ACTION FOLLOWING CONTROLS

CHAPTER I: COMMUNICATION OF INSPECTION RESULTS

1. The official veterinarian is to record and to evaluate the results of inspection activities.

2. (a) If inspections reveal the presence of any disease or condition that might affect public or animal health, or compromise animal welfare, the official veterinarian is to inform the food business operator.

(b) When the problem identified arose during primary production, the official veterinarian is to inform the veterinarian attending the holding of provenance, the food business operator responsible for the holding of provenance (provided that such information would not prejudice subsequent legal proceedings) and, where appropriate, the competent authority responsible for supervising the holding of provenance or the hunting area.

(c) If the animals concerned were raised in another Member State or in a third country, the official veterinarian is to inform to the competent authority of the Member State where the establishment is located. That competent authority is to take appropriate measures in accordance with applicable Community legislation.

3. The results of inspections and tests are to be included in relevant databases.

4. When the official veterinarian, while carrying out ante-mortem or post-mortem inspection or any other inspection activity, suspects the presence of an infectious agent mentioned on OIE List A or, where appropriate, OIE List B, the official veterinarian must immediately notify the competent authority and both must take all necessary measures and precautions to prevent the possible spread of the infectious agent in accordance with applicable Community legislation.

CHAPTER II: DECISIONS CONCERNING FOOD CHAIN INFORMATION

1. The official veterinarian is to verify that animals are not slaughtered unless the slaughterhouse operator has been provided with and checked relevant food chain information.

2. However, the official veterinarian may allow animals to undergo slaughter in the slaughterhouse even if the relevant food chain information is not available. In this case, all relevant food chain information must be supplied before the carcase is approved for human consumption. Pending a final judgement, such carcases and related offal must be stored separately from other meat.

3. Notwithstanding paragraph 2, when relevant food chain information is not available within 24 hours of an animal's arrival at the slaughterhouse, all meat from the animal is to be declared unfit for human consumption. If the animal has not yet been slaughtered, it is to be killed separately from other animals.

4. When the accompanying records, documentation or other information shows that:

   (a) animals come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health;

   (b) rules on the use of veterinary medicinal products have not been complied with;

   or

   (c) any other condition which might adversely affect human or animal health is present, animals may not be accepted for slaughter other than in accordance with procedures laid down under Community legislation to eliminate human or animal health risks.

   If the animals are already present at the slaughterhouse, they must be killed separately and declared unfit for human consumption, taking precautions to safeguard animal and public health where appropriate. Whenever the official veterinarian considers it necessary, official controls are to be carried out on the holding of provenance.

5. The competent authority is to take appropriate action if it discovers that the accompanying records, documentation or other information do not correspond with the true situation on the holding of provenance or the true condition of the animals or aim deliberately to mislead the official veterinarian. The competent authority is to take action against the food business operator responsible for the holding of provenance of the animals, or any other person involved. This action may consist in particular of extra controls. The food business operator responsible for the holding of provenance or any other person involved are to bear the costs of such extra controls.

CHAPTER III: DECISIONS CONCERNING LIVE ANIMALS

1. The official veterinarian is to verify compliance with the food business operator's duty pursuant to Regulation (EC) No 8532004 to ensure that animals accepted for slaughter for human consumption are properly identified. The official veterinarian is to ensure that animals whose identity is not reasonably ascertainable are killed separately and declared unfit for human consumption. Whenever the official veterinarian considers it necessary, official controls are to be carried out on the holding of provenance.

2. When there are overriding animal welfare considerations, horses may undergo slaughter at the slaughterhouse even if the legally required information concerning their identity has not been supplied. However, this information must be supplied before the carcase may be declared fit for human consumption. These requirements also apply in the case of emergency slaughter of horses outside the slaughterhouse.

3. The official veterinarian is to verify compliance with the food business operator's duty under Regulation (EC) No 853/2004 to ensure that animals that have such hide, skin or fleece conditions that there is an unacceptable risk of contamination of the meat during slaughter are not slaughtered for human consumption unless they are cleaned beforehand.

4. Animals with a disease or condition that may be transmitted to animals or humans through handling or eating meat and, in general, animals showing clinical signs of systemic disease or emaciation, are not to be slaughtered for human consumption. Such animals must be killed separately, under conditions such that other animals or carcases can not be contaminated, and declared unfit for human consumption.

5. The slaughter of animals suspected of having a disease or condition that may adversely affect human or animal health is to be deferred. Such animals are to undergo detailed ante-mortem examination in order to make a diagnosis. In addition, the official veterinarian may decide that sampling and laboratory examinations are to take place to supplement post-mortem inspection. If necessary, the animals are to be slaughtered separately or at the end of normal slaughtering, taking all necessary precautions to avoid contamination of other meat.

6. Animals that might contain residues of veterinary medicinal products in excess of the levels laid down in accordance with Community legislation, or residues of forbidden substances, are to be dealt with in accordance with Directive 96/23/EC.

7. The official veterinarian is to impose the conditions under which animals are to be dealt with under a specific scheme for the eradication or control of a specific disease, such as brucellosis or tuberculosis, or zoonotic agents such as salmonella, under his/her direct supervision. The competent authority is to determine the conditions under which such animals may be slaughtered. These conditions must have the aim of minimising contamination of other animals and the meat of other animals.

8. Animals that are presented to a slaughterhouse for slaughter must as a general rule be slaughtered there. However, in exceptional circumstances, such as a serious breakdown of the slaughter facilities, the official veterinarian may allow direct movements to another slaughterhouse.

CHAPTER IV: DECISIONS CONCERNING ANIMAL WELFARE

1. When the rules concerning the protection of animals at the time of slaughter or killing are not respected, the official veterinarian is to verify that the food business operator immediately takes necessary corrective measures and prevents recurrence.

2. The official veterinarian is to take a proportionate and progressive approach to enforcement action, ranging from issuing directions to slowing down and stopping production, depending on the nature and gravity of the problem.

3. Where appropriate, the official veterinarian is to inform other competent authorities of welfare problems.

4. When the official veterinarian discovers that rules concerning the protection of animals during transport are not being respected, he or she is to take necessary measures in accordance with the relevant Community legislation.

5. When:

   (a) an official auxiliary is carrying out checks on animal welfare pursuant to Sections III or IV;

   and

   (b) those checks identify non-compliance with the rules on the protection of animals,

   the official auxiliary is immediately to inform the official veterinarian and, if necessary in cases of urgency, is to take the necessary measures referred to in paragraphs 1 to 4 pending the arrival of the official veterinarian.

CHAPTER V: DECISIONS CONCERNING MEAT

1. Meat is to be declared unfit for human consumption if it:

   (a) derives from animals that have not undergone ante-mortem inspection, except for hunted wild game;

   (b) derives from animals the offal of which has not undergone post-mortem inspection, unless otherwise provided for under this Regulation or Regulation (EC) No 853/2004;

   (c) derives from animals which are dead before slaughter, stillborn, unborn or slaughtered under the age of seven days;

   (d) results from the trimming of sticking points;

   (e) derives from animals affected by an OIE List A or, where appropriate, OIE List B disease, unless otherwise provided for in Section IV;

   (f) derives from animals affected by a generalised disease, such as generalised septicaemia, pyaemia, toxaemia or viraemia;

   (g) is not in conformity with microbiological criteria laid down under Community legislation to determine whether food may be placed on the market;

   (h) exhibits parasitic infestation, unless otherwise provided for in Section IV;

   (i) contains residues or contaminants in excess of the levels laid down in Community legislation. Any overshooting of the relevant level should lead to additional analyses whenever appropriate;

(j) without prejudice to more specific Community legislation, derives from animals or carcases containing residues of forbidden substances or from animals that have been treated with forbidden substances;

(k) consists of the liver and kidneys of animals more than two years old from regions where implementation of plans approved in accordance with Article 5 of Directive 96/23/EC has revealed the generalised presence of heavy metals in the environment;

(l) has been treated illegally with decontaminating substances;

(m) has been treated illegally with ionising or UV-rays;

(n) contains foreign bodies (except, in the case of wild game, material used to hunt the animal);

(o) exceeds the maximum permitted radioactivity levels laid down under Community legislation;

(p) indicates patho-physiological changes, anomalies in consistency, insufficient bleeding (except for wild game) or organoleptic anomalies, in particular a pronounced sexual odour;

(q) derives from emaciated animals;

(r) contains specified risk material, except as provided for under Community legislation;

(s) shows soiling, faecal or other contamination;

(t) consists of blood that may constitute a risk to public or animal health owing to the health status of any animal from which it derives or contamination arising during the slaughter process;

(u) in the opinion of the official veterinarian, after examination of all the relevant information, it may constitute a risk to public or animal health or is for any other reason not suitable for human consumption.

2. The official veterinarian may impose requirements concerning the use of meat derived from animals having undergone emergency slaughter outside the slaughterhouse.

SECTION III: RESPONSIBILITIES AND FREQUENCY OF CONTROLS

CHAPTER I: OFFICIAL AUXILIARIES

Official auxiliaries may assist the official veterinarian with all tasks, subject to the following restrictions and to any specific rules laid down in Section IV:

1. in relation to auditing tasks, official auxiliaries may only collect information regarding good hygienic practices and HACCP-based procedures;

2. in relation to ante-mortem inspection and checks concerning the welfare of animals, official auxiliaries may only make an initial check of animals and help with purely practical tasks;

and

3. in relation to post-mortem inspection, the official veterinarian must regularly check the work of official auxiliaries and, in the case of animals having undergone emergency slaughter outside the slaughterhouse, carry out the inspection personally.

CHAPTER II: FREQUENCY OF CONTROLS

1. The competent authority is to ensure that at least one official veterinarian is present:

(a) in slaughterhouses, throughout both ante-mortem and post-mortem inspection;

and

(b) in game handling establishments, throughout post-mortem inspection.

2. However, the competent authority may adapt this approach in certain slaughterhouses and game handling establishments identified on the basis of a risk analysis and in accordance with criteria laid down in accordance with Article 18, point 3, if there are any. In such cases:

(a) the official veterinarian need not be present at the time of ante-mortem inspection in the slaughterhouse if:

(i) an official veterinarian or an approved veterinarian carried out ante-mortem inspection at the holding of provenance, checked the food chain information and communicated the results of the check to the official auxiliary at the slaughterhouse,

(ii) the official auxiliary at the slaughterhouse is satisfied that the food chain information does not point to any possible problem for food safety and that the animal's general state of health and welfare is satisfactory,

and

(iii) the official veterinarian regularly satisfies himself/herself that the official auxiliary is carrying out such checks properly;

(b) the official veterinarian need not be present at all times during post-mortem inspection if:

(i) an official auxiliary carries out post-mortem inspection and puts aside meat with abnormalities and all other meat from the same animal,

(ii) the official veterinarian subsequently inspects all such meat,

and

(iii) the official auxiliary documents his/her procedures and findings in a manner that allows the official veterinarian to be satisfied that standards are being met.

However, in the case of poultry and lagomorphs, the official auxiliary may discard meat with abnormalities and, subject to Section IV, the official veterinarian need not systematically inspect all such meat.

3. The flexibility provided for in paragraph 2 does not apply:

(a) to animals that have undergone emergency slaughter;

(b) to animals suspected of having a disease or condition that may adversely affect human health;

(c) to bovine animals from herds that have not been declared officially free of tuberculosis;

(d) to bovine, ovine and caprine animals from herds that have not been declared officially free of brucellosis;

(e) in the case of an outbreak of a disease listed on OIE List A or, where appropriate, OIE List B. This concerns animals susceptible to the particular disease in question that come from the particular region as defined in Article 2 of Council Directive 64/432/EEC [1];

(f) when stricter controls are necessary to take account of emerging diseases or particular OIE List B diseases.

4. In cutting plants, the competent authority is to ensure that an official veterinarian or an official auxiliary is present when meat is being worked on with a frequency appropriate to achieving the objectives of this Regulation.

[1] OJ L 121, 29.7.1964, p. 1977/64. Directive as last amended by Commission Regulation (EC) No 21/2004 (OJ L 5, 9.1.2004, p. 8).

CHAPTER III: INVOLVEMENT OF SLAUGHTERHOUSE STAFF

A. SPECIFIC TASKS CONCERNING THE PRODUCTION OF MEAT FROM POULTRY AND LAGOMORPHS

The Member States may permit slaughterhouse staff to take over the activities of the official auxiliaries in controlling the production of poultry and rabbit meat under the following conditions:

(a) Where the establishment has used good hygiene practice in accordance with Article 4(4) of this Regulation and the HACCP procedure for at least 12 months, the competent authority may authorise staff of the establishment who have been trained in the same way as the official assistants and have passed the same examination to carry out tasks of the official auxiliaries and form part of the competent authority's independent inspection team, under the supervision, direction and responsibility of the official veterinarian. In these circumstances, the official veterinarian shall be present at ante-mortem and post-mortem examinations, shall supervise these activities and carry out regular performance tests to ensure that the performance of the slaughterhouse tasks meets the specific criteria laid down by the competent authority, and shall document the results of those performance tests. Detailed rules for the performance tests shall be laid down in accordance with the procedure set out in Article 18. Where the level of hygiene of the establishment is affected by the work of this staff, where this staff does not carry out the tasks properly or where in general this staff carries out its work in a manner that the competent authority considers unsatisfactory, this staff shall be replaced by official auxiliaries.

Responsibilities for production and inspection in the establishment must be kept separate and any establishment wishing to use the establishment's own inspectors must possess internationally recognised certification.

(b) The competent authority of the Member State shall decide, in principle and on a case-by-case basis, whether to permit the implementation of the system described above. Where the Member State decides in principle in favour of this system, it shall inform the Commission of that decision and its associated conditions. For food business operators in a Member State implementing the system, the actual use of the system is optional. Food business operators shall not be forced by the competent authority to introduce the system described here. Where the competent authority is not convinced that the food business operator satisfies the requirements, the system shall not be implemented in that establishment. In order to assess this, the competent authority shall carry out an analysis of the production and inspection records, the type of activities undertaken in the establishment, the history of compliance with rules, the expertise, professional attitude and sense of responsibility of the slaughterhouse staff in regard to food safety, together with other relevant information.

B. SPECIFIC SAMPLING AND TESTING TASKS

Slaughterhouse staff who have received specific training, under the supervision of the official veterinarian, may, under the responsibility and the supervision of the official veterinarian, carry out specific sampling and testing tasks in respect of animals of all species.

CHAPTER IV: PROFESSIONAL QUALIFICATIONS

A. OFFICIAL VETERINARIANS

1. The competent authority may appoint only veterinarians who have passed a test meeting the requirements of paragraph 2 as official veterinarians.

2. The competent authority must make arrangements for the test. The test is to confirm knowledge of the following subjects to the extent necessary depending on the veterinarian's background and qualifications:

(a) national and Community legislation on veterinary public health, food safety, animal health, animal welfare and pharmaceutical substances;

(b) principles of the common agricultural policy, market measures, export refunds and fraud detection (including the global context: WTO, SPS, Codex Alimentarius, OIE);

(c) essentials of food processing and food technology;

(d) principles, concepts and methods of good manufacturing practice and quality management;

(e) pre-harvest quality management (good farming practices);

(f) promotion and use of food hygiene, food related safety (good hygiene practices);

(g) principles, concepts and methods of risk-analysis;

(h) principles, concepts and methods of HACCP, use of HACCP throughout the food production food chain;

(i) prevention and control of food-borne hazards related to human health;

(j) population dynamics of infection and intoxication;

(k) diagnostic epidemiology;

(l) monitoring and surveillance systems;

(m) auditing and regulatory assessment of food safety management systems;

(n) principles and diagnostic applications of modern testing methods;

(o) information and communication technology as related to veterinary public health;

(p) data-handling and applications of biostatistics;

(q) investigations of outbreaks of food-borne diseases in humans;

(r) relevant aspects concerning TSEs;

(s) animal welfare at the level of production, transport and slaughter;

(t) environmental issues related to food production (including waste management);

(u) precautionary principle and consumer concerns;

and

(v) principles of training of personnel working in the production chain.

Candidates may acquire the required knowledge as part of their basic veterinary training, or through training undertaken, or professional experience acquired, after qualifying as veterinarians. The competent authority may arrange for different tests to take account of candidates' background. However, when the competent authority is satisfied that a candidate has acquired all the required knowledge as part of a university degree, or through continuing education resulting in a postgraduate qualification, it may waive the requirement for a test.

3. The veterinarian is to have aptitude for multidisciplinary cooperation.

4. In addition, each official veterinarian is to undergo practical training for a probationary period of at least 200 hours before starting to work independently. During this period the probationer is to work under the supervision of existing official veterinarians in slaughterhouses, cutting plants, inspection posts for fresh meat and on holdings. The training is to concern the auditing of food safety management systems in particular.

5. The official veterinarian is to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official veterinarian is, wherever possible, to undertake annual continuing education activities.

6. Veterinarians already appointed as official veterinarians must have adequate knowledge of the subjects mentioned in paragraph 2. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.

7. Notwithstanding paragraphs 1 to 6, Member States may lay down specific rules for official veterinarians working on a part-time basis who are responsible for inspecting small businesses

B. OFFICIAL AUXILIARIES

1. The competent authority may appoint as official auxiliaries only persons who have undergone training and passed a test in accordance with the following requirements.

2. The competent authority must make arrangements for such tests. To be eligible for these tests, candidates must prove that they have received:

(a) at least 500 hours of theoretical training and at least 400 hours of practical training, covering the areas specified in paragraph 5;

and

(b) such additional training as is required to enable official auxiliaries to undertake their duties competently.

3. The practical training referred to in paragraph 2(a) is to take place in slaughterhouses and cutting plants, under the supervision of an official veterinarian, and on holdings and in other relevant establishments.

4. Training and tests are to concern principally red meat or poultrymeat. However, persons who undergo training for one of the two categories and passed the test need only undergo abridged training to pass the test for the other category. Training and test should cover wild game, farmed game and lagomorphs, where appropriate.

5. Training for official auxiliaries is to cover, and tests are to confirm knowledge of, the following subjects:

(a) in relation to holdings:

(i) theoretical part:

— familiarity with the farming industry organisation, production methods, international trade etc.,

— good livestock husbandry practices,

— basic knowledge of diseases, in particular zoonoses — viruses, bacteria, parasites etc.,

— monitoring for disease, use of medicines and vaccines, residue testing,

— hygiene and health inspection,

— animal welfare on the farm and during transport,

— environmental requirements — in buildings, on farms and in general,

— relevant laws, regulations and administrative provisions,

— consumer concerns and quality control;

(ii) practical part:

— visits to holdings of different types and using different rearing methods,

— visits to production establishments,

— observation of the loading and unloading of animals,

— laboratory demonstrations,

— veterinary checks,

— documentation;

(b) in relation to slaughterhouses and cutting plants:

(i) theoretical part:

— familiarity with the meat industry organisation, production methods, international trade and slaughter and cutting technology,

— basic knowledge of hygiene and good hygienic practices, and in particular industrial hygiene, slaughter, cutting and storage hygiene, hygiene of work,

— HACCP and the audit of HACCP-based procedures,

— animal welfare on unloading after transport and at the slaughterhouse,

— basic knowledge of the anatomy and physiology of slaughtered animals,

— basic knowledge of the pathology of slaughtered animals,

— basic knowledge of the pathological anatomy of slaughtered animals,

— relevant knowledge concerning TSEs and other important zoonoses and zoonotic agents,

— knowledge of methods and procedures for the slaughter, inspection, preparation, wrapping, packaging and transport of fresh meat,

— basic knowledge of microbiology,

— ante-mortem inspection,

— examination for trichinosis,

— post-mortem inspection,

— administrative tasks,

— knowledge of the relevant laws, regulations and administrative provisions,

— sampling procedure,

— fraud aspects;

(ii) practical part:

— animal identification,

— age checks,

— inspection and assessment of slaughtered animals,

— post-mortem inspection in a slaughterhouse,

— examination for trichinosis,

— identification of animal species by examination of typical parts of the animal,

— identifying and commenting on parts of slaughtered animals in which changes have occurred,

— hygiene control, including the audit of the good hygiene practices and the HACCP-based procedures,

— recording the results of ante-mortem inspection,

— sampling,

— traceability of meat,

— documentation.

6. Official auxiliaries are to maintain up-to-date knowledge and to keep abreast of new developments through regular continuing education activities and professional literature. The official auxiliary is, wherever possible, to undertake annual continuing education activities.

7. Persons already appointed as official auxiliaries must have adequate knowledge of the subjects mentioned in paragraph 5. Where necessary, they are to acquire this knowledge through continuing education activities. The competent authority is to make adequate provision in this regard.

8. However, when official auxiliaries carry out only sampling and analysis in connection with examinations for trichinosis, the competent authority need only ensure that they receive training appropriate to these tasks.

SECTION IV: SPECIFIC REQUIREMENTS

CHAPTER I: DOMESTIC BOVINE ANIMALS

A. BOVINE ANIMALS UNDER SIX WEEKS OLD

Carcases and offal of bovine animals under six weeks old are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and throat; incision and examination of the retropharyngeal lymph nodes (*Lnn retropharyngiales*); inspection of the mouth and fauces; palpation of the tongue; removal of the tonsils;

2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

3. visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

4. visual inspection of the diaphragm;

5. visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation and, if necessary, incision of the liver and its lymph nodes;

6. visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

9. visual inspection of the pleura and peritoneum;

10. visual inspection and palpation of the umbilical region and the joints. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

B. BOVINE ANIMALS OVER SIX WEEKS OLD

Carcases and offal of bovine animals over six weeks old are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and throat; incision and examination of the sub-maxillary, retropharyngeal and parotid lymph nodes (*Lnn retropharyngiales, mandibulares and parotidei*); examination of the external masseters, in which two incisions must be made parallel to the mandible, and the internal masseters (internal pterygoid muscles), which must be incised along one plane. The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually inspected and palpated. The tonsils must be removed;

2. inspection of the trachea and oesophagus; visual examination and palpation of the lungs; incision and examination of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthways and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

3. visual inspection of the pericardium and heart, the latter being incised lengthways so as to open the ventricles and cut through the interventricular septum;

4. visual inspection of the diaphragm;

5. visual inspection and palpation of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); incision of the gastric surface of the liver and at the base of the caudate lobe to examine the bile ducts;

6. visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection of the kidneys and incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

9. visual inspection of the pleura and the peritoneum;

10. visual inspection of the genital organs (except for the penis, if already discarded);

11. visual inspection and, if necessary, palpation and incision of the udder and its lymph nodes (*Lnn. supramammarii*). In cows, each half of the udder must be opened by a long, deep incision as far as the lactiferous sinuses (*sinus lactiferes*) and the lymph nodes of the udder must be incised, except when the udder is excluded from human consumption.

CHAPTER II: DOMESTIC SHEEP AND GOATS

Carcases and offal of sheep and goats are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head after flaying and, in the event of doubt, examination of the throat, mouth, tongue and retropharyngeal and parotid lymph nodes. Without prejudice to animal-health rules, these examinations are not necessary if the competent authority is able to guarantee that the head, including the tongue and the brains, will be excluded from human consumption;

2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*); in the event of doubt, these organs and lymph nodes must be incised and examined;

3. visual inspection of the pericardium and heart; in the event of doubt, the heart must be incised and examined;

4. visual inspection of the diaphragm;

5. visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation of the liver and its lymph nodes; incision of the gastric surface of the liver to examine the bile ducts;

6. visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*);

7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

9. visual inspection of the pleura and peritoneum;

10. visual inspection of the genital organs (except for the penis, if already discarded);

11. visual inspection of the udder and its lymph nodes;

12. visual inspection and palpation of the umbilical region and joints of young animals. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined.

CHAPTER III: DOMESTIC SOLIPEDS

Carcases and offal of solipeds are to undergo the following post-mortem inspection procedures:

1. visual inspection of the head and, after freeing the tongue, the throat; palpation and, if necessary, incision of the submaxillary, retropharyngeal and parotid lymph nodes (*Lnn retropharyngiales, mandibulares and parotidei*). The tongue must be freed to permit a detailed visual inspection of the mouth and the fauces and must itself be visually examined and palpated. The tonsils must be removed;

2. visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; palpation and, if necessary, incision of the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;

3. visual inspection of the pericardium and the heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

4. visual inspection of the diaphragm;

5. visual inspection, palpation and, if necessary, incision of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*);

6. visual inspection of the gastro-intestinal tract, the mesentery and the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); incision, if necessary, of the gastric and mesenteric lymph nodes;

7. visual inspection and, if necessary, palpation of the spleen;

8. visual inspection and palpation of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

9. visual inspection of the pleura and peritoneum;

10. visual inspection of the genital organs of stallions (except for the penis, if already discarded) and mares;

11. visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*) and, if necessary, incision of the supramammary lymph nodes;

12. visual inspection and palpation of the umbilical region and joints of young animals. In the event of doubt, the umbilical region must be incised and the joints opened; the synovial fluid must be examined;

13. all grey or white horses must be inspected for melanosis and melanomata by examination of the muscles and lymph nodes (*Lnn. subrhomboidei*) of the shoulders beneath the scapular cartilage after loosening the attachment of one shoulder. The kidneys must be exposed and examined by incision through the entire kidney.

