

12 Annex - Food safety, veterinary and phytosanitary policy

**45. RULEBOOK ON SPECIAL HYGIENE REQUIREMENTS
FOR FOOD OF ANIMAL ORIGIN**

Pursuant to the Article 44 paragraph 2 of the Law on Food Safety (Official Gazette of Montenegro 14/07) the Ministry of Agriculture, Forestry and Water Management adopted

THE RULEBOOK ON SPECIAL HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL ORIGIN

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I GENERAL PROVISIONS

Article 1

This Rulebook lays down the specific conditions and methods for meeting the special hygiene requirements for food of animal origin that food business operators (hereinafter referred to as: the business operators) should apply in all phases of production, including transport and distribution for further sale or processing, in compliance with the required general hygiene requirements; animal and public health requirements; animal welfare requirements; animal identification requirements; traceability requirements and animal waste management requirements.

This Rulebook shall also apply to the unprocessed and processed products of animal origin that the composite food contains as well.

Article 2

This Rulebook shall not apply to the following:

- 1) primary production of food for private use in a household;
- 2) preparation, handling or storage of food for private use in a household;
- 3) direct supply, by the producer, of small quantities of primary products of animal origin to the final consumer or to the local retail establishment directly supplying the final consumer;
- 4) direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to the local retail establishment;
- 5) direct supply, by hunters, of small quantities of small wild game directly to the final consumer or to the local retail establishment.

Article 3

For the purpose of this Regulation, the following definitions shall apply:

- 1) **meat** means edible parts of the domestic cleft footed animals, poultry, lagomorphs, wild game and farmed game;
- 2) **domestic cleft footed animals and solipeds** means domestic cattle, buffalos, sheep, goats, pigs and domestic solipeds;
- 3) **poultry** means farmed birds, including birds that are not considered domestic but which are farmed as domestic animals, with the exception of ratites;
- 4) **lagomorphs** means rabbits, hares and rodents;
- 5) **wild game** means: wild cleft footed animals, lagomorphs and other land mammals that are hunted for human consumption and are considered to be wild game under the specific legislation, including mammals living in an enclosed area under conditions of freedom similar to those of wild game, and wild birds that are hunted for human consumption;

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- 6) **farmed game** means farmed ratites and farmed land mammals other than those referred to in point 2 of this Article;
- 7) **small wild game** means wild game birds and lagomorphs living freely in the nature;
- 8) **large wild game** means wild land mammals living freely in the nature, other than those referred to in point 7 of this Article;
- 9) **carcass** means the body of an animal after slaughter and treatment;
- 10) **fresh meat** means meat that has not undergone any processing procedure other than chilling, freezing or quick-freezing, including the meat that is vacuum-wrapped or wrapped under the conditions of a controlled atmosphere;
- 11) **edible by-products** means fresh meat other than that of the carcass, including viscera and blood;
- 12) **viscera** means the organs of the thoracic, abdominal and pelvic cavities, as well as the trachea and oesophagus and, in birds, the crop;
- 13) **minced meat** means boned meat that has been minced into fragments and contains less than 1% salt;
- 14) **mechanically separated meat (MSM)** means the product obtained by separation of meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure;
- 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 not resulting in modification of the muscle fibre structure of the meat and in elimination of the characteristics of fresh meat;