CHAPTER IV: DOMESTIC SWINE

A. ANTE-MORTEM INSPECTION

1. The competent authority may decide that pigs intended for slaughter are to be submitted to ante-mortem inspection at the holding of provenance. In that case, slaughter of a lot of pigs from a holding may be authorised only if:

   (a) the health certificate provided for in Chapter X, Part A, accompanies them;

   and

   (b) the requirements of paragraphs 2 to 5 are complied with.

2. Ante-mortem inspection at the holding of provenance is to comprise:

   (a) checks on records or documentation at the holding, including food chain information;

   (b) the examination of the pigs to determine whether:

      (i) they have a disease or condition which may be transmitted to animals or humans through handling or eating the meat, or are behaving, individually or collectively, in a manner indicating that such a disease may occur,

      (ii) they show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption,

      or

      (iii) there is evidence or reasons to suspect that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of forbidden substances.

3. An official veterinarian or an approved veterinarian is to carry out ante-mortem inspection at the holding. The pigs are to be sent directly to slaughter and not to be mixed with other pigs.

4. Ante-mortem inspection at the slaughterhouse need cover only:

   (a) a control of the animals' identification;

   and

   (b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present. An official auxiliary may carry out this screening.

5. When pigs are not slaughtered within three days of the issue of the health certificate provided for in paragraph 1(a):

   (a) if the pigs have not left the holding of provenance for the slaughterhouse, they are to be re-examined and a new health certificate issued;

(b) if the pigs are already en route for or at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided that the pigs undergo a further veterinary ante-mortem inspection.

B. POST-MORTEM INSPECTION

1. Carcases and offal of pigs other than those referred to in paragraph 2 are to undergo the following post-mortem inspection procedures:

(a) visual inspection of the head and throat; incision and examination of the submaxillary lymph nodes (*Lnn mandibulares*); visual inspection of the mouth, fauces and tongue;

(b) visual inspection of the lungs, trachea and oesophagus; palpation of the lungs and the bronchial and mediastinal lymph nodes (*Lnn. bifucationes, eparteriales and mediastinales*). The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes; these incisions are not necessary where the lungs are excluded from human consumption;

(c) visual inspection of the pericardium and heart, the latter being incised lengthwise so as to open the ventricles and cut through the interventricular septum;

(d) visual inspection of the diaphragm;

(e) visual inspection of the liver and the hepatic and pancreatic lymph nodes, (*Lnn portales*); palpation of the liver and its lymph nodes;

(f) visual inspection of the gastro-intestinal tract, the mesentery, the gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales* and *caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;

(g) visual inspection and, if necessary, palpation of the spleen;

(h) visual inspection of the kidneys; incision, if necessary, of the kidneys and the renal lymph nodes (*Lnn. renales*);

(i) visual inspection of the pleura and peritoneum;

(j) visual inspection of the genital organs (except for the penis, if already discarded);

(k) visual inspection of the udder and its lymph nodes (*Lnn. supramammarii*); incision of the supramammary lymph nodes in sows;

(l) visual inspection and palpation of the umbilical region and joints of young animals; in the event of doubt, the umbilical region must be incised and the joints opened.

2. The competent authority may decide, on the basis of epidemiological or other data from the holding, that fattening pigs housed under controlled housing conditions in integrated production systems since weaning need, in some or all of the cases referred to in paragraph 1, only undergo visual inspection.

CHAPTER V: POULTRY

A. ANTE-MORTEM INSPECTION

1. The competent authority may decide that poultry intended for slaughter are to be submitted to ante-mortem inspection at the holding of provenance. In that case, slaughter of a flock of birds from a holding may be authorised only if:

(a) the health certificate provided for in Chapter X, Part A, accompanies them;

and

(b) the requirements of paragraphs 2 to 5 are complied with.

2. Ante-mortem inspection on the holding of provenance is to comprise:

(a) checks on records or documentation at the holding, including food chain information;

(b) a flock inspection, to determine whether the birds:

(i) have a disease or condition which may be transmitted to animals or humans through handling or eating the meat, or are behaving in a manner indicating that such a disease may occur,

(ii) show disturbance of general behaviour or signs of disease which may make the meat unfit for human consumption,

or

(iii) show evidence that they may contain chemical residues in excess of the levels laid down in Community legislation, or residues of forbidden substances.

3. An official veterinarian or an approved veterinarian is to carry out ante-mortem inspection at the holding.

4. Ante-mortem inspection at the slaughterhouse need only cover:

(a) a control of the animals' identification;

and

(b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present. An official auxiliary may carry out this screening.

5. When birds are not slaughtered within three days of the issue of the health certificate referred to in paragraph 1(a):

(a) if the flock has not left the holding of provenance for the slaughterhouse, it is to be re-examined and a new health certificate issued;

(b) if the flock is already en route for or at the slaughterhouse, slaughter may be authorised once the reason for the delay has been assessed, provided that the flock is re-examined.

6. When ante-mortem inspection is not carried out at the holding, the official veterinarian is to carry out a flock inspection at the slaughterhouse.

7. If the birds show clinical symptoms of a disease, they may not be slaughtered for human consumption. However, killing of these birds on the slaughter line may take place at the end of the normal slaughter process, if precautions are taken to avoid the risk of spreading pathogenic organisms and to clean and disinfect the facilities immediately after killing.

8. In the case of poultry reared for the production of 'foie gras' and delayed eviscerated poultry slaughtered at the holding of provenance, ante-mortem inspection is to be carried out in accordance with paragraphs 2 and 3. A certificate conforming to the model set out in Part C is to accompany the uneviscerated carcases to the slaughterhouse or cutting plant.

B. POST-MORTEM INSPECTION

1. All birds are to undergo post-mortem inspection in accordance with Sections I and III. In addition, the official veterinarian is personally to carry out the following checks:

(a) daily inspection of the viscera and body cavities of a representative sample of birds;

(b) a detailed inspection of a random sample, from each batch of birds having the same origin, of parts of birds or entire birds declared unfit for human consumption following post-mortem inspection;

and

(c) any further investigations necessary when there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.

2. In the case of poultry reared for the production of 'foie gras' and delayed eviscerated poultry obtained at the holding of provenance, post-mortem inspection is to include a check on the certificate accompanying the carcases. When such carcases are transported directly from the holding to a cutting plant, post-mortem inspection is to take place at the cutting plant.

C. SPECIMEN HEALTH CERTIFICATE

HEALTH CERTIFICATE

for poultry intended for the production of foie gras and delayed eviscerated poultry slaughtered at the holding of provenance

Competent service: .....

No: .....

1. Identification of uneviscerated carcases

Species: .....

Number: .....

2. Provenance of uneviscerated carcases

Address of holding: .....

3. Destination of uneviscerated carcases

The uneviscerated carcases will be transported to the following cutting plant: .....

.....

4. Declaration

I, the undersigned, declare that:

— the uneviscerated carcases described above are of birds which were examined before slaughter on the abovementioned holding at ..... (time) on ..... (date) and found to be healthy;

— the records and documentation concerning these animals satisfied the legal requirements and do not prohibit slaughter of the birds.

Done at: .....

(Place)

on: .....

(Date)

Stamp

.....

(Signature of the official or approved veterinarian)

CHAPTER VI: FARMED LAGOMORPHS

The requirements for poultry are to apply to farmed lagomorphs.

CHAPTER VII: FARMED GAME

A. **Ante-mortem inspection**

1. Ante-mortem inspection may be carried out at the holding of provenance when the requirements of Annex III, Section III, to Regulation (EC) No 853/2004 are satisfied. In this case, an official veterinarian or an approved veterinarian is to carry out ante-mortem inspection.

2. Ante-mortem inspection at the holding is to include checks on the records or documentation at the holding, including food chain information.

3. When ante-mortem inspection takes place no more than three days before the arrival of the animals at the slaughterhouse, and animals are delivered to the slaughterhouse live, ante-mortem inspection at the slaughterhouse need only cover:

   (a) a control of the animals' identification;

   and

   (b) a screening to ascertain whether animal welfare rules have been complied with and whether signs of any condition which might adversely affect human or animal health are present.

4. A certificate conforming to the specimen in Chapter X, Part A, is to accompany live animals inspected at the holding. A certificate conforming to the specimen in Chapter X, Part B, is to accompany animals inspected and slaughtered at the holding.

B. **Post-mortem inspection**

1. This inspection is to include palpation and, where judged necessary, incision of those parts of the animal which have undergone any change or are suspect for any other reason.

2. Post-mortem inspection procedures described for bovine and ovine animals, domestic swine and poultry are to be applied to the corresponding species of farmed game.

3. When the animals have been slaughtered at the holding, the official veterinarian at the slaughterhouse is to check the certificate accompanying them.

CHAPTER VIII: WILD GAME

A. **Post-mortem inspection**

1. Wild game is to be inspected as soon as possible after admission to the game handling establishment.

2. The official veterinarian is to take account of the declaration or information that the trained person involved in hunting the animal has provided in accordance with Regulation (EC) No 853/2004.

3. During post-mortem inspection, the official veterinarian is to carry out:

   (a) a visual examination of the carcase, its cavities and, where appropriate, organs with a view to:

      (i) detecting any abnormalities not resulting from the hunting process. For this purpose, the diagnosis may be based on any information that the trained person has provided concerning the behaviour of the animal before killing,

      (ii) checking that death was not caused by reasons other than hunting.

   If an assessment cannot be made on the basis of visual examination alone, a more extensive inspection must be carried out in a laboratory;

   (b) an investigation of organoleptic abnormalities;

   (c) palpation of organs, where appropriate;

(d) where there are serious grounds for suspecting the presence of residues or contaminants, an analysis by sampling of residues not resulting from the hunting process, including environmental contaminants. When a more extensive inspection is made on the basis of such suspicions, the veterinarian must wait until that inspection has been concluded before assessing all the game killed during a specific hunt, or those parts suspected of showing the same abnormalities;

(e) examination for characteristics indicating that the meat presents a health risk, including:

(i) abnormal behaviour or disturbance of the general condition of the live animal, as reported by the hunter,

(ii) the generalised presence of tumours or abscesses affecting different internal organs or muscles,

(iii) arthritis, orchitis, pathological changes in the liver or the spleen, inflammation of the intestines or the umbilical region,

(iv) the presence of foreign bodies not resulting from the hunting process in the body cavities, stomach or intestines or in the urine, where the pleura or peritoneum are discoloured (when relevant viscera are present),

(v) the presence of parasites,

(vi) formation of a significant amount of gas in the gastro-intestinal tract with discolouring of the internal organs (when these viscera are present),

(vii) significant abnormalities of colour, consistency or odour of muscle tissue or organs,

(viii) aged open fractures,

(ix) emaciation and/or general or localised oedema,

(x) recent pleural or peritoneal adhesions,

and

(xi) other obvious extensive changes, such as putrefaction.

4. Where the official veterinarian so requires, the vertebral column and the head are to be split lengthwise.

5. In the case of small wild game not eviscerated immediately after killing, the official veterinarian is to carry out a post-mortem inspection on a representative sample of animals from the same source. Where inspection reveals a disease transmissible to man or any of the characteristics listed in paragraph 3(e), the official veterinarian is to carry out more checks on the entire batch to determine whether it must be declared unfit for human consumption or whether each carcase must be inspected individually.

6. In the event of doubt, the official veterinarian may perform any further cuts and inspections of the relevant parts of the animals necessary to reach a final diagnosis.

B. **Decisions following controls**

In addition to the cases provided for in Section II, Chapter V, meat presenting during post-mortem inspection any of the characteristics listed in paragraph 3(e) of Part A is to be declared unfit for human consumption.

CHAPTER IX: SPECIFIC HAZARDS

A. **Transmissible spongiform encephalopathies**

Official controls carried out in relation to TSEs are to take account of the requirements of Regulation (EC) No 999/2001 and other relevant Community legislation.

B. **Cysticercosis**

1. The post-mortem inspection procedures described in Chapters I and IV are the minimum requirements for the examination for cysticercosis in bovine animals over six weeks old and swine. In addition, specific serological tests may be used. In the case of bovines over six weeks old, incision of the masseters at post-mortem inspection is not compulsory when a specific serological test is used. The same applies when bovine animals over six weeks old have been raised on a holding officially certified to be free of cysticercosis.

2. Meat infected with cysticercus is to be declared unfit for human consumption. However, when the animal is not generally infected with cysticercus, the parts not infected may be declared fit for human consumption after having undergone a cold treatment.

C. **Trichinosis**

1. Carcases of swine (domestic, farmed game and wild game), solipeds and other species susceptible to trichinosis are to be examined for trichinosis in accordance with applicable Community legislation, unless that legislation provides otherwise.

2. Meat from animals infected with trichinae is to be declared unfit for human consumption.

D. **Glanders**

1. Where appropriate, solipeds are to be examined for glanders. Examination for glanders in solipeds is to include a careful examination of mucous membranes from the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum.

2. Meat from horses in which glanders has been diagnosed are to be declared unfit for human consumption.

E. **Tuberculosis**

1. When animals have reacted positively or inconclusively to tuberculin, or there are other grounds for suspecting infection, they are to be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. All meat from animals in which post-mortem inspection has revealed localised tuberculous lesions in a number of organs or a number of areas of the carcase is to be declared unfit for human consumption. However, when a tuberculous lesion has been found in the lymph nodes of only one organ or part of the carcase, only the affected organ or part of the carcase and the associated lymph nodes need be declared unfit for human consumption.

F. **Brucellosis**

1. When animals have reacted positively or inconclusively to a brucellosis test, or there are other grounds for suspecting infection, they are to be slaughtered separately from other animals, taking precautions to avoid the risk of contamination of other carcases, the slaughter line and staff present in the slaughterhouse.

2. Meat from animals in which post-mortem inspection has revealed lesions indicating acute infection with brucellosis is to be declared unfit for human consumption. In the case of animals reacting positively or inconclusively to a brucellosis test, the udder, genital tract and blood must be declared unfit for human consumption even if no such lesion is found.

CHAPTER X: SPECIMEN HEALTH CERTIFICATE

A. SPECIMEN HEALTH CERTIFICATE FOR LIVE ANIMALS

HEALTH CERTIFICATE

for live animals transported from the holding to the slaughterhouse

Competent service: .....

No: .....

1. Identification of the animals

Species: .....

Number of animals: .....

Identification marking: .....

2. Provenance of the animals

Address of holding of provenance: .....

Identification of house (*): .....

3. Destination of the animals

The animals will be transported to the following slaughterhouse: .....

by the following means of transport: .....

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

— the animals described above were examined before slaughter at the abovementioned holding at ..... (time) on ..... (date) and were found to be healthy,

— the records and documentation concerning these animals satisfied the legal requirements and do not prohibit slaughter of the animals.

Done at: .....

(Place)

on: .....

(Date)

Stamp

.....

(Signature of official or approved veterinarian)

(*) optional

B. SPECIMEN HEALTH CERTIFICATE FOR ANIMALS SLAUGHTERED AT THE HOLDING

HEALTH CERTIFICATE

for animals slaughtered at the holding

Competent service: .....

No: .....

1. Identification of the animals

Species: .....

Number of animals: .....

Identification marking: .....

2. Provenance of the animals

Address of holding of provenance: .....

Identification of house (*): .....

3. Destination of the animals

The animals will be transported to the following slaughterhouse: .....

.....

by the following means of transport: .....

4. Other relevant information

.....

5. Declaration

I, the undersigned, declare that:

— the animals described above were examined before slaughter at the abovementioned holding at ..... (time) on ..... (date) and were found to be healthy,

— they were slaughtered at the holding at ..... (time) on ..... (date) and slaughter and bleeding were carried out correctly,

— the records and documentation concerning these animals satisfied the legal requirements and did not prohibit slaughter of the animals.

Done at: .....
(Place)

on: .....
(Date)

Stamp

.....
(Signature of official or approved veterinarian)

(*) optional

ANNEX II

LIVE BIVALVE MOLLUSCS

CHAPTER I: SCOPE

This Annex applies to live bivalve molluscs and, by analogy, to live echinoderms, live tunicates and live marine gastropods.

CHAPTER II: OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AREAS

A. *CLASSIFICATION OF PRODUCTION AND RELAYING AREAS*

1. The competent authority must fix the location and boundaries of production and relaying areas that it classifies. It may, where appropriate, do so in cooperation with the food business operator.

2. The competent authority must classify production areas from which it authorises the harvesting of live bivalve molluscs as being of one of three categories according to the level of faecal contamination. It may, where appropriate, do so in cooperation with the food business operator.

3. The competent authority may classify as being of Class A areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, of Regulation (EC) No 853/2004.

4. The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected, but placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution Most Probable Number (MPN) test of 4 600 *E.coli* per 100 g of flesh and intravalvular liquid.

5. The competent authority may classify as being of Class C areas from which live bivalve molluscs may be collected but placed on the market only after relaying over a long period so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution MPN test of 46 000 *E.coli* per 100 g of flesh and intravalvular liquid.

6. If the competent authority decides in principle to classify a production or relaying area, it must:

   (a) make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;

   (b) examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;

   (c) determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area;

   and

   (d) establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered.

B. *MONITORING OF CLASSIFIED RELAYING AND PRODUCTION AREAS*

1. Classified relaying and production areas must be periodically monitored to check:

   (a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

(b) the microbiological quality of live bivalve molluscs in relation to the production and relaying areas;

(c) for the presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs;

and

(d) for the presence of chemical contaminants in live bivalve molluscs.

2. To implement paragraph 1(b), (c) and (d), sampling plans must be drawn up providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency must ensure that the results of the analysis are as representative as possible for the area considered.

3. Sampling plans to check the microbiological quality of live bivalve molluscs must take particular account of:

(a) the likely variation in faecal contamination,

and

(b) the parameters referred to in paragraph 6 of Part A.

4. Sampling plans to check for the presence of toxin-producing plankton in production and relaying waters and for biotoxins in live bivalve molluscs must take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling must comprise:

(a) periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in mollusc flesh must be followed by intensive sampling;

(b) periodic toxicity tests using those molluscs from the affected area most susceptible to contamination.

5. The sampling frequency for toxin analysis in the molluscs is, as a general rule, to be weekly during the periods at which harvesting is allowed. This frequency may be reduced in specific areas, or for specific types of molluscs, if a risk assessment on toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. It is to be increased where such an assessment suggests that weekly sampling would not be sufficient. The risk assessment is to be periodically reviewed in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.

6. When knowledge of toxin accumulation rates is available for a group of species growing in the same area, a species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. When toxin levels in the indicator species are above the regulatory limits, harvesting of the other species is only to be allowed if further analysis on the other species shows toxin levels below the limits.

7. With regard to the monitoring of plankton, the samples are to be representative of the water column and to provide information on the presence of toxic species as well as on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency of molluscs is to be increased or precautionary closures of the areas are to be established until results of toxin analysis are obtained.

8. Sampling plans to check for the presence of chemical contaminants must enable the detection of any overshooting of the levels laid down in Commission Regulation (EC) No 466/2001 [1].

C. *DECISIONS AFTER MONITORING*

1. Where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority must close the production area concerned, preventing the

[1] OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 655/2004 (OJ L 104, 8.4.2004, p. 48).

harvesting of live bivalve molluscs. However, the competent authority may reclassify a production area as being of Class B or C if it meets the relevant criteria set out in Part A and presents no other risk to human health.

2. The competent authority may re-open a closed production area only if the health standards for molluscs once again comply with Community legislation. If the competent authority closes a production because of the presence of plankton or excessive levels of toxins in molluscs, at least two consecutive results below the regulatory limit separated at least 48 hours are necessary to re-open it. The competent authority may take account of information on phytoplankton trends when taking this decision. When there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authority may decide to re-open the area with results below the regulatory limit obtained from one single sampling.

D. *ADDITIONAL MONITORING REQUIREMENTS*

1. The competent authority is to monitor classified production areas from which it has forbidden the harvesting of bivalve molluscs or subjected harvesting to special conditions, to ensure that products harmful to human health are not placed on the market.

2. In addition to the monitoring of relaying and production zones referred to in paragraph 1 of Part B, a control system must be set up comprising laboratory tests to verify food business operators' compliance with the requirements for the end product at all stages of production, processing and distribution. This control system is, in particular, to verify that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

E. *RECORDING AND EXCHANGE OF INFORMATION*

The competent authority must:

(a) establish and keep up to date a list of approved production and relaying areas, with details of their location and boundaries, as well as the class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of this Annex. This list must be communicated to interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres;

(b) immediately inform the interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres, about any change of the location, boundaries or class of a production area, or its closure, be it temporary or final;

and

(c) act promptly where the controls prescribed in this Annex indicate that a production area must be closed or reclassified or can be re-opened.

F. *FOOD BUSINESS OPERATORS' OWN CHECKS*

To decide on the classification, opening or closure of production areas, the competent authority may take into account the results of controls that food business operators or organisations representing food business operators have carried out. In that event, the competent authority must have designated the laboratory carrying out the analysis and, if necessary, sampling and analysis must have taken place in accordance with a protocol that the competent authority and the food business operators or organisation concerned have agreed.

CHAPTER III: OFFICIAL CONTROLS CONCERNING PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Official controls on pectinidae harvested outside classified production areas are to be carried out in fish auctions, dispatch centres and processing establishments. Such official controls are to verify compliance with the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, to Regulation (EC) No 853/2004 as well as compliance with other requirements of Annex III, Section VII, Chapter IX to that Regulation.

ANNEX III

FISHERY PRODUCTS

CHAPTER I: OFFICIAL CONTROLS OF PRODUCTION AND PLACING ON THE MARKET

1. Official controls on the production and placing on the market of fishery products are to include, in particular:

   (a) a regular check on the hygiene conditions of landing and first sale;

   (b) inspections at regular intervals of vessels and establishments on land, including fish auctions and wholesale markets, to check, in particular:

      (i) where appropriate, whether the conditions for approval are still fulfilled,

      (ii) whether the fishery products are handled correctly,

      (iii) for compliance with hygiene and temperature requirements,

      and

      (iv) the cleanliness of establishments, including vessels, and their facilities and equipment, and staff hygiene;

      and

   (c) checks on storage and transport conditions.

2. However, subject to paragraph 3, official controls of vessels:

   (a) may be carried out when vessels call at a port in a Member State;

   (b) concern all vessels landing fishery products at ports in the Community, irrespective of flag;

      and

   (c) may, if necessary, when the competent authority of the Member State the flag of which the vessel is flying carries out the official control, be carried out while the vessel is at sea or when it is in a port in another Member State or in a third country.

3. (a) In the case of an inspection of a factory or freezer vessel flying the flag of a Member State carried out with a view to the approval of the vessel, the competent authority of the Member State the flag of which the vessel is flying is to carry out inspections in such a manner as to comply with the requirements of Article 3, particularly the time limits of Article 3(2). If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.

   (b) When the competent authority of the Member State the flag of which the vessel is flying has granted the vessel conditional approval in accordance with Article 3, that competent authority may authorise a competent authority of:

      (i) another Member State,

      or

      (ii) a third country that appears on a list of third countries from which imports of fishery products are permitted drawn up in accordance with Article 11, to carry out a follow-up inspection with a view to granting full approval or prolonging conditional approval in accordance with Article 3(1)(b) or to keeping approval under review in accordance with Article 3(4). If necessary, that competent authority may inspect the vessel while it is at sea or when it is in a port in another Member State or in a third country.

4. When the competent authority of a Member State authorises the competent authority of another Member State or of a third country to carry out inspections on its behalf in accordance with paragraph 3, the two competent authorities are to agree on the conditions governing such inspections. These conditions are to ensure, in particular, that the competent authority of the Member State the flag of which the vessel is flying receives reports on the results of inspections and on any suspected non-compliance without delay, so as to enable it to take the necessary measures.

CHAPTER II: OFFICIAL CONTROLS OF FISHERY PRODUCTS

Official controls of fishery products are to include at least the following elements.

A. *ORGANOLEPTIC EXAMINATIONS*

Random organoleptic checks must be carried out at all stages of production, processing and distribution. One aim of these checks is to verify compliance with the freshness criteria established in accordance with Community legislation. In particular, this includes verifying, at all stages of production, processing and distribution, that fishery products at least exceed the baselines of freshness criteria established in accordance with Community legislation.

B. *FRESHNESS INDICATORS*

When the organoleptic examination reveals any doubt as to the freshness of the fishery products, samples may be taken and subjected to laboratory tests to determine the levels of total volatile basic nitrogen (TVB-N) and trimethylamine nitrogen (TMA-N).

The competent authority is to use the criteria laid down under Community legislation.

When the organoleptic examination gives cause to suspect the presence of other conditions which may affect human health, appropriate samples are to be taken for verification purposes.

C. *HISTAMINE*

Random testing for histamine is to be carried out to verify compliance with the permitted levels laid down under Community legislation.

D. *RESIDUES AND CONTAMINANTS*

Monitoring arrangements are to be set up to control the levels of residues and contaminants in accordance with Community legislation.

E. *MICROBIOLOGICAL CHECKS*

Where necessary, microbiological checks are to be performed in accordance with the relevant rules and criteria laid down under Community legislation.

F. *PARASITES*

Random testing is to take place to verify compliance with Community legislation on parasites.

G. *POISONOUS FISHERY PRODUCTS*

Checks are to take place to ensure that the following fishery products are not placed on the market:

1. poisonous fish of the following families are not placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*;

   and

2. fishery products containing biotoxins such as *Ciguatera* or other toxins dangerous to human health. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No 853/2004 and comply with the standards laid down in Chapter V, point 2, of that section.

CHAPTER III: DECISIONS AFTER CONTROLS

Fishery products are to be declared unfit for human consumption if:

1. organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not in compliance with the relevant Community legislation;

2. they contain in their edible parts contaminants or residues in excess of the limits laid down in Community legislation or at levels where the calculated dietary intake would exceed the acceptable daily or weekly intake for humans;

3. they derive from:

   (i) poisonous fish,

   (ii) fishery products not complying with the requirement of part G, point 2, of Chapter II concerning biotoxins,

   or

   (iii) bivalve molluscs, echinoderms, tunicates or marine gastropods containing marine biotoxins in total quantities exceeding the limits referred to in Regulation (EC) No 853/2004;

   or

4. the competent authority considers that they may constitute a risk to public or animal health or are for any other reason not suitable for human consumption.

ANNEX IV

RAW MILK AND DAIRY PRODUCTS

CHAPTER I: CONTROL OF MILK PRODUCTION HOLDINGS

1. Animals on milk production holdings must be subject to official controls to verify that the health requirements for raw milk production, and in particular the health status of the animals and the use of veterinary medicinal products, are being complied with.

   These controls may take place at the occasion of veterinary checks carried out pursuant to Community provisions on animal or public health or animal welfare and may be carried out by an approved veterinarian.

2. If there are grounds for suspecting that the animal health requirements are not being complied with, the general health status of the animals is to be checked.

3. Milk production holdings are to undergo official controls to verify that hygiene requirements are being complied with. These official controls may involve inspections and/or the monitoring of controls that professional organisations carry out. If it is shown that the hygiene is inadequate, the competent authority is to verify that appropriate steps are taken to correct the situation.

CHAPTER II: CONTROL OF RAW MILK UPON COLLECTION

1. The competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III, to Regulation (EC) No 853/2004.

2. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and somatic cell count, delivery of raw milk from the production holding is to be suspended or — in accordance with a specific authorisation of, or general instructions from, the competent authority — subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these requirements are to remain in place until the food business operator has proved that the raw milk again complies with the criteria.

ANNEX V

ESTABLISHMENTS NOT SUBJECT TO THE LISTING REQUIREMENT OF ARTICLE 12(1)

The following third-country establishments need not appear on lists drawn up and updated in accordance with Article 12(4):

1. establishments handling products of animal origin for which Annex III to Regulation (EC) No 853/2004 does not lay down requirements;

2. establishments carrying out only primary production;

3. establishments carrying out only transport operations;

4. establishments carrying out only the storage of products of animal origin not requiring temperature-controlled storage conditions.

ANNEX VI

REQUIREMENTS FOR CERTIFICATES ACCOMPANYING IMPORTS

1. The representative of the competent authority of the third country of dispatch issuing a certificate to accompany a consignment of products of animal origin destined for the Community must sign the certificate and ensure that it bears an official stamp. This requirement applies to each sheet of the certificate if it consists of more than one. In the case of factory vessels, the competent authority may authorise the captain or another ship's officer to sign the certificate.

2. Certificates must be drawn up in the official language or languages of the third country of dispatch and the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or languages. If the Member State of destination so requests, certificates must also be accompanied by a certified translation into the official language or languages of that Member State. However, a Member State may consent to the use of an official Community language other than its own.

3. The original version of the certificate must accompany consignments on entry into the Community.

4. Certificates must consist of:

   (a) a single sheet of paper;

   or

   (b) two or more pages that are part of an integrated and indivisible sheet of paper;

   or

   (c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (for example, 'page 2 of four pages').

5. Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.

6. The certificate must be issued before the consignment to which it relates leaves the control of the competent authority of the third country of dispatch.

CORRIGENDA

Corrigendum to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

(Official Journal of the European Union L 165 of 30 April 2004)

Regulation (EC) No 882/2004 should read as follows:

REGULATION (EC) No 882/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 29 April 2004

on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95 and 152(4)(b) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Feed and food should be safe and wholesome. Community legislation comprises a set of rules to ensure that this objective is attained. These rules extend to the production and the placing on the market of both feed and food.

(2) The basic rules with regard to feed and food law are laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [4].

(3) In addition to those basic rules, more specific feed and food law covers different areas such as animal nutrition including medicated feedingstuffs, feed and food hygiene, zoonoses, animal by-products, residues and contaminants, control and eradication of animal diseases with a public health impact, feed and food labelling, pesticides, feed and food additives, vitamins, mineral salts, trace elements and other additives, materials in contact with food, quality and compositional requirements, drinking water, ionisation, novel foods and genetically modified organisms (GMOs).

(4) Community feed and food law is based on the principle that feed and food business operators at all stages of production, processing and distribution within the businesses under their control are responsible for ensuring that feed and food satisfy the requirements of feed and food law which are relevant to their activities.

(5) Animal health and animal welfare are important factors that contribute to the quality and safety of food, to the prevention of the spreading of animal diseases and to a humane treatment of animals. The rules covering these matters are laid down in several acts. These acts specify the obligations of natural and legal persons with regard to animal health and animal welfare as well as the duties of the competent authorities.

(6) The Member States should enforce feed and food law, animal heath and animal welfare rules and monitor and verify that the relevant requirements thereof are fulfilled by business operators at all stages of production, processing and distribution. Official controls should be organised for that purpose.

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(1) OJ C 234, 30.9.2003, p. 25.

(2) OJ C 23, 27.1.2004, p. 14.

(3) Opinion of the European Parliament of 9 March 2004 (not yet published in the Official Journal) and Council Decision of 26 April 2004.

(4) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

(7) It is therefore appropriate to establish at Community level a harmonised framework of general rules for the organisation of such controls. It is appropriate to assess in the light of experience whether such a general framework functions properly, in particular in the area of animal health and welfare. It is therefore appropriate for the Commission to present a report together with any necessary proposal.

(8) As a general rule this Community framework should not include official controls with regard to organisms harmful to plants and plant products since these controls are already adequately covered by Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community [1]. Certain aspects of this Regulation should however also apply to the plant health sector and in particular those concerning the establishment of multiannual national control plans and Community inspections within the Member States and in third countries. It is therefore appropriate to amend Directive 2000/29/EC accordingly.

(9) Council Regulations (EEC) No 2092/91 of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs [2], (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [3], and (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs [4] contain specific measures for the verification of compliance with the requirements contained therein. The requirements of this Regulation should be flexible enough so as to take account of the specificity of these areas.

(10) For the verification of compliance with the rules on the common organisation of the markets of agricultural products (arable crops, wine, olive oil, fruit and vegetables, hops, milk and milk products, beef and veal, sheepmeat and goatmeat and honey) a well established and specific control system is already in place. This Regulation should therefore not apply to these areas, all the more since the objectives of this Regulation differ from the objectives pursued by the control mechanisms for the common organisation of the markets of agricultural products.

(11) The competent authorities for performing official controls should meet a number of operational criteria so as to ensure their impartiality and effectiveness. They should have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly.

(12) The official controls should be carried out using appropriate techniques developed for that purpose, including routine surveillance checks and more intensive controls such as inspections, verifications, audits, sampling and the testing of samples. The correct implementation of those techniques requires appropriate training of the staff performing official controls. Training is also required in order to ensure that the competent authorities take decisions in a uniform way, in particular with regard to the implementation of the hazard analysis and critical control points (HACCP) principles.

(13) The frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or quality assurance programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules. Ad hoc controls should be carried out in case of suspicion of non-compliance. Additionally ad hoc controls could be carried out at any time, even where there is no suspicion of non-compliance.

(14) Official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality.

(15) The competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented.

[1] OJ L 169, 10.7.2000, p. 1. Directive as last amended by Commission Directive 2004/31/EC (OJ L 85, 23.3.2004, p. 18).

[2] OJ L 198, 22.7.1991, p. 1. Regulation as last amended by Regulation (EC) No 392/2004 (OJ L 65, 3.3.2004, p. 1).

[3] OJ L 208, 24.7.1992, p. 1. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

[4] OJ L 208, 24.7.1992, p. 9. Regulation as last amended by Regulation (EC) No 806/2003.

(16) The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level.

(17) Laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated. Such laboratories should in particular have equipment that enables the correct determination of standards such as maximum residue levels fixed by Community law.

(18) The designation of Community and national reference laboratories should contribute to a high quality and uniformity of analytical results. This objective can be achieved by activities such as the application of validated analytical methods, ensuring that reference materials are available, the organisation of comparative testing and the training of staff from laboratories.

(19) The activities of reference laboratories should cover all the areas of feed and food law and animal health, in particular those areas where there is a need for precise analytical and diagnostic results.

(20) For a number of activities related to official controls, the European Committee for Standardisation (CEN) has developed European standards (EN standards) appropriate for the purpose of this Regulation. These EN standards relate in particular to the operation and assessment of testing laboratories and to the operation and accreditation of control bodies. International standards have also been drawn up by the International Organisation for Standardisation (ISO) and the International Union of Pure and Applied Chemistry (IUPAC). These standards might, in certain well defined cases, be appropriate for the purposes of this Regulation, taking into account that performance criteria are laid down in feed and food law in order to ensure flexibility and cost effectiveness.

(21) Provision should be made for delegating competence for performing specific control tasks from the competent authority to a control body, and for the conditions under which such delegation can take place.

(22) Appropriate procedures should be available for the cooperation of the competent authorities in and between the Member States, in particular when official controls reveal that feed and food problems extend to more than one Member State. In order to facilitate such cooperation, Member States should designate one or more liaison bodies with the role of coordinating the transmission and reception of requests for assistance.

(23) In accordance with Article 50 of Regulation (EC) No 178/2002, the Member States shall inform the Commission where information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed is available.

(24) It is important to create uniform procedures for the control of feed and food from third countries introduced into the territory of the Community, taking into account that harmonised import procedures have already been established for food of animal origin by virtue of Council Directive 97/78/EC [1], and for live animals by virtue of Council Directive 91/496/EEC [2].

These existing procedures function properly and should be maintained.

(25) The checks on feed and food from third countries referred to in Directive 97/78/EC are limited to veterinary aspects. It is necessary to supplement these checks with official controls on aspects that are not covered by veterinary checks, such as those on additives, labelling, traceability, irradiation of food and materials in contact with food.

(26) Community legislation also provides for procedures for the control of imported feed by virtue of Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition [3]. That Directive contains principles and procedures that must be applied by the Member States when releasing imported feed for free circulation.

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[1] Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

[2] Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries (OJ L 268, 24.9.1991, p. 56). Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).

[3] OJ L 265, 8.11.1995, p. 17. Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

(27) It is appropriate to establish Community rules in order to ensure that feed and food from third countries is submitted to official controls before release for free circulation in the Community. Special attention should be paid to import controls of feed and food for which there may be an increased risk of contamination.

(28) Provision should also be made for the organisation of official controls of feed and food that is introduced into the territory of the Community under customs procedures other than free circulation, and in particular those introduced under the customs procedures referred to in points (b) to (f) of Article 4(16) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [1], as well as their entry into a free zone or free warehouse. This includes the introduction of feed and food from third countries by passengers of international means of transport and through parcels sent by mail.

(29) For the purpose of official controls on feed and food, it is necessary to define the territory of the Community in which the rules apply in order to ensure that feed and food that is introduced into this territory is submitted to the controls laid down by this Regulation. This territory is not necessarily the same as provided for in Article 299 of the Treaty, or as defined in Article 3 of Regulation (EEC) No 2913/92.

(30) In order to ensure a more efficient organisation of the official controls on feed and food from third countries and in order to facilitate commercial flows, it may be necessary to designate specific points of entry for feed and food from third countries into the territory of the Community. Likewise, it may be necessary to require prior notification of the arrival of goods at the territory of the Community. It should be ensured that each designated point of entry has access to the appropriate facilities to operate controls within reasonable time limits.

(31) In establishing rules on the official controls of feed and food from third countries, it should be ensured that the competent authorities and the customs services work together, taking into account the fact that rules to that effect already exist in Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries [2].

(32) Adequate financial resources should be available for organising official controls. Hence, the competent authorities of the Member States should be able to levy the fees or charges to cover the costs incurred through official controls. In the process, the competent authorities of the Member States will be at liberty to establish the fees and charges as flat-rate amounts based on the costs incurred and taking the specific situation of the establishments into account. Where fees are imposed on operators, common principles should apply. It is appropriate therefore to lay down the criteria for setting the level of inspection fees. With regard to fees applicable for import controls, it is appropriate to establish directly the rates for main import items with a view to ensuring their uniform application and to avoiding trade distortions.

(33) Community feed and food law provides for the registration or approval of certain feed and food businesses by the competent authority. This is particularly the case in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [3], Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [3], Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector [4] and the future regulation on feed hygiene.

Procedures should be put in place in order to ensure that registration and approval of feed and food businesses are carried out in an effective and transparent way.

(34) In order to have a global and uniform approach with regard to official controls, Member States should establish and implement multiannual national control plans in accordance with broad guidelines drawn up at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy should take a comprehensive, integrated approach to the operation of controls. In view of the non-binding character of certain technical guidelines to be established it is appropriate to establish them by means of a consultative Committee procedure.

(35) The multiannual national control plans should cover feed and food law, and the legislation on animal health and animal welfare.

[1] OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 2700/2000 of the European Parliament and of the Council (OJ L 311, 12.12.2000, p. 17).

[2] OJ L 40, 17.2.1993, p. 1. Regulation as last amended by Regulation (EC) No 806/2003.

[3] OJ L 139, 30.4.2004, p.55.

[4] OJ L 332, 30.12.1995, p. 15. Directive as last amended by Regulation (EC) No 806/2003.

(36) The multiannual national control plans should establish a solid basis for the Commission inspection services to carry out controls in the Member States. The control plans should enable the Commission inspection services to verify whether the official controls in the Member States are organised in accordance with the criteria laid down in this Regulation. Where appropriate and, in particular, where the audit of the Member States against the multiannual national control plans shows weaknesses or failures, detailed inspections and audits should be carried out.

(37) Member States should be required to present an annual report to the Commission with information on the implementation of the multiannual national control plans. This report should provide the results of the official controls and audits carried out during the previous year and, where necessary, an update of the initial control plan in response to these results.

(38) Community controls in the Member States should allow the Commission control services to verify whether feed and food law and the legislation on animal health and animal welfare are implemented in a uniform and correct way throughout the Community.

(39) Community controls in third countries are required in order to verify compliance or equivalence with Community feed and food law as well as with the legislation on animal health and, where appropriate, welfare. Third countries may also be requested to provide information on their control systems. This information, which should be established on the basis of Community guidelines, should form the basis for subsequent Commission controls, which should be carried out within a multidisciplinary framework covering the main sectors exporting to the Community. This evolution should allow a simplification of the current regime, enhance effective control cooperation, and consequently facilitate trade flows.

(40) In order to ensure that imported goods comply with or are equivalent to Community feed and food law, it is necessary to establish procedures that allow the definition of import conditions and certification requirements as appropriate.

(41) Breaches of feed and food law and of animal health and animal welfare rules may constitute a threat to human health, animal health, and animal welfare. Such breaches should therefore be subject to effective, dissuasive and proportionate measures at national level throughout the Community.

(42) Such measures should include administrative action by the competent authorities in the Member States who should have procedures in place for that purpose. The advantage of such procedures is that quick action can be undertaken in order to restore the situation.

(43) Operators should have a right to appeal against the decisions taken by the competent authority as a result of the official controls, and be informed of such a right.

(44) It is appropriate to take account of the special needs of developing countries, and in particular of the least-developed countries, and to introduce measures to that effect. The Commission should be committed to support developing countries with regard to feed and food safety, which is an important element of human health and trade development. Such support should be organised in the context of the Community's development cooperation policy.

(45) The rules contained in this Regulation underpin the integrated and horizontal approach necessary to implement a coherent control policy on feed and food safety, animal health and animal welfare. There should be room however to develop specific control rules where required, for example with regard to the setting of maximum residue levels for certain contaminants at Community level. Likewise, more specific rules existing in the area of feed and food and animal health and animal welfare controls should be kept in place.

These include in particular the following acts: Directive 96/22/EC Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in [1], Directive 96/23/EC [2], Regulation (EC)

[1] stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, (OJ L 125, 23.5.1996, p. 3). Directive as last amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

[2] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as last amended by Regulation (EC) No 806/2003.

No 854/2004 [1], Regulation (EC) No 999/2001 [2], Regulation (EC) No 2160/2003 [3], Directive 86/362/EEC [4], Directive 90/642/EEC [5] and the implementing rules resulting therefrom, Directive 92/1/EEC [6], Directive 92/2/EEC [7], and acts on the control of animal diseases such as foot-and-mouth disease, swine fever etc., as well as requirements on the official controls on the welfare of animals.

(46) This Regulation covers areas that are already covered in certain acts in force at present. It is appropriate therefore to repeal in particular the following acts on feed and food controls and to replace them by the rules of this Regulation: Directive 70/373/EEC [8]; Directive 85/591/EEC [9]; Directive 89/397/EEC [10]; Directive 93/99/EEC [11]; Decision 93/383/EEC [12]; Directive 95/53/EC; Directive 96/43/EC [13]; Decision 98/728/EC [14]; and Decision 1999/313/EC [15].

(47) In the light of this Regulation, Directives 96/23/EC, 97/78/EC and 2000/29/EC should be amended.

(48) Since the objective of this Regulation, namely to ensure a harmonised approach with regard to official controls, cannot be sufficiently achieved by the Member States and can therefore, by reason of its complexity, its trans-border character and, with regard to feed and food imports, its international character, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(49) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [16],

HAVE ADOPTED THIS REGULATION:

TITLE I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation lays down general rules for the performance of official controls to verify compliance with rules aiming, in particular, at:

(a) preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment;

and

(1) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

(2) Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1). Regulation as last amended by Commission Regulation (EC) No 2245/2003 (OJ L 333, 20.12.2003, p. 28).

(3) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

(4) Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals (OJ L 221, 7.8.1986, p. 37). Directive as last amended by Commission Directive 2004/2/EC (OJ L 14, 21.1.2004, p. 10).

(5) Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables (OJ L 350, 14.12.1990, p. 71). Directive as last amended by Commission Directive 2004/2/EC.

(6) Commission Directive 92/1/EEC of 13 January 1992 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption (OJ L 34, 11.2.1992, p. 28).

(7) Commission Directive 92/2/EEC of 13 January 1992 laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption (OJ L 34, 11.2.1992, p. 30).

(8) Council Directive 70/373/EEC of 20 July 1970 on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs (OJ L 170, 3.8.1970, p. 2). Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

(9) Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption (OJ L 372, 31.12.1985, p. 50). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)

(10) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs (OJ L 186, 30.6.1989, p. 23)

(11) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (OJ L 290, 24.11.1993, p. 14). Directive as amended by Regulation (EC) No 1882/2003.

(12) Council Decision 93/383/EEC of 14 June 1993 of reference laboratories for the monitoring of marine biotoxins (OJ L 166, 8.7.1993, p. 31). Decision as amended by Decision 1999/312/EC (OJ L 120, 8.5.1999, p. 37).

(13) Council Directive 96/43/EC of 26 June 1996 amending and consolidating Directive 85/73/EEC in order to ensure financing of veterinary inspections and controls on live animals and certain animal products (OJ L 162, 1.7.1996, p. 1).

(14) Council Decision 98/728/EC of 14 December 1998 concerning a Community system for fees in the animal feed sector (OJ L 346, 22.12.1998, p. 51).

(15) Council Decision 1999/313/EC of 29 April 1999 on reference laboratories for monitoring bacteriological and viral contamination of bivalve molluscs (OJ L 120, 8.5.1999, p. 40).

(16) OJ L 184, 17.7.1999, p. 23.

(b) guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information.

2. This Regulation shall not apply to official controls for the verification of compliance with the rules on common market organisations of agricultural products.

3. This Regulation shall be without prejudice to specific Community provisions concerning official controls.

4. The performance of official controls pursuant to this Regulation shall be without prejudice to feed and food business operators' primary legal responsibility for ensuring feed and food safety, as laid down in Regulation (EC) No 178/2002, and any civil or criminal liability arising from the breach of their obligations.

Article 2

Definitions

For the purposes of this Regulation, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 shall apply.

The following definitions shall also apply:

1. 'official control' means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules;

2. 'verification' means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;

3. 'feed law' means the laws, regulations and administrative provisions governing feed in general and feed safety in particular, whether at Community or national level; it covers all stages of production, processing and distribution of feed and the use of feed;

4. 'competent authority' means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country;

5. 'control body' means an independent third party to which the competent authority has delegated certain control tasks;

6. 'audit' means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;

7. 'inspection' means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules;

8. 'monitoring' means conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules;

9. 'surveillance' means a careful observation of one or more feed or food businesses, feed or food business operators or their activities;

10. 'non-compliance' means non-compliance with feed or food law, and with the rules for the protection of animal health and welfare;

11. 'sampling for analysis' means taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules;

12. 'official certification' means the procedure by which the competent authority or control bodies, authorised to act in such a capacity, provide written, electronic or equivalent assurance concerning compliance;

13. 'official detention' means the procedure by which the competent authority ensures that feed or food is not moved or tampered with pending a decision on its destination; it includes storage by feed and food business operators in accordance with instructions from the competent authority;

14. 'equivalence' means the capability of different systems or measures to meet the same objectives; and 'equivalent' means different systems or measures capable of meeting the same objectives;

15. 'import' means the release for free circulation of feed or food or the intention to release feed or food for free circulation within the meaning of Article 79 of Regulation (EEC) No 2913/92 in one of the territories referred to in Annex I;

16. 'introduction' means import as defined in point 15 above, and the placing of goods under the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92, as well as their entry into a free zone or free warehouse;

17. 'documentary check' means the examination of commercial documents and, where appropriate, of documents required under feed or food law that are accompanying the consignment;

18. 'identity check' means a visual inspection to ensure that certificates or other documents accompanying the consignment tally with the labelling and the content of the consignment;

19. 'physical check' means a check on the feed or food itself which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other check necessary to verify compliance with feed or food law;

20. 'control plan' means a description established by the competent authority containing general information on the structure and organisation of its official control systems.

TITLE II

OFFICIAL CONTROLS BY MEMBER STATES

CHAPTER I

GENERAL OBLIGATIONS

Article 3

General obligations with regard to the organisation of official controls

1. Member States shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Regulation taking account of:

(a) identified risks associated with animals, feed or food, feed or food businesses, the use of feed or food or any process, material, substance, activity or operation that may influence feed or food safety, animal health or animal welfare;

(b) feed or food business operators' past record as regards compliance with feed or food law or with animal health and animal welfare rules;

(c) the reliability of any own checks that have already been carried out;

and

(d) any information that might indicate non-compliance.

2. Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis.

3. Official controls shall be carried out at any of the stages of production, processing and distribution of feed or food and of animals and animal products. They shall include controls on feed and food businesses, on the use of feed and food, on the storage of feed and food, on any process, material, substance, activity or operation including transport applied to feed or food and on live animals, required to achieve the objectives of this Regulation.

4. Official controls shall be applied, with the same care, to exports outside the Community, to the placing on the market within the Community and to introductions from third countries into the territories referred to in Annex I.

5. Member States shall take all necessary measures to ensure that products intended for dispatch to another Member State are controlled with the same care as those intended to be placed on the market in their own territory.

6. The competent authority of the Member State of destination may check compliance of feed and food with feed and food law by means of non-discriminatory checks. To the extent strictly necessary for the organisation of the official controls, Member States may ask operators who have goods delivered to them from another Member State to report the arrival of such goods.

7. If, during a check carried out at the place of destination or during storage or transport, a Member State establishes non-compliance, it shall take the appropriate measures, which may include re-dispatch to the Member State of origin.

CHAPTER II

COMPETENT AUTHORITIES

Article 4

Designation of competent authorities and operational criteria

1. Member States shall designate the competent authorities responsible for the purposes and official controls set out in this Regulation.

2. The competent authorities shall ensure:

(a) the effectiveness and appropriateness of official controls on live animals, feed and food at all stages of production, processing and distribution, and on the use of feed;

(b) that staff carrying out official controls are free from any conflict of interest;

(c) that they have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively;

(d) that they have appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;

(e) that they have the legal powers to carry out official controls and to take the measures provided for in this Regulation;

(f) that they have contingency plans in place, and are prepared to operate such plans in the event of an emergency;

(g) that the feed and food business operators are obliged to undergo any inspection carried out in accordance with this Regulation and to assist staff of the competent authority in the accomplishment of their tasks.

3. When a Member State confers the competence to carry out official controls on an authority or authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection.

4. Competent authorities shall ensure the impartiality, quality and consistency of official controls at all levels. The criteria listed in paragraph 2 must be fully respected by every authority on which the competence to carry out official controls is conferred.

5. When, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

6. Competent authorities shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Regulation. These audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

7. Detailed rules for the implementation of this Article may be adopted in accordance with the procedure referred to in Article 62(3).

Article 5

Delegation of specific tasks related to official controls

1. The competent authority may delegate specific tasks related to official controls to one or more control bodies in accordance with paragraphs 2 to 4.

A list of tasks that may or may not be delegated may be established in accordance with the procedure referred to in Article 62(3).

However, the activities referred to in Article 54 shall not be the subject of such a delegation.

2. The competent authority may delegate specific tasks to a particular control body only if:

(a) there is an accurate description of the tasks that the control body may carry out and of the conditions under which it may carry them out;

(b) there is proof that the control body:

(i) has the expertise, equipment and infrastructure required to carry out the tasks delegated to it;

(ii) has a sufficient number of suitably qualified and experienced staff;

and

(iii) is impartial and free from any conflict of interest as regards the exercise of the tasks delegated to it;

(c) the control body works and is accredited in accordance with European Standard EN 45004 'General criteria for the operation of various types of bodies performing inspection' and/or another standard if more relevant to the delegated tasks in question;

(d) laboratories operate in accordance with the standards referred to in Article 12(2);

(e) the control body communicates the results of the controls carried out to the competent authority on a regular basis and whenever the competent authority so requests. If the results of the controls indicate non-compliance or point to the likelihood of non-compliance, the control body shall immediately inform the competent authority;

(f) there is efficient and effective coordination between the delegating competent authority and the control body.

3. Competent authorities delegating specific tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it appears that such bodies are failing to carry out properly the tasks delegated to them, the delegating competent authority may withdraw the delegation. It shall withdraw it without delay if the control body fails to take appropriate and timely remedial action.

4. Any Member State wishing to delegate a specific control task to a control body shall notify the Commission. This notification shall provide a detailed description of:

(a) the competent authority that would delegate the task;

(b) the task that it would delegate;

and

(c) the control body to which it would delegate the task.

Article 6

Staff performing official controls

The competent authority shall ensure that all of its staff performing official controls:

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. This training shall cover as appropriate the areas referred to in Annex II, Chapter I;

(b) keep up to date in their area of competence and receive regular additional training as necessary;

and

(c) have aptitude for multidisciplinary cooperation.

Article 7

Transparency and confidentiality

1. The competent authorities shall ensure that they carry out their activities with a high level of transparency. For that purpose, relevant information held by them shall be made available to the public as soon as possible.

In general, the public shall have access to:

(a) information on the control activities of the competent authorities and their effectiveness;

and

(b) information pursuant to Article 10 of Regulation (EC) No 178/2002.

2. The competent authority shall take steps to ensure that members of their staff are required not to disclose information acquired when undertaking their official control duties which by its nature is covered by professional secrecy in duly justified cases. Protection of professional secrecy shall not prevent the dissemination by the competent authorities of information referred to in paragraph 1(b). The rules of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1] remain unaffected.

3. Information covered by professional secrecy includes in particular:

— the confidentiality of preliminary investigation proceedings or of current legal proceedings,

— personal data,

— the documents covered by an exception in Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [2],

— information protected by national and Community legislation concerning in particular professional secrecy, the confidentiality of deliberations, international relations and national defence.

Article 8

Control and verification procedures

1. Competent authorities shall carry out official controls in accordance with documented procedures. These procedures shall contain information and instructions for staff performing official controls including, *inter alia*, the areas referred to in Annex II, Chapter II.

[1] OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003.

[2] OJ L 145, 31.5.2001, p. 43.

2. Member States shall ensure that they have legal procedures in place in order to ensure that staff of the competent authorities have access to premises of and documentation kept by feed and food business operators so as to be able to accomplish their tasks properly.

3. Competent authorities shall have procedures in place:

(a) to verify the effectiveness of official controls that they carry out;

and

(b) to ensure that corrective action is taken when needed and that the documentation referred to in paragraph 1 is updated as appropriate.

4. The Commission may establish guidelines for official controls in accordance with the procedure referred to in Article 62(2).

The guidelines may, in particular, contain recommendations concerning official controls on:

(a) the implementation of HACCP principles;

(b) management systems that feed or food business operators operate with a view to meeting the requirements of feed or food law;

(c) the microbiological, physical and chemical safety of feed and food.

Article 9

Reports

1. The competent authority shall draw up reports on the official controls that it has carried out.

2. These reports shall include a description of the purpose of the official controls, the control methods applied, the results of the official controls and, where appropriate, action that the business operator concerned is to take.

3. The competent authority shall provide the business operator concerned with a copy of the report referred to in paragraph 2, at least in case of non-compliance.

Article 10

Control activities, methods and techniques

1. Tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

2. Official controls on feed and food shall include, *inter alia,* the following activities:

(a) examination of any control systems that feed and food business operators have put in place and the results obtained;

(b) inspection of:

(i) primary producers' installations, feed and food businesses, including their surroundings, premises, offices, equipment, installations and machinery, transport, as well as of feed and food;

(ii) raw materials, ingredients, processing aids and other products used for the preparation and production of feed and food;

(iii) semi-finished products;

(iv) materials and articles intended to come into contact with food;

(v) cleaning and maintenance products and processes, and pesticides;

(vi) labelling, presentation and advertising;

(c) checks on the hygiene conditions in feed and food businesses;

(d) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP), good farming practices and HACCP, taking into account the use of guides established in accordance with Community legislation;

(e) examination of written material and other records which may be relevant to the assessment of compliance with feed or food law;

(f) interviews with feed and food business operators and with their staff;

(g) the reading of values recorded by feed or food business measuring instruments;

(h) controls carried out with the competent authority's own instruments to verify measurements taken by feed and food business operators;

(i) any other activity required to ensure that the objectives of this Regulation are met.

CHAPTER III

SAMPLING AND ANALYSIS

Article 11

Methods of sampling and analysis

1. Sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or,

(a) if no such rules exist, with internationally recognised rules or protocols, for example those that the European Committee for Standardisation (CEN) has accepted or those agreed in national legislation;

or,

(b) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.

2. Where paragraph 1 does not apply, validation of methods of analysis may take place within a single laboratory according to an internationally accepted protocol.

3. Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III.

4. The following implementing measures may be taken in accordance with the procedure referred to in Article 62(3):

(a) methods of sampling and analysis, including the confirmatory or reference methods to be used in the event of a dispute;

(b) performance criteria, analysis parameters, measurement uncertainty and procedures for the validation of the methods referred to in (a);

and

(c) rules on the interpretation of results.

5. The competent authorities shall establish adequate procedures in order to guarantee the right of feed and food business operators whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of competent authorities to take prompt action in case of emergency.

6. In particular, they shall ensure that feed and food business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substrate.

7. Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.

Article 12

Official laboratories

1. The competent authority shall designate laboratories that may carry out the analysis of samples taken during official controls.

2. However, competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with the following European standards:

(a) EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories';

(b) EN 45002 on 'General criteria for the assessment of testing laboratories';

(c) EN 45003 on 'Calibration and testing laboratory accreditation system — General requirements for operation and recognition',

taking into account criteria for different testing methods laid down in Community feed and food law.

3. The accreditation and assessment of testing laboratories referred to in paragraph 2 may relate to individual tests or groups of tests.

4. The competent authority may cancel the designation referred to in paragraph 1 when the conditions referred to in paragraph 2 are no longer fulfilled.

CHAPTER IV

CRISIS MANAGEMENT

Article 13

Contingency plans for feed and food

1. For the implementation of the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002, Member States shall draw up operational contingency plans setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment.

2. These contingency plans shall specify:

(a) the administrative authorities to be engaged;

(b) their powers and responsibilities;

and

(c) channels and procedures for sharing information between the relevant parties.

3. Member States shall review these contingency plans as appropriate, particularly in the light of changes in the organisation of the competent authority and of experience, including experience gained from simulation exercises.

4. Where necessary, implementing measures may be adopted in accordance with the procedure referred to in Article 62(3). Such measures shall establish harmonised rules for contingency plans to the extent necessary to ensure that such plans are compatible with the general plan for crisis management referred to in Article 55 of Regulation (EC) No 178/2002. They shall also indicate the role of stakeholders in the establishment and operation of contingency plans.

CHAPTER V

OFFICIAL CONTROLS ON THE INTRODUCTION OF FEED AND FOOD FROM THIRD COUNTRIES

Article 14

Official controls on feed and food of animal origin

1. This Regulation shall not affect the requirements for veterinary checks on feed and food of animal origin provided for in Directive 97/78/EC. However, the competent authority designated in accordance with Directive 97/78/EC shall, in addition, carry out official controls to verify compliance with aspects of feed or food law that that Directive does not cover, as appropriate, including those aspects referred to in Title VI, Chapter II of this Regulation.

2. The general rules of Articles 18 to 25 of this Regulation shall also apply to official controls on all feed and food, including feed and food of animal origin.

3. Satisfactory results of checks on goods that are:

(a) placed under one of the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92;

or

(b) to be handled in free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92,

shall neither affect the duty of feed and food business operators to ensure that feed and food comply with feed and food law from the moment of release for free circulation nor prevent further official controls on the feed or food concerned from being carried out.

Article 15

Official controls on feed and food of non-animal origin

1. The competent authority shall carry out regular official controls on feed and food of non-animal origin not included in the scope of Directive 97/78/EC, imported into the territories referred to in Annex I. It shall organise these controls on the basis of the multi-annual national control plan drawn up in accordance with Articles 41 to 43 and in the light of potential risks. The controls shall cover all aspects of feed and food law.

2. These controls shall be carried out at an appropriate place, including the point of entry of the goods into one of the territories referred to in Annex I, the point of release for free circulation, warehouses, the premises of the importing feed and food business operator, or other points of the feed and food chain.

3. These controls may also be carried out on goods that are:

(a) placed under one of the customs procedures referred to in points (b) to (f) of Article 4(16) of Regulation (EEC) No 2913/92;

or

(b) to enter free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92.

4. Satisfactory results of checks referred to in paragraph 3 shall neither affect the duty of feed and food business operators to ensure that feed and food comply with feed and food law from the moment of release for free circulation nor prevent further official controls on the feed or food concerned from being carried out.

5. A list of feed and food of non-animal origin that is, on the basis of known or emerging risk, to be subject to an increased level of official controls at the point of entry into territories referred to in Annex I shall be drawn up and updated, in accordance with the procedure referred to in Article 62(3). The frequency and nature of these controls shall be laid down in accordance with the same procedure. At the same time, the fees related to such controls may be established in accordance with the same procedure.

Article 16

Types of checks on feed and food of non-animal origin

1. The official controls referred to in Article 15(1) shall include at least a systematic documentary check, a random identity check and, as appropriate, a physical check.

2. Physical checks shall be carried out at a frequency depending on:

(a) the risks associated with different types of feed and food;

(b) the history of compliance with the requirements for the product concerned of the third country and establishment of origin and of the feed or food business operators importing and exporting the product;

(c) the controls that the feed or food business operator importing the product has carried out;

(d) the guarantees that the competent authority of the third country of origin has given.

3. The Member States shall ensure that physical checks are carried out under appropriate conditions and at a place with access to appropriate control facilities allowing investigations to be conducted properly, a number of samples adapted to the risk management to be taken, and the feed and food to be handled hygienically. Samples must be handled in such a way as to guarantee both their legal and analytical validity. Member States shall ensure that the equipment and methodology are adequate for measuring the limit values laid down under Community or national legislation.

Article 17

Points of entry and prior notification

1. Member States shall, for the organisation of the official controls referred to in Article 15(5):

— designate particular points of entry in their territory which have access to the appropriate control facilities for different types of feed and food;

and

— require feed and food business operators responsible for consignments to give prior notification of their arrival and nature.

Member States may apply the same rules for other feed of non-animal origin.

2. Member States shall inform the Commission and other Member States of any measures that they take in accordance with paragraph 1.

They shall design those measures in such a way as to avoid unnecessary disruption of trade.

Article 18

Action in case of suspicion

In case of suspicion of non-compliance or if there is doubt as to the identity or the actual destination of the consignment, or as to the correspondence between the consignment and the certified guarantees, the competent authority shall carry out official controls in order to confirm or to eliminate the suspicion or doubt. The competent authority shall place the consignment concerned under official detention until it obtains the results of such official controls.

Article 19

Action following official controls on feed and food from third countries

1. The competent authority shall place under official detention feed or food from third countries that does not comply with feed or food law and, having heard the feed or food business operators responsible for the consignment, it shall take the following measures in respect of such feed or food:

(a) order that such feed or food be destroyed, subjected to a special treatment in accordance with Article 20 or re-dispatched outside the Community in accordance with Article 21; other appropriate measures such as the use of feed or food for purposes other than those for which they were originally intended may also be taken;

(b) if the feed or food has already been placed on the market, monitor or, if necessary, order its recall or withdrawal before taking one of the measures referred to above;

(c) verify that feed and food does not give rise to any adverse effects on human or animal health, either directly or through the environment, during or pending the implementation of any of the measures referred to in subparagraphs (a) and (b).

2. If, however:

(a) the official controls provided for in Articles 14 and 15 indicate that a consignment is injurious to human or animal health or unsafe, the competent authority shall place the consignment in question under official detention pending its destruction or any other appropriate measure necessary to protect human and animal health;

(b) feed or food of non-animal origin for which an increased level of controls has been laid down in accordance with

Article 15(5) is not presented for official controls, or is not presented in accordance with any specific requirements established in accordance with Article 17, the competent authority shall order that it be recalled and placed under official detention without delay and that it be then either destroyed or re-dispatched in accordance with Article 21.

3. When it does not permit the introduction of feed or food, the competent authority shall notify the Commission and other Member States of its findings and of the identification of the products concerned in accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002 and shall notify its decisions to the customs services, together with information as regards the final destination of the consignment.

4. Decisions on consignments shall be subject to the right of appeal referred to in Article 54(3).

Article 20

Special treatment

1. The special treatment referred to in Article 19 may include:

(a) treatment or processing to bring the feed or food into line with the requirements of Community law, or with the requirements of a third country of re-dispatch, including decontamination, where appropriate, but excluding dilution;

(b) processing in any other suitable manner for purposes other than animal or human consumption.

2. The competent authority shall ensure that special treatment takes place in establishments under its control, or under the control of another Member State, and in accordance with conditions laid down in accordance with the procedure referred to in Article 62(3) or, in the absence of such conditions, with national rules.

Article 21

Re-dispatch of consignments

1. The competent authority shall allow re-dispatch of consignments only if:

(a) the destination has been agreed with the feed or food business operator responsible for the consignment; and

(b) the feed and food business operator has first informed the competent authority of the third country of origin or third country of destination, if different, of the reasons and circumstances preventing the placing on the market of the feed or food concerned within the Community;

and

(c) when the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority of its preparedness to accept the consignment.

2. Without prejudice to the national rules applicable with respect to the time limits for applying for a supplementary expert opinion, and where the results of official controls do not preclude it, re-dispatch shall, as a general rule, take place no more than 60 days after the day on which the competent authority decided on the destination of the consignment, unless legal action has been undertaken. If, after the expiry of the 60-day period, re-dispatch does not take place, the consignment shall be destroyed, unless a delay is justified.

3. Pending re-dispatch of consignments or confirmation of the reasons for rejection, the competent authority shall place consignments under official detention.

4. The competent authority shall notify the Commission and other Member States in accordance with the procedure provided for in Article 50(3) of Regulation (EC) No 178/2002 and shall notify its decisions to the customs services. Competent authorities shall cooperate in accordance with Title IV to take any further measures necessary to ensure that it is not possible to reintroduce the rejected consignments into the Community.

Article 22

Costs

The feed or food business operator responsible for the consignment or its representative shall be liable for the costs incurred by competent authorities for the activities referred to in Articles 18, 19, 20 and 21.

Article 23

Approval of pre-export checks by third countries

1. Specific pre-export checks that a third country carries out on feed and food immediately prior to export to the Community with a view to verifying that the exported products satisfy Community requirements may be approved in accordance with the procedure referred to in Article 62(3). The approval may apply only to feed and food originating in the third country concerned and may be granted for one or more products.

2. Where such approval has been granted, the frequency of import controls for feed or food may be reduced as a consequence. However, Member States shall carry out official controls on feed and food imported in accordance with the approval referred to in paragraph 1 so as to ensure that the pre-export checks carried out in the third country remain effective.

3. The approval referred to in paragraph 1 may only be granted to a third country if:

(a) a Community audit has shown that feed or food exported to the Community meets Community requirements, or equivalent requirements;

(b) the controls carried out in the third country prior to dispatch are considered sufficiently effective and efficient as to replace or reduce the documentary, identity and physical checks laid down in Community law.

4. The approval referred to in paragraph 1 shall specify the competent authority of the third country under the responsibility of which the pre-export checks are performed and, if appropriate, any control body to which that competent authority may delegate certain tasks. Such delegation may be approved only if it meets the criteria of Article 5 or equivalent conditions.

5. The competent authority and any control body specified in the approval shall be responsible for contacts with the Community.

6. The competent authority or control body of the third country shall ensure the official certification of each consignment checked prior to its entry into one of the territories referred to in Annex I. The approval referred to in paragraph 1 shall specify a model for such certificates.

7. Without prejudice to Article 50(3) of Regulation (EC) No 178/2002, when official controls on imports subject to the procedure referred to in paragraph 2 reveal significant non-compliance, Member States shall immediately notify the Commission and other Member States and the operators concerned in accordance with the procedure provided for in Title IV of this Regulation; Member States shall increase the number of consignments checked and, where necessary to allow a proper analytical examination of the situation, keep an appropriate number of samples under appropriate storage conditions.

8. If it is found that, in a significant number of consignments, the goods do not correspond to the information in the certificates that the competent authority or control body of the third country has issued, the reduced frequency referred to in paragraph 2 shall no longer apply.

Article 24

Competent authorities and customs services

1. For the organisation of the official controls referred to in this Chapter, the competent authorities and the customs services shall cooperate closely.

2. With regard to consignments of feed and food of animal origin and of feed and food referred to in Article 15(5), customs services shall not allow their entry or handling in free zones or free warehouses without the agreement of the competent authority.

3. Where samples are taken, the competent authority shall inform the customs services and the operators concerned and indicate whether or not the goods can be released before the results of the analysis of the samples are available, provided the traceability of the consignment is ensured.

4. In the case of release for free circulation, competent authorities and customs services shall work together in accordance with the requirements laid down in Articles 2 to 6 of Regulation (EEC) No 339/93.

Article 25

Implementing measures

1. Measures necessary to ensure the uniform implementation of official controls on the introduction of feed and food shall be laid down in accordance with the procedure referred to in Article 62(3).

2. In particular, detailed rules may be laid down for:

(a) feed and food imported or placed under one of the customs procedures referred to in Article 4(16)(b) to (f) of Regulation (EEC) No 2913/92 or that are to be handled in free zones or free warehouses, as defined in Article 4(15)(b) of Regulation (EEC) No 2913/92;

(b) food for the supply of the crew and passengers of international means of transport;

(c) feed and food ordered remotely (for example, by mail, by telephone or via the internet) and delivered to the consumer;

(d) feed intended for pets or horses and food carried by passengers and crew of international means of transport;

(e) specific conditions or exemptions concerning certain territories referred to in Article 3 of Regulation (EEC) No 2913/92, so as to take account of the natural constraints specific to those territories;

(f) the purpose of ensuring the consistency of decisions by competent authorities concerning feed and food from third countries within the framework of Article 19;

(g) consignments of Community origin that are returned from a third country;

(h) documents that must accompany consignments when samples have been taken.

CHAPTER VI

FINANCING OF OFFICIAL CONTROLS

Article 26

General principle

Member States shall ensure that adequate financial resources are available to provide the necessary staff and other resources for official controls by whatever means considered appropriate, including through general taxation or by establishing fees or charges.

Article 27

Fees or charges

1. Member States may collect fees or charges to cover the costs occasioned by official controls.

2. However, as regards the activities referred to in Annex IV, section A, and Annex V, section A, Member States shall ensure the collection of a fee.

3. Without prejudice to paragraphs 4 and 6, fees collected as regards the specific activities mentioned in Annex IV, section A and Annex V, section A shall not be lower than the minimum rates specified in Annex IV, section B and Annex V, section B. However, for a transitional period until 1 January 2008, as regards the activities referred to in Annex IV, section A, Member States may continue to use the rates currently applied pursuant to Directive 85/73/EEC.

The rates in Annex IV, Section B and Annex V, Section B shall be updated at least every two years, in accordance with the procedure referred to in Article 62(3), in particular to take account of inflation.

4. Fees collected for the purposes of official controls in accordance with paragraph 1 or 2:

(a) shall not be higher than the costs borne by the responsible competent authorities in relation to the items listed in Annex VI;

and

(b) may be fixed at a flat-rate on the basis of the costs borne by the competent authorities over a given period of time or, where applicable, at the amounts fixed in Annex IV, section B or in Annex V, section B.

5. In setting the fees Member States shall take into consideration:

(a) the type of business concerned and relevant risk factors;

(b) the interests of businesses with a low throughput;

(c) traditional methods used for production, processing and distribution;

(d) the needs of businesses located in regions subject to particular geographical constraints.

6. When, in view of own-check and tracing systems implemented by the feed or food business as well as of the level of compliance found during official controls, for a certain type of feed or food or activities, official controls are carried out with a reduced frequency or to take account of the criteria referred to in paragraph 5(b) to (d), Member States may set the official control fee below the minimum rates referred to in paragraph 4(b), provided that the Member State concerned provides the Commission with a report specifying:

(a) the type of feed or food or activity concerned;

(b) the controls performed in the feed and food business concerned;

and

(c) the method for calculating the reduction of the fee.

7. When the competent authority carries out several official controls at the same time in a single establishment, it shall consider these controls as a single activity and charge a single fee.

8. Fees relating to import controls are to be paid by the operator or his representative to the competent authority in charge of import controls.

9. Fees shall not directly or indirectly be refunded, unless unduly collected.

10. Without prejudice to the costs deriving from the expenses referred to in Article 28, Member States shall not collect any fees other than those referred to in this Article for the implementation of this Regulation.

11. Operators or other relevant businesses or their representatives shall receive proof of their payment of fees.

12. The Member States shall make public the method of calculation of fees and communicate it to the Commission. The Commission shall examine whether the fees comply with the requirements of this Regulation.

Article 28

Expenses arising from additional official controls

When the detection of non-compliance leads to official controls that exceed the competent authority's normal control activities, the competent authority shall charge the operators responsible for the non-compliance, or may charge the operator owning or keeping the goods at the time when the additional official controls are carried out, for the expenses arising from the additional official controls. Normal control activities are the routine control activities required under Community or national law and, in particular, those described in the plan provided for in Article 41. Activities that exceed normal control activities include the taking and analysis of samples as well as other controls that are required to check the extent of a problem, to verify whether corrective action has been taken, or to detect and/or substantiate non-compliance.

Article 29

Level of expenses

When setting the level of expenses referred to in Article 28, account shall be taken of the principles laid down in Article 27.

CHAPTER VII

OTHER PROVISIONS

Article 30

Official certification

1. Without prejudice to requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted, in accordance with the procedure referred to in Article 62(3), concerning:

(a) the circumstances in which official certification is required;

(b) model certificates;

(c) qualifications of the certifying staff;

(d) the principles to be respected to ensure reliable certification, including electronic certification;

(e) the procedures to be followed in case of withdrawal of certificates and for replacement certificates;

(f) consignments that are split into smaller consignments or that are mixed with other consignments;

(g) documents that must follow goods after official controls have been carried out.

2. Where official certification is required, it shall be ensured that:

(a) a link exists between the certificate and the consignment;

(b) the information in the certificate is accurate and authentic.

3. A single model certificate shall, where appropriate, combine requirements concerning the official certification of feed and food and other requirements for official certification.

Article 31

Registration/approval of feed and food business establishments

1. (a) Competent authorities shall establish procedures for feed and food business operators to follow when applying for the registration of their establishments in accordance with Regulation (EC) No 852/2004, Directive 95/69/EC or with the future regulation on feed hygiene;

(b) They shall draw up and keep up to date a list of feed and food business operators which have been registered. Where such a list already exists for other purposes, it may also be used for the purposes of this Regulation.

2. (a) Competent authorities shall establish procedures for feed and food business operators to follow when applying for the approval of their establishments in accordance with Regulation (EC) No 852/2004, Regulation (EC) No 854/2004, Directive 95/69/EC or with the future regulation on feed hygiene.

(b) Upon receipt of an application for approval from a feed or food business operator, the competent authority shall make an on-site visit.

(c) It shall approve an establishment for the activities concerned only if the feed or food business operator has demonstrated that it complies with the relevant requirements of feed or food law.

(d) The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of feed or food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.

(e) The competent authority shall keep the approval of establishments under review when carrying out official controls. If the competent authority identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval. However, the competent authority may suspend an establishment's approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time;

(f) The competent authorities shall maintain up-to--date lists of approved establishments and make them available to other Member States and to the public in a manner that may be specified in accordance with the procedure referred to in Article 62(3).

TITLE III

REFERENCE LABORATORIES

Article 32

Community reference laboratories

1. The Community reference laboratories for feed and food referred to in Annex VII shall be responsible for:

(a) providing national reference laboratories with details of analytical methods, including reference methods;

(b) coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;

(c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;

(d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

(e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;

(f) collaborating with laboratories responsible for analysing feed and food in third countries.

2. The Community reference laboratories in the animal health sector shall be responsible for:

(a) coordinating the methods employed in the Member States for diagnosing diseases;

(b) assisting actively in the diagnosis of disease outbreaks in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies;

(c) facilitating the initial or further training of experts in laboratory diagnosis with a view to the harmonisation of diagnostic techniques throughout the Community;

(d) collaborating, as regards methods of diagnosing animal diseases falling within their competence, with the competent laboratories in third countries where those diseases are prevalent:

(e) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

3. Article 12(2) and (3) shall apply to Community reference laboratories.

4. Community reference laboratories shall fulfil the following requirements. They must:

(a) have suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence;

(b) possess the equipment and products needed to carry out the tasks assigned to them;

(c) have an appropriate administrative infrastructure;

(d) ensure that their staff respect the confidential nature of certain subjects, results or communications;

(e) have sufficient knowledge of international standards and practices;

(f) have available, if appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents;

(g) take account of research activities at national and Community level;

(h) have trained personnel available for emergency situations occurring within the Community.

5. Other Community reference laboratories relevant to the areas referred to in Article 1 may be included in Annex VII in accordance with the procedure referred to in Article 62(3). In accordance with the same procedure, Annex VII may be updated.

6. Additional responsibilities and tasks for Community reference laboratories may be laid down in accordance with the procedure referred to in Article 62(3).

7. Community reference laboratories may be granted a Community financial contribution in accordance with Article 28 of Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1].

8. Community reference laboratories may be subject to Community controls to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements or tasks for which they have been designated, necessary measures may be taken in accordance with the procedure referred to in Article 62(3).

9. Paragraphs 1 to 7 shall apply without prejudice to more specific rules, and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

Article 33

National reference laboratories

1. Member States shall arrange for the designation of one or more national reference laboratories for each Community reference laboratory referred to in Article 32. A Member State may designate a laboratory situated in another Member State or European Free Trade Association (EFTA) Member and a single laboratory may be the national reference laboratory for more than one Member State.

2 These national reference laboratories shall:

(a) collaborate with the Community reference laboratory in their area of competence;

(b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;

(c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;

(d) ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies;

(e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;

(f) be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

3. Article 12(2) and (3) shall apply to national reference laboratories.

4. Member States shall communicate the name and address of each national reference laboratory to the Commission, the relevant Community reference laboratory and other Member States.

5. Member States that have more than one national reference laboratory for a Community reference laboratory must ensure that these laboratories work closely together, so as to ensure efficient coordination between them, with other national laboratories and with the Community reference laboratory.

6. Additional responsibilities and tasks for national reference laboratories may be laid down in accordance with the procedure referred to in Article 62(3).

7. Paragraphs 1 to 5 shall apply without prejudice to more specific rules and in particular Chapter VI of Regulation (EC) No 999/2001 and Article 14 of Directive 96/23/EC.

[1] OJ L 224, 18.8.1990, p. 19. Decision as last amended by Regulation (EC) No 806/2003.

TITLE IV

ADMINISTRATIVE ASSISTANCE AND COOPERATION IN THE AREAS OF FEED AND FOOD

Article 34

General principles

1. Where the outcome of official controls on feed and food requires action in more than one Member State, competent authorities in the Member States concerned shall provide each other with administrative assistance.

2. Competent authorities shall provide administrative assistance upon request, or spontaneously when the course of investigations so requires. Administrative assistance may include, where appropriate, participation in on-the-spot controls that the competent authority of another Member State carries out.

3. Articles 35 to 40 shall not prejudice national rules applicable to the release of documents that are the object of, or are related to, court proceedings, or rules aimed at the protection of natural or legal persons' commercial interests.

Article 35

Liaison bodies

1. Each Member State shall designate one or more liaison bodies to liaise as appropriate with other Member States' liaison bodies. The role of liaison bodies shall be to assist and coordinate communication between competent authorities and, in particular, the transmission and reception of requests for assistance.

2. Member States shall inform the Commission and other Member States of all the relevant details of their designated liaison bodies, and of any modification of these details.

3. Without prejudice to paragraph 1, the designation of liaison bodies shall not preclude direct contacts, exchange of information or cooperation between the staff of competent authorities in different Member States.

4. The competent authorities to which Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure correct application of the legislation on veterinary and zootechnical matters [1] applies, shall liaise as appropriate with the authorities operating under this title.

Article 36

Assistance on request

1. Upon receiving a reasoned request, the requested competent authority shall ensure that the requesting competent authority is provided with all necessary information and documents enabling the latter to verify compliance with feed and food law within its jurisdiction. For that purpose, the requested competent authority shall arrange for the conduct of any administrative enquiries necessary to obtain such information and documents.

2. Information and documents provided pursuant to paragraph 1 shall be forwarded without undue delay. Documents may be transmitted in their original form or copies may be provided.

3. By agreement between the requesting authority and the requested authority, staff designated by the requesting authority may be present during administrative enquiries.

Such enquiries shall always be carried out by staff of the requested authority.

The requesting authority's staff may not, on their own initiative, exercise the powers of enquiry conferred on officials of the requested authority. They shall, however, have access to the same premises and documents as the latter, through their intermediary, and for the sole purpose of the administrative enquiry being carried out.

4. Staff of the requesting authority present in another Member State in accordance with paragraph 3 shall at all times be able to produce written authority stating their identity and their official capacity.

[1] OJ L 351, 2.12.1989, p. 34.

Article 37

Assistance without request

1. When a competent authority becomes aware of non-compliance, and if such non-compliance may have implications for another Member State or States, it shall pass such information to the other Member State(s) without prior request and without delay.

2. Member States receiving such information shall investigate the matter and inform the Member State that provided the information of the results of this investigation and, where appropriate, of any measures taken.

Article 38

Assistance in the event of non-compliance

1. If, during an official control carried out at the place of destination of the goods, or during their transport, the competent authority of the Member State of destination establishes that the goods do not comply with feed or food law in such a way as to create a risk to human or animal health or to constitute a serious infringement of feed or food law, it shall contact the competent authority of the Member State of dispatch without delay.

2. The competent authority of the Member State of dispatch shall investigate the matter, take all necessary measures and notify the competent authority of the Member State of destination of the nature of the investigations and official controls carried out, the decisions taken and the reasons for such decisions.

3. If the competent authority of the Member State of destination has reason to believe that such measures are inadequate, the two Member States' competent authorities shall together seek ways and means of remedying the situation including, if appropriate, a joint on-the-spot inspection carried out in accordance with Article 36(3) and (4). They shall inform the Commission if they are not able to agree on appropriate measures.

Article 39

Relations with third countries

1. When a competent authority receives information from a third country indicating non-compliance and/or a risk to human or animal health, that authority shall pass that information on to competent authorities in other Member States if it considers that they might be interested in it or if they request it. It shall also communicate such information to the Commission whenever it is of relevance at Community level.

2. If the third country has given a legal undertaking to provide the assistance required to gather evidence of the irregular nature of transactions that are or appear to be contrary to the relevant feed and food law, information obtained under this Regulation may be communicated to that third country, with the consent of the competent authorities that supplied the information, in accordance with laws applying to the communication of personal data to third countries.

Article 40

Coordinated assistance and follow-up by the Commission

1. The Commission shall coordinate without delay the action undertaken by Member States when it, further to information received from Member States or from other sources, becomes aware of activities that are, or appear to be, contrary to feed or food law and are of particular interest at Community level, and in particular when:

(a) such activities have, or might have, ramifications in several Member States;

(b) it appears that similar activities have been carried out in several Member States;

or

(c) Member States are unable to agree on appropriate action to address non-compliance.

2. When official controls at destination show repeated non-compliance or other risks to humans, plants or animals from feed or food, either directly or through the environment, the competent authority of the Member State of destination shall inform the Commission and the competent authorities of the other Member States without delay.

3. The Commission may:

(a) in collaboration with the Member State concerned, send an inspection team to carry out an official control on the spot;

(b) request that the competent authority of the Member State of dispatch intensify relevant official controls and report on the action and measures taken.

4. Where the measures provided for in paragraphs 2 and 3 are taken to deal with repeated non-compliance by a feed or food business, the competent authority shall charge any expenses arising from such measures to the business in question.

TITLE V

CONTROL PLANS

Article 41

Multi-annual national control plans

In order to ensure the effective implementation of Article 17(2) of Regulation (EC) No 178/2002, of animal health and animal welfare rules and of Article 45 of this Regulation, each Member State shall prepare a single integrated multi-annual national control plan.

Article 42

Principles for the preparation of multi-annual national control plans

1. Member States shall:

(a) implement the plan referred to in Article 41 for the first time no later than 1 January 2007;

and

(b) regularly update it in the light of developments;

and

(c) provide the Commission with the latest version of the plan on request.

2. Each multi-annual national control plan shall contain general information on the structure and organisation of the systems of feed and food control, and of animal health and animal welfare control in the Member State concerned, in particular on:

(a) the strategic objectives of the plan and on how the prioritisation of controls and allocation of resources reflect these objectives;

(b) the risk categorisation of the activities concerned;

(c) the designation of competent authorities and their tasks at central, regional and local level, and on resources available to these authorities;

(d) the general organisation and management of official controls at national, regional and local level, including official controls in individual establishments;

(e) control systems applied to different sectors and coordination between the different services of competent authorities responsible for official controls in these sectors;

(f) where appropriate, the delegation of tasks to control bodies;

(g) methods to ensure compliance with the operational criteria of Article 4(2);

(h) the training of staff performing official controls referred to in Article 6;

(i) the documented procedures referred to in Articles 8 and 9;

(j) the organisation and operation of contingency plans for animal or food-borne disease emergencies, feed and food contamination incidents and other human health risks;

(k) the organisation of cooperation and mutual assistance.

3. Multi-annual national control plans may be adjusted during their implementation. Amendments may be made in the light of, or in order to take account of, factors including:

(a) new legislation;

(b) the emergence of new diseases or other health risks;

(c) significant changes to the structure, management or operation of the competent national authorities;

(d) the results of Member States' official controls;

(e) the results of Community controls carried out in accordance with Article 45;

(f) any amendment of the guidelines referred to in Article 43;

(g) scientific findings;

(h) the outcome of audits performed by a third country in a Member State.

Article 43

Guidelines for multi-annual national control plans

1. The multi-annual national control plans referred to in Article 41 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2). These guidelines shall in particular:

(a) promote a consistent, comprehensive and integrated approach to official controls of feed and food, animal health and animal welfare legislation, and embrace all sectors and all stages of the feed and food chain, including import and introduction;

(b) identify risk-based priorities and criteria for the risk categorisation of the activities concerned and the most effective control procedures;

(c) identify other priorities and the most effective control procedures;

(d) identify the stages of production, processing and distribution of feed and food, including the use of feed, which will provide the most reliable and indicative information about compliance with feed and food law;

(e) encourage the adoption of best practices at all levels of the control system;

(f) encourage the development of effective controls on traceability systems;

(g) provide advice on the development of systems to record the performance and results of control actions;

(h) reflect relevant international bodies' standards and recommendations regarding the organisation and operation of official services;

(i) lay down criteria for the conduct of the audits referred to in Article 4(6);

(j) lay down the structure of, and information to be included in, the annual reports required in Article 44;

(k) indicate the main performance indicators to be applied in assessing multi-annual national control plans.

2. Where necessary, the guidelines shall be adapted in the light of the analysis of annual reports that Member States submit in accordance with Article 44 or Community controls carried out in accordance with Article 45.

Article 44

Annual reports

1. One year after starting the implementation of multi-annual national control plans, and subsequently every year, Member States shall submit to the Commission a report indicating:

(a) any amendments made to multi-annual national control plans to take account of the factors referred to in Article 42(3);

(b) the results of controls and audits conducted in the previous year under the provisions of the multi-annual national control plan;

(c) the type and number of cases of non-compliance identified;

(d) actions to ensure the effective operation of multi-annual national control plans, including enforcement action and its results.

2. In order to promote the consistent presentation of this report and in particular of the results of official controls, the information referred to in paragraph 1 shall take account of guidelines to be drawn up by the Commission in accordance with the procedure referred to in Article 62(2).

3. Member States shall finalise their reports and transmit them to the Commission, within six months of the end of the year to which the reports relate.

4. In the light of the reports referred to in paragraph 1, the outcome of Community controls carried out in accordance with Article 45 and any other relevant information, the Commission shall establish an annual report on the overall operation of official controls in Member States. This report may, where appropriate, include recommendations on:

(a) possible improvements to official control and audit systems in Member States, including their scope, management and implementation;

(b) specific control actions concerning sectors or activities, regardless of whether these are covered by multi-annual national control plans;

(c) coordinated plans aiming at addressing issues of particular interest.

5. Multi-annual national control plans and the related guidelines shall, where appropriate, be adapted on the basis of the conclusions and recommendations contained in the Commission's report.

6. The Commission shall submit its report to the European Parliament and the Council and make it available to the public.

TITLE VI

COMMUNITY ACTIVITIES

CHAPTER I

COMMUNITY CONTROLS

Article 45

Community controls in Member States

1. Commission experts shall carry out general and specific audits in Member States. The Commission may appoint experts from Member States to assist its own experts. General and specific audits shall be organised in cooperation with Member States' competent authorities. Audits shall be carried out on a regular basis. Their main purpose shall be to verify that, overall, official controls take place in Member States in accordance with the multi-annual national control plans referred to in Article 41 and in compliance with Community law. For this purpose, and in order to facilitate the efficiency and effectiveness of the audits, the Commission may, in advance of carrying out such audits, request that the Member States provide, as soon as possible, up-to-date copies of national control plans.

2. Specific audits and inspections in one or more specific areas may supplement general audits. These specific audits and inspections shall in particular serve to:

(a) verify the implementation of the multi-annual national control plan, feed and food law and animal health and animal welfare legislation and may include, as appropriate, on-the-spot inspections of official services and of facilities associated with the sector being audited;

(b) verify the functioning and organisation of competent authorities;

(c) investigate important or recurring problems in Member States;

(d) investigate emergency situations, emerging problems or new developments in Member States.

3. The Commission shall report on the findings of each control carried out. Its report shall, if appropriate, contain recommendations for Member States on the improvement of compliance with feed and food law and animal health and animal welfare rules. The Commission shall make its reports publicly available. In the case of reports on controls carried out in a Member State, the Commission shall provide the relevant competent authority with a draft report for comments, take those comments into consideration in preparing the final report and publish the competent authority's comments together with the final report.

4. The Commission shall establish an annual control programme, communicate it to Member States in advance, and report on its results. The Commission may amend the programme to take account of developments in the fields of feed and food safety, animal health, animal welfare and plant health.

5. Member States shall:

(a) take appropriate follow-up action in the light of the recommendations resulting from Community controls;

(b) give all necessary assistance and provide all documentation and other technical support that Commission experts request to enable them to carry out controls efficiently and effectively;

(c) ensure that Commission experts have access to all premises or parts of premises and to information, including computing systems, relevant to the execution of their duties.

6. Detailed rules concerning Community controls in Member States may be drawn up or amended in accordance with the procedure referred to in Article 62(3).

Article 46

Community controls in third countries

1. Commission experts may carry out official controls in third countries in order to verify, on the basis of the information referred to in Article 47(1), the compliance or equivalence of third-country legislation and systems with Community feed and food law and Community animal health legislation. The Commission may appoint experts from Member States to assist its own experts. Such official controls shall have particular regard to:

(a) the legislation of the third country;

(b) the organisation of the third country's competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;

(c) the training of staff in the performance of official controls;

(d) the resources including diagnostic facilities available to competent authorities;

(e) the existence and operation of documented control procedures and control systems based on priorities;

(f) where applicable, the situation regarding animal health, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal and plant diseases;

(g) the extent and operation of official controls on imports of animals, plants and their products;

(h) the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements.

2. In order to facilitate the efficiency and effectiveness of the controls in a third country, the Commission may, in advance of carrying out such controls, request that the third country concerned provide the information referred to in Article 47(1) and, where appropriate, the written records on the implementation of such controls.

3. The frequency of Community controls in third countries shall be determined on the basis of:

(a) a risk assessment of the products exported to the Community;

(b) the provisions of Community legislation;

(c) the volume and nature of imports from the country concerned;

(d) the results of controls that the Commission services or other inspection bodies have already carried out;

(e) the results of import controls and of any other controls that competent authorities of Member States have carried out;

(f) information received from the European Food Safety Authority or similar bodies;

(g) information received from internationally recognised bodies such as the World Health Organisation (WHO), the Codex Alimentarius Commission and the World Organisation for Animal Health (OIE), or from other sources;

(h) evidence of emerging disease situations or other circumstances that might result in live animals, live plants or feed or food imported from a third country presenting health risks;

(i) the need to investigate or respond to emergency situations in individual third countries.

The criteria for determining risk for the purpose of the risk assessment referred to in point (a) shall be decided in accordance with the procedure referred to in Article 62(3).

4. The procedure and detailed rules for controls in third countries may be determined or amended in accordance with the procedure referred to in Article 62(3).

They shall include, in particular, procedures for and detailed rules on:

(a) controls in third countries in the context of a bilateral agreement;

(b) controls in other third countries.

According to the same procedure, charges for the abovementioned controls may be established on a reciprocal basis.

5. If, during a Community control, a serious risk to human or animal health is identified, the Commission shall immediately take any necessary emergency measures in accordance with Article 53 of Regulation (EC) No 178/2002 or safeguard provisions in other relevant Community legislation.

6. The Commission shall report on the findings of each Community control carried out. Its report shall, if appropriate, contain recommendations. The Commission shall make its reports publicly available.

7. The Commission shall communicate its programme of controls in third countries to Member States in advance and report on the results. It may amend the programme to take account of developments in the fields of feed and food safety, animal health and plant health.

CHAPTER II

IMPORT CONDITIONS

Article 47

General import conditions

1. The Commission shall be responsible for requesting third countries intending to export goods to the Community to provide the following accurate and up-to-date information on the general organisation and management of sanitary control systems:

(a) any sanitary or phytosanitary regulations adopted or proposed within its territory;

(b) any control and inspection procedures, production and quarantine treatment, pesticide tolerance and food additive approval procedures operated within its territory;

(c) risk-assessment procedures, factors taken into consideration, as well as the determination of the appropriate level of sanitary or phytosanitary protection;

(d) where appropriate, the follow-up given to the recommendations made pursuant to controls referred to in Article 46.

2. The information referred to in paragraph 1 shall be proportionate to the nature of the goods and may take account of the specific situation and structure of the third country and the nature of the products exported to the Community. Its scope shall cover at least the goods intended to be exported to the Community.

3. The information referred to in paragraphs 1 and 2 may also relate to:

(a) results of the national controls carried out on goods intended to be exported to the Community;

(b) important changes which have been made to the structure and functioning of the relevant control systems, in particular to meet Community requirements or recommendations.

4. Where a third country does not provide such information or where such information is inadequate, specific import conditions may be fixed in accordance with the procedure referred to in Article 62(3) on a case by case and strictly temporary basis following consultations with the third country concerned.

5. Guidelines, specifying how the information referred to in paragraphs 1, 2 and 3 shall be drawn up and presented to the Commission, as well as transitional measures allowing time for third countries to prepare this information shall be established in accordance with the procedure referred to in Article 62(2).

Article 48

Specific import conditions

1. To the extent that the conditions and detailed procedures to be respected when importing goods from third countries or their regions are not provided for by Community law and in particular by Regulation (EC) No 854/2004, they shall, if necessary, be laid down in accordance with the procedure referred to in Article 62(3).

2. The conditions and detailed procedures referred to in paragraph 1 may include:

(a) the establishment of a list of third countries from which specific products may be imported into one of the territories referred to in Annex I;

(b) the establishment of models of certificates accompanying consignments;

(c) special import conditions, depending on the type of product or animal and the possible risks associated therewith.

3. Third countries shall appear on the lists referred to in paragraph 2(a) only if their competent authorities provide appropriate guarantees as regards compliance or equivalence with Community feed and food law and animal health rules.

4. When drawing up or updating lists, particular account shall be taken of the following criteria:

(a) the third country's legislation in the sector concerned;

(b) the structure and organisation of the competent authority of the third country and its control services, as well as the powers available to it/them and the guarantees that can be provided with regard to the implementation of the legislation concerned;

(c) the existence of adequate official controls;

(d) the regularity and rapidity of information supplied by the third country on the presence of hazards in feed and food, and in live animals;

(e) the guarantees given by a third country that:

(i) conditions applied to the establishments from which feed and food may be imported in the Community comply with or are equivalent to the requirements in Community feed and food law;

(ii) a list of such establishments is drawn up and kept up to date;

(iii) the list of establishments and its updated versions are communicated to the Commission without delay;

(iv) the establishments are the subject of regular and effective controls by the competent authority of the third country.

5. When adopting the special import conditions referred to in paragraph 2(c), account shall be taken of information that the third countries concerned have provided and, where necessary, the results of Community controls carried out in such third countries. Special import conditions may be established for a single product or for a group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries.

Article 49

Equivalence

1. Following the implementation of an equivalence agreement, or a satisfactory audit, a decision may be taken, in accordance with the procedure referred to in Article 62(3), recognising that measures that third countries or their regions apply in specific areas offer guarantees equivalent to those applied in the Community, if the third countries supply objective proof in this respect.

2. The decision referred to in paragraph 1 shall set out the conditions governing the imports from that third country or region of a third country.

The conditions may include:

(a) the nature and content of the certificates that must accompany the products;

(b) specific requirements applicable to importation into the Community;

(c) where necessary, procedures for drawing up and amending lists of regions or establishments from which imports are permitted.

3. The decision referred to in paragraph 1 shall be repealed in accordance with the same procedure and without delay where any of the conditions for recognition of equivalence established at the time of its adoption cease to be fulfilled.

Article 50

Support for developing countries

1. In accordance with the procedure referred to in Article 62(3) the following measures may be adopted and maintained so long as they have a demonstrable effect in ensuring that developing countries are able to comply with the provisions of this Regulation:

(a) a phased introduction of the requirements referred to in Articles 47 and 48 for products exported to the Community. Progress in meeting these requirements shall be evaluated and taken into account in determining the need for specified time-limited exemptions in whole or in part from the requirements. The phased introduction shall also take into account the progress in building the institutional capacity referred to in paragraph 2;

(b) assistance with providing the information referred to in Article 47, if necessary by Community experts;

(c) the promotion of joint projects between developing countries and Member States;

(d) the development of guidelines to assist developing countries in organising official controls on products exported to the Community;

(e) sending Community experts to developing countries so as to assist in the organisation of official controls;

(f) the participation of control staff from developing countries in the training courses referred to in Article 51.

2. In the context of the Community's development cooperation policy, the Commission shall promote support to developing countries with regard to feed and food safety in general and compliance with feed and food standards in particular, in order to build the institutional capacity required to meet the requirements referred to in Articles 5, 12, 47 and 48.

CHAPTER III

TRAINING OF CONTROL STAFF

Article 51

Training of control staff

1. The Commission may organise training courses for the staff of the competent authorities of Member States responsible for the official controls referred to in this Regulation. These training courses shall serve to develop a harmonised approach to official controls in Member States. They may include in particular training on:

(a) Community feed and food law and animal health and animal welfare rules;

(b) control methods and techniques, such as the auditing of systems that operators design to comply with feed and food law, animal health and animal welfare rules;

(c) controls to be carried out on goods imported into the Community;

(d) feed and food production, processing and marketing methods and techniques.

2. The training courses referred to in paragraph 1 may be open to participants from third countries, in particular developing countries.

3. Detailed rules for the organisation of training courses may be laid down in accordance with the procedure referred to in Article 62(3).

CHAPTER IV

OTHER COMMUNITY ACTIVITIES

Article 52

Third-country controls in Member States

1. Commission experts may, at the request of and in cooperation with the competent authorities of Member States, assist Member States during controls that third countries carry out.

2. In such cases, Member States in whose territory a third country is to carry out a control shall inform the Commission about the planning, scope, documentation and any other relevant information enabling the Commission to take part effectively in the control.

3. The Commission's assistance shall serve in particular to:

(a) clarify Community feed and food law and animal health and animal welfare rules;

(b) provide information and data available at Community level that may be useful for the control carried out by the third country;

(c) ensure uniformity with regard to controls carried out by third countries.

Article 53

Coordinated control plans

The Commission may recommend coordinated plans in accordance with the procedure referred to in Article 62(2). These plans shall be:

(a) organised annually in accordance with a programme;

and

(b) where considered necessary, organised on an ad hoc basis, in particular with a view to establishing the prevalence of hazards in feed, food or animals.

TITLE VII

ENFORCEMENT MEASURES

CHAPTER I

NATIONAL ENFORCEMENT MEASURES

Article 54

Action in case of non-compliance

1. When the competent authority identifies non-compliance, it shall take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance.

2. Such action shall include, where appropriate, the following measures:

(a) the imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with feed or food law, animal health or animal welfare rules;

(b) the restriction or prohibition of the placing on the market, import or export of feed, food or animals;

(c) monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food;

(d) the authorisation to use feed or food for purposes other than those for which they were originally intended;

(e) the suspension of operation or closure of all or part of the business concerned for an appropriate period of time;

(f) the suspension or withdrawal of the establishment's approval;

(g) the measures referred to in Article 19 on consignments from third countries;

(h) any other measure the competent authority deems appropriate.

3. The competent authority shall provide the operator concerned, or a representative, with:

(a) written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision;

and

(b) information on rights of appeal against such decisions and on the applicable procedure and time limits.

4. Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

5. All expenditure incurred pursuant to this Article shall be borne by the responsible feed and food business operator.

Article 55

Sanctions

1. Member States shall lay down the rules on sanctions applicable to infringements of feed and food law and other Community provisions relating to the protection of animal health and welfare and shall take all measures necessary to ensure that they are implemented. The sanctions provided for must be effective, proportionate and dissuasive.

2. Member States shall notify the provisions applicable to infringements of feed and food law and any subsequent amendment to the Commission without delay.

CHAPTER II

COMMUNITY ENFORCEMENT MEASURES

Article 56

Safeguard measures

1. Measures shall be taken under the procedures provided for in Article 53 of Regulation (EC) No 178/2002 if:

(a) the Commission has evidence of a serious failure in a Member State's control systems;

and

(b) such failure may constitute a possible and widespread risk for human health, animal health or animal welfare, either directly or through the environment.

2 Such measures shall be adopted only after:

(a) Community controls have shown and reported non-compliance with Community legislation;

and

(b) the Member State concerned has failed to correct the situation upon request and within the time limit set by the Commission.

TITLE VIII

ADAPTATION OF COMMUNITY LEGISLATION

Article 57

Amendment of Directive 96/23/EC

Directive 96/23/EC is hereby amended as follows:

1. Article 14(2) is replaced by the following:

'2 The Community reference laboratories shall be those referred to in the relevant part of Annex VII of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*).

(*) OJ L 165, 30.4.2004, p. 1.'

2. In Article 30, the part of paragraph 1 beginning 'Where such additional checks demonstrate…' and ending '…or to use it for other purposes authorised by Community legislation, without indemnity or compensation', is replaced by the following:

'Where checks demonstrate the presence of unauthorised substances or products or when maximum limits have been exceeded, the provisions of Articles 19 to 22 of Regulation (EC) No 882/2004 shall apply.'

3. Annex V is deleted.

Article 58

Amendment of Directive 97/78/EC

Directive 97/78/EC is hereby amended as follows:

1. Article 1 is replaced by the following:

'Veterinary checks on products from third countries introduced into one of the territories listed in Annex I shall be carried out by Member States in accordance with this Directive and with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*).

(*) OJ L 165, 30.4.2004, p. 1.'

2. Article 2(2)(a) is replaced by the following:

'(a) "products" means the products of animal origin referred to in Directives 89/662/EEC and 90/425/EEC, in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (*), in Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (**) and in Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (***); it also includes the plant products referred to in Article 19.

(*) OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 808/2003 (OJ L 117, 13.5.2003, p. 1).
(**) OJ L 18, 23.1.2003, p. 11.
(***) OJ L 139, 30.4.2004.'

3. In Article 7(3), 'inspection fees referred to in Council Directive 85/73/EEC of 29 January 1985 on the financing of veterinary inspections and controls covered by Directives 89/662/EEC, 90/425/EEC, 90/675/EEC and 91/496/EEC (amended and consolidated)' is replaced by the following:

'inspection fees referred to in Regulation (EC) No 882/2004'.

4. In Article 10(1)(b), the following phrase is deleted: 'or, in the case of establishments approved in accordance with Council Decision 95/408/EC of 22 June 1995 on the conditions for drawing up, for an interim period, provisional lists of third-country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs, from an establishment which has undergone either a Community or a national inspection.'

5. Article 12(9) is deleted.

6. Article 15(5) is deleted.

7. In Article 16, the following paragraph is inserted:

'4 Detailed rules for the introduction of products of animal origin for the supply of the crew and passengers of international means of transport, and for products of animal origin ordered remotely (for example, by mail, by telephone or via the internet) and delivered to the consumer, shall be laid down in accordance with Article 25 of Regulation (EC) No 882/2004.'

8. Article 21 is deleted.

9. Article 23 is deleted.

10. In Article 24(1), second indent, 'in accordance with Article 17(2)(a) and (b)' is replaced by 'in accordance with Article 17'.

Article 59

Amendment of Directive 2000/29/EC

The following Article is inserted in Directive 2000/29/EC:

'*Article 27a*

For the purpose of this Directive and without prejudice to Article 21 thereof, Articles 41 to 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*) shall apply, as appropriate.

(*) OJ L 165, 30.4.2004, p. 1.'

Article 60

Amendment of Regulation (EC) No 854/2004

Regulation (EC) No 854/2004 is hereby amended as follows:

1. In Article 1, the following paragraph is added:

'1a. This Regulation shall apply in addition to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*).

(*) OJ L 165, 30.4.2004, p. 1.'

2. In Article 2:

(a) in paragraph 1, subparagraphs (a), (b), (d) and (e) are deleted;

and

(b) the following subparagraph is added to paragraph 2:

'(b)(a) Regulation (EC) No 882/2004.'

3. In Article 3:

(a) paragraph 1 is replaced by the following:

'1. The competent authorities shall approve establishments when, and in the manner, specified in Article 31(2) of Regulation (EC) No 882/2004';

and

(b) paragraphs 4(a) and (b) and paragraph 6 are deleted.

4. Article 9 is deleted.

5. Article 10 is replaced with the following:

'*Article 10*

To ensure the uniform application of the principles and conditions laid down in Article 11 of Regulation (EC) No 178/2002 and Title VI, Chapter II, of Regulation (EC) No 882/2004 the procedures laid down in this Chapter shall apply.'

6. In Article 11:

(a) paragraph 2 is replaced by the following:

'2 A third country shall appear on such lists only if a Community control in that country has taken place and demonstrates that the competent authority provides appropriate guarantees as specified in Article 48(3) of Regulation (EC) No 882/2004. However, a third country may appear on such lists without a Community control having taken place if:

(a) the risk determined in accordance with Article 46(3)(a) of Regulation (EC) No 882/2004 does not warrant it;

and

(b) it is determined, when deciding to add a particular third country to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.'

(b) in paragraph 4, the introduction is replaced by the following:

'4 When drawing up or updating lists, particular account shall be taken of the criteria listed in Articles 46 and 48(3) of Regulation (EC) No 882/2004. Regard shall also be had to.';

and

(c) subparagraphs (b) to (h) of paragraph 4 are deleted.

7. Article 14(2)(b) is replaced by the following:

'(b) any specific import conditions established in accordance with Article 48 of Regulation (EC) No 882/2004.'

8. Article 18(17) to (20) are deleted.

Article 61

Repeal of Community acts

1. Directives 70/373/EEC, 85/591/EEC, 89/397/EEC, 93/99/EEC and 95/53/EC and Decisions 93/383/EEC, 98/728/EC and 1999/313/EC are hereby repealed with effect from 1 January 2006. Directive 85/73/EEC is hereby repealed with effect from 1 January 2008.

2. However, the implementing rules adopted on the basis of those acts, in particular those referred to in Annex VIII, shall remain in force in so far as they are not in contradiction with this Regulation, pending the adoption of the necessary provisions on the basis of this Regulation.

3. Reference to the repealed acts shall be construed as references to this Regulation.

TITLE IX

GENERAL PROVISIONS

Article 62

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002 or, where dealing with matters mainly relating to plant health, by the Standing Committee on plant health set up by Council Decision 76/894/EEC [1].

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

4. The Committee shall adopt its Rules of Procedure.

Article 63

Implementing and transitional measures

1. Implementing and transitional measures necessary to ensure the uniform application of this Regulation may be laid down in accordance with the procedure referred to in Article 62(3).

This applies in particular to:

(a) the delegation of control tasks to control bodies referred to in Article 5, where these control bodies were already in operation before the entry into force of this Regulation;

[1] OJ L 340, 9.12.1976, p. 25.

(b) any modification with regard to the standards referred to in Article 12(2);

(c) the non-compliance referred to in Article 28 which gives rise to expenses arising from additional official controls;

(d) expenditure incurred pursuant to Article 54;

(e) rules on microbiological, physical and/or chemical analysis in official controls, in particular in case of suspicion of risk and including the surveillance of the safety of products imported from third countries;

(f) defining what feed is to be considered as feed of animal origin for the purpose of this Regulation.

2. In order to take account of the specificity of Regulations (EEC) No 2092/91, (EEC) No 2081/92 and (EEC) No 2082/92, specific measures to be adopted in accordance with the procedure referred to in Article 62(3) may provide for the necessary derogations from and adjustments to the rules laid down in this Regulation.

Article 64

Amendment of Annexes and references to European standards

In accordance with the procedure referred to in Article 62(3):

1. the Annexes to this Regulation may be updated, except for Annex I, Annex IV and Annex V, without prejudice to Article 27(3), in particular in order to take account of administrative changes and scientific and/or technological progress;

2. the references to the European standards referred to in this Regulation may be updated in the event that CEN amends these references.

Article 65

Report to the European Parliament and the Council

1. The Commission shall, not later than 20 May 2007, submit a report to the European Parliament and the Council.

2. The report shall, in particular, review the experience gained from the application of this Regulation and consider in particular the following issues:

(a) re-evaluating the scope, in relation to animal health and animal welfare;

(b) ensuring that other sectors contribute to the financing of official controls by extending the list of activities referred to in Annex IV, section A and in Annex V, section A, and taking into account in particular the impact of the Community feed and food hygiene legislation after its adoption;

(c) setting updated minimum rates for fees referred to in Annex IV, section B and in Annex V, section B, taking into account in particular risk factors.

3 The Commission shall, if appropriate, accompany the report with relevant proposals.

Article 66

Community financial support

1. The appropriations required for:

(a) the travel and subsistence expenses that Member States' experts incur as a result of the Commission appointing them to assist its experts as provided for in Articles 45(1) and 46(1);

(b) the training of control staff provided for in Article 51;

(c) the financing of other measures necessary to ensure the application of this Regulation,

shall be authorised each year in the framework of the budgetary procedure.

2. The measures referred to in paragraph 1(c) shall include in particular the organisation of conferences, the establishment of databases, the publication of information, the organisation of studies and the organisation of meetings to prepare the sessions of the Standing Committee on the Food Chain and Animal Health.

3. Technical support and a financial contribution from the Community for the organisation of the activities referred to in Article 50 may be granted within the limits of the human and financial resources available to the Commission.

TITLE X

FINAL PROVISION

Article 67

Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2006.

However, Articles 27 and 28 shall apply from 1 January 2007.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 29 April 2004.

For the European Parliament
The President
P. COX

For the Council
The President
M. McDOWELL

ANNEX I

TERRITORIES REFERRED TO IN ARTICLE 2(15)

1. The territory of the Kingdom of Belgium
2. The territory of the Kingdom of Denmark with the exception of the Faroe Islands and Greenland
3. The territory of the Federal Republic of Germany
4. The territory of the Kingdom of Spain with the exception of Ceuta and Melilla
5. The territory of the Hellenic Republic
6. The territory of the French Republic
7. The territory of Ireland
8. The territory of the Italian Republic
9. The territory of the Grand Duchy of Luxembourg
10. The territory of the Kingdom of the Netherlands in Europe
11. The territory of the Portuguese Republic
12. The territory of the United Kingdom of Great Britain and Northern Ireland
13. The territory of the Republic of Austria
14. The territory of the Republic of Finland
15. The territory of the Kingdom of Sweden

ANNEX II

COMPETENT AUTHORITIES

CHAPTER I: SUBJECT MATTER FOR THE TRAINING OF STAFF PERFORMING OFFICIAL CONTROLS

1. Different control techniques, such as auditing, sampling and inspection

2. Control procedures

3. Feed and food law

4. The different stages of production, processing and distribution, and the possible risks for human health, and where appropriate for the health of animals and plants and for the environment

5. Assessment of non-compliance with feed and food law

6. Hazards in animal feed and food production

7. The evaluation of the application of HACCP procedures

8. Management systems such as quality assurance programmes that feed and food businesses operate and their assessment in so far as these are relevant for feed or food law requirements

9. Official certification systems

10. Contingency arrangements for emergencies, including communication between Member States and the Commission

11. Legal proceedings and implications of official controls

12. Examination of written, documentary material and other records, including those related to proficiency testing, accreditation and risk assessment, which may be relevant to the assessment of compliance with feed or food law; this may include financial and commercial aspects

13. Any other area, including animal health and animal welfare, necessary to ensure that official controls are carried out in accordance with this Regulation.

CHAPTER II: SUBJECT AREAS FOR CONTROL PROCEDURES

1. The organisation of the competent authority and the relationship between central competent authorities and authorities to which they have delegated tasks to carry out official controls

2. The relationship between competent authorities and control bodies to which they have delegated tasks related to official controls

3. A statement on the objectives to be achieved

4. Tasks, responsibilities and duties of staff

5. Sampling procedures, control methods and techniques, interpretation of results and consequent decisions

6. Monitoring and surveillance programmes

7. Mutual assistance in the event that official controls require more than one Member State to take action

8. Action to be taken following official controls

9. Cooperation with other services or departments that may have relevant responsibilities

10. Verification of the appropriateness of methods of sampling, methods of analysis and detection tests

11. Any other activity or information required for the effective functioning of the official controls.

ANNEX III

CHARACTERISATION OF METHODS OF ANALYSIS

1. Methods of analysis should be characterised by the following criteria:

   (a) accuracy;

   (b) applicability (matrix and concentration range);

   (c) limit of detection;

   (d) limit of determination;

   (e) precision;

   (f) repeatability;

   (g) reproducibility;

   (h) recovery;

   (i) selectivity;

   (j) sensitivity;

   (k) linearity;

   (l) measurement uncertainty;

   (m) other criteria that may be selected as required.

2. The precision values referred to in 1(e) shall either be obtained from a collaborative trial which has been conducted in accordance with an internationally recognised protocol on collaborative trials (e.g. ISO 5725:1994 or the IUPAC International Harmonised Protocol) or, where performance criteria for analytical methods have been established, be based on criteria compliance tests. The repeatability and reproducibility values shall be expressed in an internationally recognised form (e.g. the 95 % confidence intervals as defined by ISO 5725:1994 or IUPAC). The results from the collaborative trial shall be published or freely available.

3. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

4. In situations where methods of analysis can only be validated within a single laboratory then they should be validated in accordance with e.g. IUPAC Harmonised Guidelines, or where performance criteria for analytical methods have been established, be based on criteria compliance tests.

5. Methods of analysis adopted under this Regulation should be edited in the standard layout for methods of analysis recommended by the ISO.

ANNEX IV

ACTIVITIES AND MINIMUM RATES FOR FEES OR CHARGES RELATED TO OFFICIAL CONTROLS IN RELATION TO COMMUNITY ESTABLISHMENTS

SECTION A: ACTIVITIES

1. The activities covered by Directives 89/662/EEC, 90/425/EEC, 93/119/EC and 96/23/EC for which Member States are currently collecting fees pursuant to Directive 85/73/EEC

2. The approval of feed establishments

SECTION B: MINIMUM RATES

Member States shall collect for controls relating to the following list of products, at least the corresponding minimum rates for fees or charges.

CHAPTER I

Minimum rates for fees or charges applicable to slaughter inspection

(a) beef meat	
— adult bovine animals:	5 EUR/animal
— young bovine animals:	2 EUR/animal
(b) solipeds and equidae:	3 EUR/animal
(c) pigmeat: animals of a carcase weight	
— of less than 25 kg:	0,5 EUR/animal
— equal to or greater than 25 kg:	1 EUR/animal
(d) sheepmeat and goatmeat: animals of a carcase weight	
— of less than 12 kg:	0,15 EUR/animal
— equal to or greater than 12 kg:	0,25 EUR/animal
(e) poultrymeat	
— poultry of genus Gallus and guinea fowl:	0,005 EUR/animal
— ducks and geese:	0,01 EUR/animal
— turkeys:	0,025 EUR/animal
— farmed rabbit meat:	0,005 EUR/animal.

CHAPTER II

Minimum rates for fees or charges applicable to cutting plants controls

Per tonne of meat:

— beef, veal, pig, solipeds/equidae, sheep and goatmeat:	2 EUR
— poultry and farmed rabbit meat:	1,5 EUR
— farmed and wild game meat:	
— small game birds and ground game:	EUR 1,5
— ratites meat (ostrich, emu, nandou):	EUR 3
— boars and ruminants:	EUR 2.

CHAPTER III

Minimum rates for fees or charges applicable to game processing houses

(a) small game birds:	0,005 EUR/animal
(b) small ground game:	0,01 EUR/animal
(c) ratites:	0,5 EUR/animal
(d) land mammals:	
— boar:	1,5 EUR/animal
— ruminants:	0,5 EUR/animal

CHAPTER IV

Minimum rates for fees or charges applicable to milk production

— EUR 1 per 30 tonnes

and

— EUR 0,5 per tonne, thereafter.

CHAPTER V

Minimum rates for fees or charges applicable to the producing and placing on the market of fishery products and aquaculture products

(a) first placing on the market of fishery and aquaculture products:

— 1 EUR/tonne for the first 50 tonnes in the month;

— 0,5 EUR/tonne thereafter.

(b) first sale in fish market

— 0,5 EUR/tonne for the first 50 tonnes in the month;

— 0,25 EUR/tonne thereafter.

(c) first sale in case of lack of or insufficient gradation for freshness and/or size in accordance with Regulations (EEC) No 103/76 and (EEC) No 104/76:

— 1 EUR/tonne for the first 50 tonnes in the month;

— 0,5 EUR/tonne thereafter.

The fees collected on the species referred to in Annex II to Commission Regulation (EEC) No 3703/85 must not exceed EUR 50 per consignment.

Member States will collect 0,5 EUR/tonne for the processing of fishery and aquaculture products.

ANNEX V

ACTIVITIES AND MINIMUM RATES FOR FEES OR CHARGES RELATED TO THE OFFICIAL CONTROLS OF GOODS AND LIVE ANIMALS INTRODUCED INTO THE COMMUNITY

SECTION A: ACTIVITIES OR CONTROLS

The activities covered by Directives 97/78/EC and 91/496/EEC for which Member States are currently collecting fees pursuant to Directive 85/73/EEC.

SECTION B: FEES OR CHARGES

CHAPTER I

Fees applicable to imported meat

The minimum fee rates for the official control on the import of a consignment of meat are fixed at:

— EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes.

CHAPTER II

Fees applicable to imported fishery products

1. The minimum fee for the official control on the import of a consignment of fishery products is fixed at:

   — EUR 55 per consignment, up to six tonnes,

   and

   — EUR 9 per tonne, up to 46 tonnes, thereafter,

   or

   — EUR 420 per consignment, over 46 tonnes.

2. The above amount for the official control on the import of a consignment of fishery products, transported as break bulk shipment, shall be:

   — EUR 600 per vessel, with a cargo of fishery products up to 500 tonnes,

   — EUR 1 200 per vessel, with a cargo of fishery products up to 1 000 tonnes,

   — EUR 2 400 per vessel, with a cargo of fishery products up to 2 000 tonnes,

   — EUR 3 600 per vessel, with a cargo of fishery products of more than 2 000 tonnes.

3. In the case of fishery products caught in their natural environment directly landed by a fishing vessel flying the flag of a third country, the provisions laid down in Annex IV, Section B, Chapter V, point (a) shall apply.

CHAPTER III

Fees or charges applicable to meat products, poultrymeat, wild game meat, rabbit meat, farmed game meat, by-products and feed of animal origin

1. The minimum fee for the official control on the import of a consignment of products of animal origin other than those mentioned in Chapters I and II or a consignment of by-products of animal origin or a consignment of feed, is fixed at:

— EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes.

2. The above amount for the official control on the import of a consignment of products of animal origin other than those mentioned in Chapters I and II, a consignment of by-products of animal origin or a consignment of feed transported as break bulk shipment, shall be:

— EUR 600 per vessel, with a cargo of products up to 500 tonnes,

— EUR 1 200 per vessel, with a cargo of products up to 1 000 tonnes,

— EUR 2 400 per vessel, with a cargo of products up to 2 000 tonnes,

— EUR 3 600 per vessel, with a cargo products of more than 2 000 tonnes.

CHAPTER IV

Fees applicable to transit through the community of goods and live animals

The amount of fees or charges for the official control on the transit of goods and live animals through the Community is fixed at a minimum level of EUR 30, increased by EUR 20 per quarter of an hour for every member of staff involved in the controls.

CHAPTER V

Fees applicable to imported live animals

1. The fee for the official control on the import of a consignment of live animals is fixed:

(a) for bovine animals, equidae, pigs, sheep, goats, poultry, rabbits and small game birds or ground game and the following land mammals: wild boar and ruminants, at:

— EUR 55 per consignment, up to six tonnes,

and

— EUR 9 per tonne, up to 46 tonnes, thereafter,

or

— EUR 420 per consignment, over 46 tonnes,

(b) for animals of other species at the actual cost of inspection expressed either per animal or per tonne imported, at:

— EUR 55 per consignment, up to 46 tonnes,

or

— EUR 420 per consignment, over 46 tonnes,

it being understood that this minimum does not apply to imports of species referred to in Commission Decision 92/432/EEC.

2. At the request of a Member State, accompanied by appropriate supporting documents and in accordance with the procedure laid down in Article 18 of Directive 89/662/EEC, a lower level of fees may be applied to imports from certain third countries.

ANNEX VI

CRITERIA TO BE TAKEN INTO CONSIDERATION FOR THE CALCULATION OF FEES

1. The salaries of the staff involved in the official controls

2. The costs for the staff involved in the official controls, including facilities, tools, equipment, training, travel and associated costs

3. The laboratory analysis and sampling costs

ANNEX VII

COMMUNITY REFERENCE LABORATORIES

I. **Community reference laboratories for feed and food**

1. Community reference laboratory for milk and milk products

Afssa-Lerhqa
F-94700 Maisons-Alfort

2. Community reference laboratories for the analysis and testing of zoonoses (salmonella)

Rijksinstituut voor Volksgezondheid en Milieu (RIVM)
3720 BA Bilthoven
The Netherlands

3. Community reference laboratory for the monitoring of marine biotoxins

Ministerio de Sanidad y Consumo
Vigo
Spain

4. Community reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs

The laboratory of the Centre for Environment, Fisheries and Aquaculture Science, Weymouth, United Kingdom.

5. Community reference laboratories for residues

(a) For the residues listed in Annex I, Group A 1, 2, 3, 4, Group B 2 (d) and Group B 3 (d) to Council Directive 96/23/EC

Rijksinstituut voor Volksgezondheid en Milieu (RIVM)
3720 BA Bithoven
The Netherlands

(b) For the residues listed in Annex I, Group B 1 and B 3 (e) to Council Directive 96/23/EC and carbadox and olaquidonx

Laboratoires d'études et de recherches sur les médicaments vétérinaires et les désinfectants
AFSSA - Site de Fougères
BP 90203
France

(c) For the residues listed in Annex I, Group A 5 and Group B 2 (a), (b), (e) to Council Directive 96/23/EC

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Postfach 140162
D-53056 Bonn

(d) For the residues listed in Annex I, Group B 2 (c) and Group B 3 (a), (b), (c) to Council Directive 96/23/EC

Instituto Superiore di Sanità
I-00161 -Roma

6. Community reference laboratory for transmissible spongiform encephalopathies (TSEs)

The laboratory referred to in Annex X, Chapter B of Regulation (EC) No 999/2001

7. Community reference laboratory for additives for use in animal nutrition

The laboratory referred to in Annex II of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1]

8. Community reference laboratory for genetically modified organisms (GMOs)

The laboratory referred to in the Annex to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2].

9. Community reference laboratory for material intended to come into contact with foodstuffs

The Joint Research Centre of the Commission

II. **Community reference laboratories for animal health**

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(1) OJ L 268, 18.10.2003, p. 29.
(2) OJ L 268, 18.10.2003, p. 1.

ANNEX VIII

IMPLEMENTING RULES THAT REMAIN IN FORCE PURSUANT TO ARTICLE 61

1. Implementing rules based on Directive 70/373/EEC on the introduction of Community methods of sampling and analysis for the official control of feedingstuffs

(a) First Commission Directive 71/250/EEC of 15 June 1971 establishing Community methods of analysis for the official control of feedingstuffs ([1])

(b) Second Commission Directive 71/393/EEC of 18 November 1971 establishing Community methods of analysis for the official control of feedingstuffs ([2])

(c) Third Commission Directive 72/199/EEC of 27 April 1972 establishing Community methods of analysis for the official control of feedingstuffs ([3])

(d) Fourth Commission Directive 73/46/EEC of 5 December 1972 establishing Community methods of analysis for the official control of feedingstuffs ([4])

(e) First Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feedingstuffs ([5])

(f) Seventh Commission Directive 76/372/EEC of 1 March 1976 establishing Community methods of analysis for the official control of feedingstuffs ([6])

(g) Eighth Commission Directive 78/633/EEC of 15 June 1978 establishing Community methods of analysis for the official control of feedingstuffs ([7])

(h) Ninth Commission Directive 81/715/EEC of 31 July 1981 establishing Community methods of analysis for the official control of feedingstuffs ([8])

(i) Tenth Commission Directive 84/425/EEC of 25 July 1984 establishing Community methods of analysis for the official control of feedingstuffs ([9])

(j) Eleventh Commission Directive 93/70/EEC of 28 July 1993 establishing Community methods of analysis for the official control of feedingstuffs ([10])

(k) Twelfth Commission Directive 93/117/EC of 17 December 1993 establishing Community methods of analysis for the official control of feedingstuffs ([11])

(l) Commission Directive 98/64/EC of 3 September 1998 establishing Community methods of analysis for the determination of amino acids, crude oils and fats, and olaquindox in feedingstuffs ([12])

([1]) OJ L 155, 12.7.1971, p. 13. Directive as last amended by Commission Directive 1999/27/EC (OJ L 118, 6.5.1999, p. 36).
([2]) OJ L 279, 20.12.1971, p. 7. Directive as last amended by Commission Directive 98/64/EC (OJ L 257, 19.9.1998, p. 14).
([3]) OJ L 123, 29.5.1972, p. 6. Directive as last amended by Commission Directive 1999/79/EC (OJ L 209, 7.8.1999, p. 23).
([4]) OJ L 83, 30.3.1973, p. 21. Directive as last amended by Commission Directive 1999/27/EC.
([5]) OJ L 102, 15.4.1976, p. 1.
([6]) OJ L 102, 15.4.1976, p. 8. Directive as last amended by Commission Directive 94/14/EC (OJ L 94, 13.4.1994, p. 30).
([7]) OJ L 206, 29.7.1978, p. 43. Directive as last amended by Commission Directive 84/4/EEC (OJ L 15, 18.1.1984, p. 28).
([8]) OJ L 257, 10.9.1981, p. 38.
([9]) OJ L 238, 6.9.1984, p. 34.
([10]) OJ L 234, 17.9.1993, p. 17.
([11]) OJ L 329, 30.12.1993, p. 54.
([12]) OJ L 257, 19.9.1998, p. 14.

(m) Commission Directive 2003/126/EC of 23 December 2003 on the analytical method for the determination of constituents of animal origin for the official control of foodstuffs [1]

(n) Commission Directive 1999/27/EC of 20 April 1999 establishing Community methods of analysis for the determination of amprolium, diclazuril and carbadox in feedingstuffs [2]

(o) Commission Directive 1999/76/EC of 23 July 1999 establishing a Community method of analysis for the determination of lasalocid sodium in feedingstuffs [3]

(p) Commission Directive 2000/45/EC of 6 July 2000 establishing Community methods of analysis for the determination of vitamin A, vitamin E and tryptophan in feedingstuffs [4]

(q) Directive 2002/70/EC of 26 July 2002 establishing requirements for the determination of levels of dioxins and dioxin-like PCBs in feedingstuffs [5]

2. Implementing rules based on Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition

Commission Directive 98/68/EC of 10 September 1998 laying down the standard document referred to in Article 9(1) of Council Directive 95/53/EC and certain rules for checks at the introduction into the Community of feedingstuffs from third countries [6].

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(1) OJ L 339, 24.12.2003, p. 78.
(2) OJ L 118, 6.5.1999, p. 36.
(3) OJ L 207, 6.8.1999, p. 13.
(4) OJ L 174, 13.7.2000, p. 32.
(5) OJ L 209, 6.8.2002, p. 15.
(6) OJ L 261, 24.9.1998, p. 32.

COMMISSION REGULATION (EC) No 1216/2007

of 18 October 2007

laying down detailed rules for the implementation of Council Regulation (EC) No 509/2006 on agricultural products and foodstuffs as traditional specialities guaranteed

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed [1], and in particular Article 19(1) thereof,

Whereas:

(1) Regulation (EC) No 509/2006 has repealed Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs [2]. For the sake of clarity, Commission Regulation (EEC) No 1848/93 [3], which lays down detailed rules for the application of Regulation (EEC) No 2082/92 should be repealed and replaced by a new Regulation.

(2) Regulation (EC) No 509/2006 provides that in order to qualify as a traditional speciality guaranteed, an agricultural product or foodstuff shall comply with a product specification. Detailed rules on the information to be included in the product specification, especially concerning names to be registered, description of the product and the production method and checking the specific character, should be provided for.

(3) Specific rules for names not in Latin characters and for registrations in more than one language should be laid down.

(4) Article 13(3) of Regulation (EC) No 509/2006 provides that a specification may refer to the possibility of accompanying the registered name by a label with a particular form of words intended to be translated into languages other than the language in which the name is registered. Although the specification need not provide translations of this form of words, the original text to be translated should be provided in the specification.

(5) The product specification should be presented in a concise way, avoiding description of historical practices that are no longer followed and repetition of general obligations. A maximum length for the product specification should be set.

(6) The Community symbol referred to in Article 12(2) of Regulation (EC) No 509/2006 should be defined. The second paragraph of Article 22 of that Regulation provides that the symbol will be compulsory for Community products from 1 May 2009, without prejudice to products already placed on the market before that date. However, since the symbol may be used voluntarily by operators before that date, it is appropriate to define rules concerning the use of the symbol with effect from 1 July 2008.

(7) Regulation (EC) No 509/2006 provides that a producer intending to produce a traditional speciality guaranteed for the first time shall notify this beforehand to the designated authorities or bodies verifying compliance with the product specification. To ensure transparency and proper functioning of controls, the designated authorities or bodies should communicate to the Member State or, in case of third countries, to the Commission, the names and addresses of producers for which they verify compliance with the product specifications.

(8) To ensure coherent implementation of Regulation (EC) No 509/2006, procedures should be specified and models concerning product specifications, objections and amendments should be provided for.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Traditional Specialities Guaranteed,

HAS ADOPTED THIS REGULATION:

Article 1

Product specification

1. The product specification referred to in Article 6 of Regulation (EC) No 509/2006 shall include the information requested under point 3 in Annex I to this Regulation.

2. The type of the agricultural product or foodstuff shall be indicated in accordance with the classification set out in Annex II to this Regulation.

3. The product specification shall be concise and shall not exceed 10 pages except in justified cases.

[1] OJ L 93, 31.3.2006, p. 1.
[2] OJ L 208, 24.7.1992, p. 9. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
[3] OJ L 168, 10.7.1993, p. 35. Regulation as last amended by Regulation (EC) No 2167/2004 (OJ L 371, 18.12.2004, p. 8).

Article 2

Specific rules for a name

1. Where the original script of a name to be registered is not in Latin characters, a transcription in Latin characters shall also be registered together with the name in its original script.

2. Where registration is sought in more than one language, all forms of the name for which registration is sought shall appear in the product specification.

3. Where Article 13(3) of Regulation (EC) No 509/2006 is applied, and the group specifies that, when the product is marketed, the label may contain an indication in the other official languages that the product has been obtained in accordance with the tradition of the region, Member State or third-country from which the application originates, the indication to be translated into the other official languages shall appear in the product specification.

Article 3

Specific rules for description of the product and the production method

1. A description of the product shall only mention the characteristics necessary to identify the product and its specific characteristics. It shall not repeat general obligations.

2. A description of the production method shall only include the production method in force. Historical practices are not to be included if they are no longer followed.

Only the method necessary for obtaining the specific product shall be described in a way that enables reproduction of the product.

3. The key elements defining the product's specific character shall include a comparison with a category of products to which the product in question belongs, showing the difference. Existing standards may be quoted as a reference or as a comparison.

4. The key elements that prove the product's traditional character shall include the main elements that have remained unchanged, with precise and well established references.

Article 4

Minimum requirements and procedures to check the specific character

The product specification shall set out the characteristics to be checked to ensure the specific character of the product as well as procedures to be used and frequency of these checks.

Article 5

Specific rules on labelling

A Member State may provide that the name of the authority or body referred to in point (c) of Article 7(3) of Regulation (EC) No 509/2006 must appear on the label of the agricultural product or foodstuff designated as a traditional speciality guaranteed that is produced within its territory.

Article 6

Applying for registration

1. An application for registration shall be drawn up in accordance with the form set out in Annex I to this Regulation. A duly completed electronic copy of the form shall also be provided.

2. Where the applicant group is established in a Member State, the application shall be accompanied by the declaration referred to in point (d) of Article 7(6) of Regulation (EC) No 509/2006.

Where the applicant group is established in a third country, the application shall be accompanied by the documents referred to in point (d) of Article 7(3) of that Regulation.

3. The date of submission of an application to the Commission is the date on which the application is entered in the Commission's mail registry in Brussels.

Article 7

Joint applications

1. Where pursuant to the second subparagraph of Article 7(1) of Regulation (EC) No 509/2006 several groups from different Member States submit a joint application, the objection procedure referred to in paragraph 5 of that Article shall be carried out in all Member States concerned.

2. The application, accompanied by the declarations referred to in Article 7(6)(d) of Regulation (EC) No 509/2006 from all the Member States concerned, shall be submitted to the Commission by any Member State concerned, or by any of the applicant groups in third countries concerned, directly or via the authorities of the third country concerned.

Article 8

Objections

1. A statement of objection for the purposes of Article 9 of Regulation (EC) No 509/2006 may be drawn up in accordance with the form set out in Annex III to this Regulation.

2. In determining the admissibility of the objection pursuant to Article 9(3) of Regulation (EC) No 509/2006, the Commission shall check that the statement includes reasons and justification for the objection.

3. The period of six months referred to in Article 9(5) of Regulation (EC) No 509/2006 shall commence on the date of dispatch of the Commission's invitation to the interested parties to reach agreement among them.

4. When the procedure referred to in the first sentence of the second subparagraph of Article 9(5) of Regulation (EC) No 509/2006 has terminated, the Member State of application or the third-country applicant shall communicate the results of each consultation to the Commission within one month and may use the form set out in Annex IV to this Regulation.

Article 9

Indications and symbols

1. The Community symbol referred to in Article 12(2) of Regulation (EC) No 509/2006 shall take the form defined in Annex V to this Regulation. The words 'TRADITIONAL SPECIALITY GUARANTEED' within the symbol may be replaced by the equivalent term in another official language of the Community as laid down in Annex V to this Regulation.

2. Where the Community symbols or the indications referred to in Article 12 of Regulation (EC) No 509/2006 appear on the label of a product, they shall be accompanied by the registered name, or one of them, if the name has been registered in several languages.

Article 10

Register

1. The Commission shall maintain at its seat in Brussels the 'Register of traditional specialities guaranteed', hereafter referred to as 'the Register'.

2. Upon entry into force of a legal instrument registering a name, the Commission shall record the following data in the Register:

(a) the registered name of the product in one or more languages;

(b) information whether the registration is with or without reservation of the name;

(c) information whether the group applies to benefit from the provisions of Article 13(3) of Regulation (EC) No 509/2006;

(d) the class of the product as referred to in Annex II to this Regulation;

(e) indication of the country or countries of the group or groups that made the application; and

(f) reference to the instrument registering the name.

3. In respect of the names automatically registered by virtue of Article 19(2) of Regulation (EC) No 509/2006, the Commission shall record in the Register, by 31 July 2008, the data provided for in paragraph 2 of this Article.

Article 11

Amendments to specification

1. An application for approval of changes to the product specification shall be drawn up in accordance with the form set out in Annex VI to this Regulation.

2. In the case of an application for approval of changes to product specifications under Article 11 of Regulation (EC) No 509/2006:

(a) the information required under Article 7 of Regulation (EC) No 509/2006 shall comprise the duly completed application referred to in paragraph 1 of this Article and, where the applicant group is established in a Member State, the declaration referred to in point (d) of Article 7(6) of that Regulation;

(b) the information to be published under Article 8(2) of Regulation (EC) No 509/2006 shall comprise the duly completed application referred to in paragraph 1 of this Article.

3. For an amendment to be regarded as minor, within the meaning of the fourth subparagraph of Article 11(1) of Regulation (EC) No 509/2006, it cannot:

(a) relate to the essential characteristics of the product;

(b) introduce essential changes to the production method;

(c) include a change to the name, or to any part of the name, or use of the name, of the product.

4. Where the application concerns a temporary amendment to the product specification resulting from imposition of obligatory sanitary or phyto-sanitary measures by public authorities as laid down in Article 11(3) of Regulation (EC) No 509/2006, evidence of these measures shall be provided.

5. Where the Commission decides to accept an amendment to the specification that includes or comprises a change to the information recorded in the Register provided for in Article 10 of this Regulation, it shall strike the original data from the Register and record the new data in the Register with effect from the entry into force of the said decision.

6. Information submitted to the Commission pursuant to this Article shall be in both paper and electronic form. The date of submission of an amendment application to the Commission shall be the date on which the application is entered in the Commission's mail registry in Brussels.

Article 12

Communication from the designated authorities or bodies

1. The authorities referred to in Article 14(1) of Regulation (EC) No 509/2006 or the control bodies referred to in the second indent of the first subparagraph of Article 15(1) of that Regulation shall communicate to the Member State the names and addresses of the producers for which they verify compliance with the product specifications. Member States shall keep the list of producers available for the other Member States and the Commission.

2. The authorities or control bodies referred to in Article 15(2) of Regulation (EC) No 509/2006 shall communicate to the Commission the names and addresses of the producers for which they verify compliance with the product specifications.

Article 13

Cancellation

1. The Commission may take the view that the compliance with the conditions of the product specification for an agricultural product or foodstuff covered by a name of a traditional speciality guaranteed is no longer possible or cannot be ensured, in particular if no authority or control body referred to in Article 15 of Regulation (EC) No 509/2006 has been communicated to the Commission within a time period of 5 years.

2. Before cancelling a registration, the Commission shall allow the group which applied for registration to be heard, and may set a deadline for the group to comment.

3. When a cancellation takes effect, the Commission shall remove the name from the Register provided for in Article 10 of this Regulation.

Article 14

Transitional rules

The provisions of this Regulation shall apply with effect from the date of entry into force, subject to the following:

(a) The provisions of Articles 1 to 4 shall apply only in respect of procedures for registration and approval of amendments where the publication pursuant to Article 8(2) of Regulation (EC) No 509/2006 or pursuant to Article 8(1) of Regulation (EEC) No 2082/92 has not taken place before the entry into force of this Regulation;

(b) The provisions of Articles 6, 7, 11(1), 11(2), 11(4) and 11(6) shall only apply in respect of applications for registration and approval of amendments received after 19 April 2006;

(c) The provisions of paragraphs 1, 2 and 3 of Article 8 shall only apply in respect of objection procedures for which the six-month period in Article 9(1) of Regulation (EC) No 509/2006 has not commenced at the date of entry into force of this Regulation;

(d) The provisions of Article 8(4) shall only apply in respect of objection procedures for which the six-month period in Article 9(1) of Regulation (EC) No 509/2006 has not expired at the date of entry into force of this Regulation;

(e) The provisions of Article 9(2) shall apply not later than 1 July 2008, without prejudice to products placed on the market before that date.

Article 15

Repeal

Regulation (EEC) No 1848/93 is repealed.

Article 16

Entry into force

This Regulation shall enter into force on the seventh day following that of its publication in the *Official Journal of the European Union*.

However, point (b) of Article 14 shall apply with effect from 20 April 2006.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 October 2007.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

ANNEX I

(When this form is completed, the text in square parentheses shall be omitted.)

APPLICATION FOR REGISTRATION OF A TSG

COUNCIL REGULATION (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed

[Insert name, as in 3.1. below:] ‘ ’

EC No: [for EC use only]

1. **Name and address of the applicant group**

[In case of several applicant groups, provide information concerning each of them]

— Name of group/or organisation (if relevant):

— Address:

— Telephone:

— e-mail address:

2. **Member State or third country**

3. **Product specification**

3.1. *Name(s) to be registered (Article 2 of Regulation (EC) No 1216/2007)*

[Where registration is sought for in more than one language, include all forms of the name to be used. Where Article 13(3) of Regulation (EC) No 509/2006 is applied, i.e. the group specifies that, when the product is marketed, the label may contain, in addition to the name of the product in the original language, an indication in the other official languages that the product has been obtained in accordance with the tradition of the region, Member State or third-country from which the application originates, include also the indication to be translated into the other official languages.]

3.2. *Whether the name:*

☐ is specific in itself

☐ expresses the specific character of the agricultural product or foodstuff

[Provide explanation]

3.3. *Whether reservation of the name is sought under Article 13(2) of Regulation (EC) No 509/2006*

[Select one, ‘X’]

☐ Registration with reservation of the name

☐ Registration, without reservation of the name

3.4. *Type of product* [as in Annex II]

3.5. *Description of the agricultural product or foodstuff to which the name under point 3.1. applies (Article 3(1) of Regulation (EC) No 1216/2007)*

3.6. *Description of the production method of the agricultural product or foodstuff to which the name under point (3.1.) applies (Article 3(2) of Regulation (EC) No 1216/2007)*

3.7. *Specific character of the agricultural product or foodstuff (Article 3(3) of Regulation (EC) No 1216/2007)*

3.8. *Traditional character of the agricultural product or foodstuff (Article 3(4) of Regulation (EC) No 1216/2007)*

3.9. *Minimum requirements and procedures to check the specific character (Article 4 of Regulation (EC) No 1216/2007)*

4. **Authorities or bodies verifying compliance with the product specification**

[Where more than one authority or body is verifying compliance with the product specification, include information on all of them.]

4.1. *Name and address*

— Name:

— Address:

— Telephone:

— e-mail address:

[Select one, 'X':] ☐ Public ☐ Private

4.2. *Specific tasks of the authority or body*

[Only tasks related to verification of compliance with the provisions of the specification]

ANNEX II

CLASSIFICATION OF PRODUCTS FOR THE PURPOSES OF COUNCIL REGULATION (EC) No 509/2006

1. **Products of Annex I to the EC Treaty intended for human consumption**
   - — Class 1.1. Fresh meat (and offal)
   - — Class 1.2. Meat products (cooked, salted, smoked, etc.)
   - — Class 1.3. Cheeses
   - — Class 1.4. Other products of animal origin (eggs, honey, various dairy products except butter, etc.)
   - — Class 1.5. Oils and fats (butter, margarine, oils, etc.)
   - — Class 1.6. Fruit, vegetables and cereals, fresh or processed
   - — Class 1.7. Fresh fish, molluscs and crustaceans and products derived therefrom
   - — Class 1.8. Other products of Annex I of the Treaty

2. **Foodstuffs referred to in Annex I of Regulation (EC) No 509/2006**
   - — Class 2.1. Beer
   - — Class 2.2. Chocolate and other food preparations containing cocoa
   - — Class 2.3. Confectionery, bread, pastry, cakes, biscuits and other baker's wares
   - — Class 2.4. Pasta, whether or not cooked or stuffed
   - — Class 2.5. Pre-cooked meals
   - — Class 2.6. Prepared condiment sauces
   - — Class 2.7. Soups or broths
   - — Class 2.8. Beverages made from plant extracts
   - — Class 2.9. Ice-creams and sorbets.

ANNEX III

(When this form is completed, the text in square parentheses shall be omitted.)

STATEMENT OF OBJECTION

Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed

1. **Name of product**

[as given in Official Journal (OJ) publication]

2. **Official reference**

[as given in Official Journal (OJ) publication]

Reference number:

Date of OJ publication:

3. **Contact details**

Contact person: Title (Mr, Ms …): Name:

Group/organisation/individual:

Or national authority:

Department:

Address:

Telephone +

e-mail address:

4. **Reason for the objection:**

— ☐ Non-compliance with the conditions laid down in Article 2 of Regulation (EC) No 509/2006

— ☐ Non-compliance with the conditions laid down in Article 4 of Regulation (EC) No 509/2006

— ☐ Non-compliance with the conditions laid down in Article 5 of Regulation (EC) No 509/2006

— ☐ In the case of applications under Article 13(2), use of the name is lawful, renowned and economically significant for similar agricultural products or foodstuffs

5. **Detail of objection**

Provide a statement setting out the reasons and justification for the objection. Provide also a statement explaining the legitimate interest of the objector, unless the objection is lodged by the national authorities, in which case no statement of legitimate interest is required. The statement of objection should be signed and dated.

ANNEX IV

(When this form is completed, the text in square parentheses shall be omitted.)

NOTIFICATION OF END OF CONSULTATIONS FOLLOWING OBJECTION PROCEDURE

Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed

1. **Name of product**

   [as given in Official Journal (OJ) publication]

2. **Official reference** [as given in Official Journal (OJ) publication]

   Reference number:

   Date of OJ publication:

3. **Result of consultations**

3.1. *Agreement was reached with the following objector(s):*

   [annex copies of letters showing agreement]

3.2. *Agreement was not reached with the following objector(s):*

4. **Product specification**

   The specification has been amended

   Yes ☐ No ☐

   If 'Yes', annex the amended product specification

5. **Dated and signed**

   [Name]

   [Department/Organisation]

   [Address]

   [Telephone: +]

   [e-mail address:]

ANNEX V

REPRODUCTION OF THE COMMUNITY SYMBOLS AND INDICATIONS

1. **Community symbols in colour or black and white**

When used in colour, direct colours (Pantone) or four-colour process may be used. The reference colours are indicated below.

Community symbols in pantone:

Community symbols in four-colour process:

Community symbols in black and white:

2. **Community symbols in negative**

If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.

3. **Contrast with background colours**

If a symbol is used in colour on a coloured background, which makes it difficult to see, a delimiting outer circle around the symbol should be used to improve contrast with the background:

4. **Typography**

Times Roman capitals must be used for the text.

5. **Reduction**

The minimum size of the Community symbols is 15 mm in diameter.

6. **'Traditional speciality guaranteed' and its abbreviation in EC languages**

EC language	Term	Abbreviation
BG	храна с традиционно специфичен характер	ХТСХ
ES	especialidad tradicional garantizada	ETG
CS	zaručená tradiční specialita	ZTS
DA	garanteret traditionel specialitet	GTS
DE	garantiert traditionelle Spezialität	g.t.S.
ET	garanteeritud traditsiooniline eritunnus	GTE
EL	εγγυημένο παραδοσιακό ιδιότυπο προϊόν	Ε Π Ι Π
EN	traditional speciality guaranteed	TSG
FR	spécialité traditionnelle garantie	STG
GA	speisialtacht thraidisiúnta ráthaithe	STR
IT	specialità tradizionale garantita	STG
LV	garantēta tradicionālā īpatnība	GTI
LT	garantuotas tradicinis gaminys	GTG
HU	hagyományos különleges termék	HKT
MT	speċjalità tradizzjonali garantita	STG
NL	gegarandeerde traditionele specialiteit	GTS
PL	gwarantowana tradycyjna specjalność	GTS
PT	especialidade tradicional garantida	ETG
RO	specialitate tradițională garantată	STG
SK	zaručená tradičná špecialita	ZTŠ
SL	zajamčena tradicionalna posebnost	ZTP
FI	aito perinteinen tuote	APT
SV	garanterad traditionell specialitet	GTS

ANNEX VI

(When this form is completed, the text in square parentheses shall be omitted.)

AMENDMENT APPLICATION

Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed

Amendment application according to Article 11

[Registered name] ‘ ’

EC No: [for EC use only]

1. **Applicant group**

— Name of the group

— Address

— Telephone: +

— e-mail address:

2. **Member State or third country**

3. **Heading in the specification affected by the amendment**

☐ Name of product,

☐ Reservation of the name (Article 13(2) of Council Regulation (EC) No 509/2006)

☐ Description of product

☐ Method of production

☐ Other (specify):

4. **Type of amendment(s)**

☐ Amendment to specification of registered TSG

☐ Temporary amendment to specification resulting from imposition of obligatory sanitary or phyto-sanitary measures by public authorities (Article 11(3) of Regulation (EC) No 509/2006) (provide evidence of these measures)

5. **Amendment(s)**

[For each heading checked in section 3 above, provide a short explanation of each amendment. Provide also a statement explaining the legitimate interest of the group proposing the amendment.]

6. **Updated product specification**

Decree dated 6th November 2007, no. 193, implementation of Directive 2004/41/EC *(in Italian)*

Decreto Legislativo 6 novembre 2007, n. 193

"Attuazione della direttiva 2004/41/CE relativa ai controlli in materia di sicurezza alimentare e applicazione dei regolamenti comunitari nel medesimo settore"

pubblicato nella *Gazzetta Ufficiale* n. 261 del 9 novembre 2007 - Suppl. Ordinario n.228
(Rettifica G.U. n. 31 del 6 febbraio 2008)

IL PRESIDENTE DELLA REPUBBLICA

Visti gli articoli 76 e 87, della Costituzione;

Vista la direttiva 2004/41/CE del Parlamento europeo e del Consiglio, del 21 aprile 2004, che abroga alcune direttive recanti norme sull'igiene dei prodotti alimentari e le disposizioni sanitarie per la produzione e la commercializzazione di determinati prodotti di origine animale destinati al consumo umano e che modifica le direttive 89/662/CEE e 92/118/CEE e la decisione 95/408/CE del Consiglio;

Vista la legge 25 gennaio 2006, n. 29, ed in particolare l'articolo 1, commi 1 e 3, l'articolo 3, comma 1, lettera b), e l'allegato A);

Visto il decreto del Presidente della Repubblica 21 luglio 1982, n. 728, recante attuazione della direttiva 72/461/CEE relativa a problemi di polizia sanitaria in materia di scambi intracomunitari di carni fresche;

Visto il decreto del Presidente della Repubblica 10 settembre 1982, n. 889, recante attuazione della direttiva 72/462/CEE relativa ai problemi sanitari e di polizia sanitaria all'importazione di animali della specie bovina e suina e di carni fresche in provenienza da Paesi terzi nonche' direttiva 77/96/CEE relativa alla ricerca delle trichine all'importazione da Paesi terzi di carni fresche provenienti da animali domestici della specie suina;

Visto il decreto del Presidente della Repubblica 17 maggio 1988, n. 194, attuazione delle direttive 77/99/CEE, 80/214/CEE, 80/215/CEE, 80/1100/CEE, 83/201/CEE, 85/321/CEE, 85/327 ed 85/328/CEE relative ai problemi sanitari in materia di scambi intracomunitari di prodotti a base di carne;

Visto il decreto del Ministro della sanità 5 ottobre 1991, n. 375, recante regolamento concernente l'attuazione delle direttive 87/491/CEE e 88/660/CEE, che modificano la direttiva 80/215/CEE, relativa a problemi di polizia sanitaria negli scambi intracomunitari di prodotti a base di carne;

Visto il decreto legislativo 30 dicembre 1992, n. 530, recante attuazione della direttiva 91/492/CEE che stabilisce le norme sanitarie applicabili alla produzione e commercializzazione dei molluschi bivalvi vivi;

Visto il decreto legislativo 30 dicembre 1992, n. 531, attuazione della direttiva 91/493/CEE che stabilisce le norma sanitarie applicabili alla produzione e commercializzazione dei prodotti della pesca, tenuto conto delle modifiche apportate dalla direttiva 92/48/CEE che stabilisce le norme igieniche minime applicabili ai prodotti della pesca ottenuti a bordo di talune navi;

Visto il decreto legislativo 30 dicembre 1992, n. 537, recante attuazione della direttiva 92/5 che modifica e sostituisce la direttiva 77/99/CEE relativa a problemi sanitari in materia di produzione e commercializzazione di prodotti a base di carne e di alcuni prodotti di origine animale;

Visto il decreto del Presidente della Repubblica 30 dicembre 1992, n. 558, recante regolamento per l'attuazione della direttiva 91/494/CEE relativa alle norme di polizia sanitaria intracomunitaria e le importazioni in provenienza da Paesi terzi di carni fresche di volatili da cortile;

Visto il decreto del Presidente della Repubblica 30 dicembre 1992, n. 559, recante regolamento per l'attuazione della direttiva 91/495/CEE relativa ai problemi sanitari e di polizia in materia di produzione e commercializzazione di carni di coniglio e di selvaggina di allevamento;

Visto il decreto legislativo 4 febbraio 1993, n. 65, recante attuazione della direttiva 89/437/CEE concernente i problemi igienici e sanitari relativi alla produzione ed immissione sul mercato degli ovoprodotti;

Visto il decreto legislativo 18 aprile 1994, n. 286, attuazione delle direttive 91/497/CEE e 91/498/CEE, che modificano e sostituiscono la direttiva 64/433, concernente problemi sanitari in materia di produzione ed immissione sul mercato di carni fresche;

Visto il decreto del Presidente della Repubblica 17 ottobre 1996, n. 607, concernente regolamento recante norme per l'attuazione della direttiva 92/45/CEE relativa ai problemi sanitari e di polizia sanitaria in materia di uccisione di selvaggina e di commercializzazione delle relative carni;

Visto il decreto del Presidente della Repubblica 14 gennaio 1997, n. 54, concernente regolamento recante attuazione delle direttive 92/46/CEE e 92/47/CEE in materia di produzione ed immissione sul mercato di latte e di prodotti a base di latte;

Visto il decreto del Presidente della Repubblica 10 dicembre 1997, n. 495, concernente regolamento recante norme di attuazione della direttiva 92/116/CEE, che modifica la direttiva 71/118/CEE, relativa a problemi sanitari in materia di produzione ed immissione sul mercato di carni fresche di volatili da cortile;

Visto il decreto del Presidente della Repubblica 3 agosto 1998, n. 309, concernente regolamento recante norme di attuazione della direttiva 94/65/CE relativa ai requisiti applicabili all'immissione sul mercato di carni macinate e di preparazioni di carni.

Visto il regolamento (CE) n. 178/2002 del Parlamento europeo e del Consiglio, del 28 gennaio 2002, che stabilisce i principi ed i requisiti generali della legislazione alimentare, istituisce l'Autorità europea per la sicurezza alimentare e fissa procedure nel campo della sicurezza alimentare;

Visto il regolamento (CE) n. 852/2004 del Parlamento europeo e del Consiglio, del 29 aprile 2004, sull'igiene dei prodotti alimentari, e successive modificazioni;

Visto il regolamento (CE) n. 853/2004 del Parlamento europeo e del Consiglio, del 29 aprile 2004, che stabilisce norme specifiche in materia di igiene per gli alimenti di origine animale e successive modificazioni;

Visto il regolamento (CE) n. 854/2004 del Parlamento europeo e del Consiglio, del 29 aprile 2004, che stabilisce norme specifiche per l'organizzazione di controlli ufficiali sui prodotti di origine animale destinati al consumo umano, e successive modificazioni;

Visto il regolamento (CE) n. 882/2004 del Parlamento europeo e del Consiglio, relativo ai controlli ufficiali intesi a verificare la conformità alla normativa in materia di mangimi e di alimenti e alle norme sulla salute e sul benessere degli animali e successive modificazioni;

Vista la legge 30 aprile 1962, n. 283, in materia di disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande, e successive modificazioni;

Visto il decreto del Presidente della Repubblica 26 marzo 1980, n. 327, recante regolamento di esecuzione della legge 30 aprile 1962, n. 283, e successive modificazioni, in materia di disciplina igienica della produzione e della vendita delle sostanze alimentari e delle bevande;

Vista la preliminare deliberazione del Consiglio dei Ministri, adottata nella riunione del 27 luglio 2007;

Acquisiti i pareri delle competenti Commissioni parlamentari della Camera dei deputati e del Senato della Repubblica;

Acquisito il parere della Conferenza permanente per i rapporti tra lo Stato, le regioni e le province autonome di Trento e di Bolzano;

Vista la deliberazione definitiva del Consiglio dei Ministri, adottata nella riunione del 23 ottobre 2007;

Sulla proposta del Ministro per le politiche europee e del Ministro della salute, di concerto con i Ministri degli affari esteri, della giustizia, dell'economia e delle finanze, per gli affari regionali e le autonomie locali e delle politiche agricole alimentari e forestali;

E m a n a
il seguente decreto legislativo:

Art. 1.
Finalità ed ambito di applicazione

1. Le disposizioni del presente decreto legislativo sono emanate al fine di abrogare la normativa nazionale di attuazione delle direttive comunitarie a loro volta abrogate dalla direttiva 2004/41.

Art. 2.
Autorità competenti

1. Ai fini dell'applicazione dei regolamenti (CE) 852/2004, 853/2004, 854/2004 e 882/2004, e successive modificazioni, per le materie disciplinate dalla normativa abrogata di cui all'art. 3, le Autorità competenti sono il Ministero della salute, le regioni, le province autonome di Trento e di Bolzano e le Aziende unità sanitarie locali, nell'ambito delle rispettive competenze.

Art. 3.
Abrogazioni

1. Sono abrogati i seguenti provvedimenti:
a) art. 2, secondo comma, lettera *z)*, articoli 12, 15, 27, 28 e 29 del decreto del Presidente della Repubblica 10 settembre 1982, n. 889;
b) decreto del Presidente della Repubblica del 17 maggio 1988, n. 194; restano abrogati i commi 1, 2, 3, 4, e 5 dell'articolo 55 del regio decreto 20 dicembre 1928, n. 3298;
c) decreto legislativo 30 dicembre 1992, n. 530, ad eccezione dell'articolo 20;
d) decreto legislativo 30 dicembre 1992, n. 531;
e) decreto legislativo 30 dicembre 1992, n. 537; restano abrogati gli articoli 50, 51, 52, 53, 54, 55, commi 6, 7 ed 8, 56, 57 e 58 del regio decreto 20 dicembre 1928, n. 3298;
f) decreto del Presidente della Repubblica 30 dicembre 1992, n. 558;
g) decreto del Presidente della Repubblica 30 dicembre 1992, n. 559; restano abrogati gli articoli 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 13-*bis* e 14 e l'allegato *A)* del decreto del Presidente della Repubblica 10 agosto 1972, n. 967;
h) decreto legislativo 4 febbraio 1993, n. 65;
i) decreto legislativo 3 marzo 1993, n. 123, ad eccezione degli articoli 4 e 2, comma 3;
l) decreto legislativo 18 aprile 1994, n. 286; restano abrogati gli articoli da 4 a 6, da 8 a 12, da 14 a 16, da 18 a 28, 33, 34, 37 e da 39 a 49 del regio decreto 20 dicembre 1928, n. 3298; resta abrogato l'articolo 7 della legge 29 novembre 1971, n. 1073; restano abrogati gli articoli da 1 a 11 del decreto del Presidente della Repubblica, 10 settembre 1991, n. 312;
m) decreto del Presidente della Repubblica 17 ottobre 1996, n. 607;
n) decreto del Presidente della Repubblica 14 gennaio 1997, n. 54, ad eccezione degli articoli 19, 26 e dell'allegato *C)*, capitolo I, lettera *A)*, punti 4 e 7;
o) decreto legislativo 26 maggio 1997, n. 155;
p) decreto legislativo 26 maggio 1997, n. 156;
q) decreto del Presidente della Repubblica del 10 dicembre 1997, n. 495; restano abrogati gli articoli da 1 a 25 del decreto del Presidente della Repubblica 8 giugno 1982, n. 503, e gli allegati al decreto medesimo;
r) decreto del Presidente della Repubblica 3 agosto 1998, n. 309; rimane abrogato il decreto del Presidente della Repubblica, 1° marzo 1992, n. 227;
s) articolo 2 della legge 30 aprile 1962, n. 283.

Art. 4.
Macellazioni d'urgenza al di fuori del macello

1. Le carcasse, le mezzene, i quarti e le mezzene tagliate in massimo tre parti, ottenute da macellazioni d'urgenza di ungulati domestici al di fuori del macello, di cui all'allegato III, sezione I, capitolo VI del regolamento (CE) n. 853/2004, devono recare un bollo sanitario di forma rettangolare che misuri almeno 6 cm in larghezza e 4 cm in altezza recante le seguenti indicazioni:
a) nella parte superiore l'indicazione dell'unità sanitaria locale nel cui territorio si trova il macello in cui le

carni, ottenute da macellazione d'urgenza, vengono trasportate;
b) al centro la sigla MSU seguita dal numero d'identificazione del macello;
c) nella parte inferiore il nome della regione o provincia autonoma nel cui territorio si trova il macello.

2. Le carni ottenute dalle carcasse, dalle mezzene, dai quarti e dalle mezzene tagliate in massimo tre parti di cui al comma 1, devono recare un marchio d'identificazione di forma rettangolare che misuri almeno 6 cm in larghezza e 4 cm in altezza recante le seguenti indicazioni:
a) nella parte superiore l'indicazione dell'unità sanitaria locale nel cui territorio si trova il macello in cui le carni, ottenute da macellazione d'urgenza, vengono trasportate;
b) al centro la sigla MSU seguita dal numero d'identificazione del macello;
c) nella parte inferiore il nome della regione o provincia autonoma nel cui territorio si trova il macello.

Art. 5.
Modifiche alla normativa in materia di scambi ed importazioni

1. Al decreto legislativo 13 dicembre 1996, n. 674, sono apportate le seguenti modificazioni:
a) le parole: «allegato I e allegato II», ovunque ricorrenti, sono sostituite dalle seguenti: «allegato I»;
b) l'allegato II e' abrogato.

2. Tutte le disposizioni di cui alle direttive recepite con i provvedimenti indicati nell'articolo 3 e quelle indicate nell'allegato II del decreto legislativo 13 dicembre 1996, n. 674, come modificato al comma 1, sono riferite a quelle corrispondenti nei regolamenti (CE) n. 853/2004 e 854/2004 e nel decreto legislativo 27 maggio 2005, n. 117.

3. L'allegato A), Parte I, del decreto legislativo 30 gennaio 1993, n. 28 , e' sostituito dall'allegato I al presente decreto.

4. I riferimenti ai provvedimenti abrogati all'articolo 3 contenuti nella normativa in vigore devono intendersi riferiti a quelli corrispondenti di cui ai regolamenti (CE) n. 852/2004, 853/2004, 854/2004 e 882/2004.

Art. 6.
Sanzioni

1. Chiunque, nei limiti di applicabilità del regolamento (CE) n. 853/2004, effettua attività di macellazione di animali, di produzione e preparazione di carni in luoghi diversi dagli stabilimenti o dai locali a tale fine riconosciuti ai sensi del citato regolamento ovvero la effettua quando il riconoscimento e' sospeso o revocato e' punito con l'arresto da sei mesi ad un anno o con l'ammenda fino a euro 150.000, in relazione alla gravità dell'attività posta in essere.

2. Salvo che il fatto costituisca reato, chiunque, nei limiti di applicabilità del regolamento (CE) n. 853/2004, effettua attività in stabilimenti diversi da quelli di cui al comma 1, non riconosciuti ai sensi di tale regolamento ovvero le effettua quando il riconoscimento e' sospeso o revocato, o che, pur essendo condotte presso un impianto riconosciuto, non siano state comunicate all'Autorità competente per l'aggiornamento del riconoscimento, e' punito, con la sanzione amministrativa pecuniaria da euro 5.000 a euro 30.000.

3. Salvo che il fatto costituisca reato, chiunque, nei limiti di applicabilità del regolamento (CE) n. 852/2004 ed essendovi tenuto, non effettua la notifica all'Autorità competente di ogni stabilimento posto sotto il suo controllo che esegua una qualsiasi delle fasi di produzione, trasformazione e distribuzione di alimenti ovvero le effettua quando la registrazione e' sospesa o revocata, e' punito con la sanzione amministrativa pecuniaria da euro 1.500 a euro 9.000 o con la sanzione amministrativa pecuniaria da euro 500 a euro 3.000, nel caso in cui, pur essendo condotte presso uno stabilimento già registrato, non siano state comunicate all'Autorità competente per l'aggiornamento della registrazione.

4. Salvo che il fatto costituisca reato, l'operatore del settore alimentare operante a livello di produzione primaria e operazioni connesse che non rispetta i requisiti generali in materia di igiene di cui alla parte A dell'allegato I al regolamento (CE) n. 852/2004 e gli altri requisiti specifici previsti dal regolamento (CE) n. 853/2004 e' punito con la sanzione amministrativa pecuniaria da euro 250 a euro 1.500;

5. Salvo che il fatto costituisca reato, l'operatore del settore alimentare operante ai sensi dei regolamenti (CE) n. 852/2004 e n. 853/2004 a livello diverso da quello della produzione primaria che non

rispetta i requisiti generali in materia di igiene di cui all'allegato II al regolamento (CE) n. 852/2004 e gli altri requisiti specifici previsti dal regolamento (CE) n. 853/2004 e' punito con la sanzione amministrativa pecuniaria da euro 500 a euro 3.000;

6. L'operatore del settore alimentare operante ai sensi dei regolamenti (CE) n. 852/2004 e n. 853/2004, a livello diverso da quello della produzione primaria, che omette di predisporre procedure di autocontrollo basate sui principi del sistema HACCP, comprese le procedure di verifica da predisporre ai sensi del regolamento (CE) n. 2073/2005 e quelle in materia di informazioni sulla catena alimentare, e' punito con la sanzione amministrativa pecuniaria da euro 1.000 a euro 6.000;

7. Nel caso in cui l'autorità competente riscontri inadeguatezze nei requisiti o nelle procedure di cui ai commi 4, 5 e 6 fissa un congruo termine di tempo entro il quale tali inadeguatezze devono essere eliminate. Il mancato adempimento entro i termini stabiliti e' punito con la sanzione amministrativa pecuniaria da euro 1.000 a euro 6.000;

8. La mancata o non corretta applicazione dei sistemi e/o delle procedure predisposte ai sensi dei commi 4, 5 e 6 e' punita con la sanzione amministrativa pecuniaria da euro 1000 a euro 6.000.

9. L'operatore del settore alimentare che, pur in possesso di riconoscimento, omette di indicare sull'etichetta del prodotto alimentare di origine animale il numero di riconoscimento dello stabilimento di produzione di cui al regolamento (CE) n. 853/2004, e' punito con la sanzione amministrativa pecuniaria da 500 euro a 3.000 euro;

10. Salvo che il fatto costituisca reato, chiunque immette in commercio carni fresche refrigerate o congelate senza la bollatura sanitaria di cui all'articolo 5, paragrafo 2 del regolamento (CE) n. 854/2004, e' punito con la sanzione amministrativa pecuniaria da euro 3000 a 18000 euro per ogni lotto di carne non bollato.

11. Chiunque trasporta lotti di molluschi bivalvi vivi senza il documento di accompagnamento di cui al regolamento (CE) n. 853/2004, allegato III, sezione VII, capitolo 1, e' punito con la sanzione amministrativa pecuniaria da euro 1.000 a euro 6.000.

12. Chiunque immette sul mercato molluschi bivalvi vivi senza che gli stessi transitino per un centro di spedizione, fatte salve le disposizioni relative ai pettinidi di cui al regolamento (CE) n. 853/2004 all. III, sez. VII, cap. IX, punto 3, e' punito con la sanzione amministrativa pecuniaria da euro 1.000 a euro 6.000. Alla stessa sanzione sono sottoposti gli operatori che immettono sul mercato molluschi bivalvi vivi, provenienti da zone di produzione della classe B o C senza che gli stessi siano stati sottoposti al previsto periodo di depurazione.

13. Chiunque immette sul mercato molluschi bivalvi vivi, diversi dai pettinidi, provenienti da una zona non classificata dalle autorità competenti, e' punito con la sanzione amministrativa pecuniaria da euro 2.000 a euro 12.000.

14. Chiunque immette sul mercato molluschi bivalvi vivi, provenienti da zone giudicate non idonee o precluse dalle autorità competenti, e' punito con la sanzione amministrativa pecuniaria da euro 5.000 a euro 30.000.

15. Per quanto non previsto dal presente articolo, si applicano le disposizioni di cui alla legge 24 novembre 1981, n. 689, al decreto legislativo 30 dicembre 1999, n. 507, e al decreto del Ministro della sanità in data 11 ottobre 2000, pubblicato nella *Gazzetta Ufficiale* della Repubblica italiana n. 302 del 29 dicembre 2000.

16. Ai fini dell'applicazione del presente articolo, per «operatore del settore alimentare» si intende la persona fisica o giuridica responsabile del rispetto delle disposizioni della legislazione alimentare nell'impresa alimentare posta sotto il suo controllo.

Art. 7.

Disposizioni relative al riconoscimento degli stabilimenti

1. Gli stabilimenti riconosciuti ai sensi della normativa abrogata all'art. 3 si intendono riconosciuti ai sensi del regolamento (CE) n. 853/2004.

2. Gli elenchi degli stabilimenti di cui al comma 1 rimangono pubblicati sul sito informatico del Ministero della salute, aggiornato attraverso il sistema informatico SINTESI STABILIMENTI.

3. Il sistema informatico di cui al comma 2 continuerà ad essere aggiornato dalle regioni e dalle province autonome di Trento e di Bolzano.

Art. 8.
Clausola di invarianza finanziaria

1. Dal presente decreto non devono derivare nuovi o maggiori oneri, ne' minori entrate a carico della finanza pubblica.

2. Le amministrazioni interessate svolgono le attività previste dal presente decreto con le risorse umane, finanziarie e strumentali disponibili a legislazione vigente.

3. Le spese relative alle registrazioni e ai riconoscimenti degli stabilimenti previsti dai regolamenti di cui all'articolo 2 sono a carico delle imprese, secondo tariffe e modalità di versamento da stabilirsi con disposizioni regionali, sulla base del costo effettivo del servizio.

Art. 9.
Clausola di cedevolezza

1 In relazione a quanto disposto dall'articolo 117, quinto comma, della Costituzione e dall'articolo 16, comma 3, della legge 4 febbraio 2005, n. 11, le disposizioni del presente decreto legislativo riguardanti ambiti di competenza legislativa delle regioni e delle province autonome si applicano, nell'esercizio del potere sostituivo dello Stato e con carattere di cedevolezza, a decorrere dalla scadenza del termine stabilito per l'attuazione della direttiva oggetto del presente decreto legislativo, nelle regioni e nelle province autonome nelle quali non sia ancora stata adottata la normativa di attuazione regionale o provinciale e perdono comunque efficacia dalla data di entrata in vigore di quest'ultima, fermi restando i principi fondamentali ai sensi dell'articolo 117, comma terzo, della Costituzione.

Art. 10.
Disposizioni transitorie

1. I contributi dovuti dalle imprese per le ispezioni e i controlli veterinari dei prodotti di cui ai regolamenti dell'articolo 2, ottenuti nel territorio nazionale, sono quelli stabiliti dal regolamento (CE) n. 882/2004.

2. Fino alla data di entrata in vigore delle disposizioni attuative del regolamento (CE) n. 882/2004 si applicano, ove di misura superiore a quelle previste dallo stesso regolamento (CE) n. 882/2004, le disposizioni del decreto legislativo 19 novembre 1998, n. 432, o quelle eventualmente rideterminate con disposizioni regionali, fino a concorrenza della copertura integrale dei costi.

ALLEGATO I
(previsto all'art. 5)

Allegato A» - Parte I
Capo I

Decreto legislativo 27 maggio 2005, n. 117 che stabilisce norme di polizia sanitaria per la produzione, la trasformazione, la distribuzione e l'introduzione di prodotti di origine animale destinati al consumo umano.
Regolamento (CE) n. 853/2004 del Parlamento e del Consiglio del 29 aprile 2004, che stabilisce norme specifiche in materia d'igiene per i prodotti di orgine animale.

Capo II

Decreto legislativo 13 dicembre 1996, n. 674 che stabilisce le condizioni sanitarie e di polizia sanitaria per gli scambi e le importazioni nella Comunità di prodotti non soggetti, per quanto riguarda tali condizioni, alle normative comunitarie specifiche di cui all'allegato *A)*, capitolo I del decreto legislativo 30 gennaio 1993, n. 28 e, per quanto riguarda i patogeni, allo stesso decreto legislativo.
Regolamento CE n. 1774/2002 del Parlamento europeo e del Consiglio del 3 ottobre 2002, recante norme sanitarie relative ai sottoprodotti di origine animale non destinati al consumo umano.

COMMISSION REGULATION (EC) No 628/2008

of 2 July 2008

amending Regulation (EC) No 1898/2006 laying down detailed rules of implementation of Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [1], and in particular Article 16(g) thereof,

Whereas:

(1) Annex V to Commission Regulation (EC) No 1898/2006 [2] sets out the characteristics of the Community symbols that may be used on the label or packaging of products whose name has been registered as a protected geographical indication or protected designation of origin.

(2) Those Community symbols have contributed to the development of protected geographical indications and protected designations of origin and have enabled consumers to identify certain products whose characteristics are linked to their origin.

(3) The symbols relating to protected designations of origin and protected geographical indications are currently identical in terms of shape, colour and design. Only the wording inside the symbols makes it possible to distinguish between them.

(4) In the light of experience gained since they were adopted and with the aim of promoting their use, it should be made easier for consumers to distinguish between protected designations of origin and protected geographical indications. Different colours should therefore be used for the symbols relating to the two different indications.

(5) In order to ensure that changing the colours of the Community symbols does not cause the producers and traders concerned to suffer economic loss, there should be a transitional period during which it will be possible to use Community symbols complying with the provisions applicable prior to the entry into force of this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Protected Geographical Indications and Protected Designations of Origin,

HAS ADOPTED THIS REGULATION:

Article 1

Annex V to Regulation (EC) No 1898/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

However, the packaging or labels including the Community symbols used in accordance with Annex V to Regulation (EC) No 1898/2006, as applicable prior to the entry into force of this Regulation, may be used until 1 May 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 2 July 2008.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

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[1] OJ L 93, 31.3.2006, p. 12. Regulation as last amended by Commission Regulation (EC) No 510/2008 (OJ L 149, 7.6.2008, p. 61).
[2] OJ L 369, 23.12.2006, p. 1.

ANNEX

Points 1, 2 and 3 of Annex V to Regulation (EC) No 1898/2006 are replaced by the following:

'1. COMMUNITY SYMBOLS IN COLOUR OR BLACK AND WHITE

When used in colour, direct colours (Pantone) or four-colour process may be used. The reference colours are indicated below.

Community symbol for "Protected designation of origin" in Pantone

Pantone © 711

Pantone © Yellow 109

Community symbol for "Protected geographical indication" in Pantone

Pantone © Reflex Blue

Pantone © Yellow 109

Community symbols in four-colour process:

Community symbol for "Protected designation of origin" in four-colour process

100 % magenta
80 % yellow

10 % magenta
90 % yellow

Community symbol for "Protected geographical indication" in four-colour process

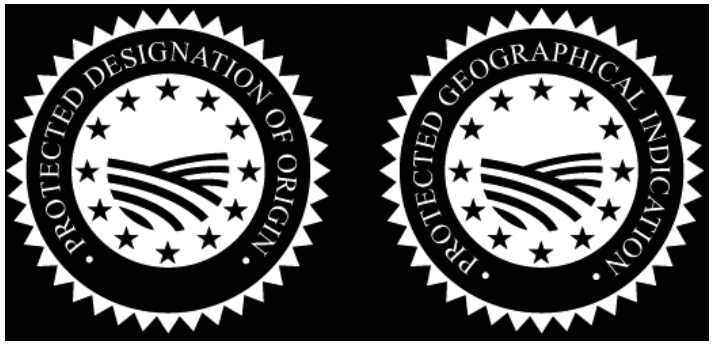
100 % cyan
80 % magenta

10 % magenta
90 % yellow

Community symbols in black and white

2. COMMUNITY SYMBOLS IN NEGATIVE

If the background colour of the packaging or label is dark, the symbols may be used in negative format, using the background colour of the packaging or label.



3. CONTRAST WITH BACKGROUND COLOURS

If a symbol is used in colour on a coloured background which makes it difficult to see, a delimiting outer circle around the symbol should be used to improve contrast with the background colours.

Community symbol for "Protected designation of origin"

Community symbol for "Protected geographical indication"

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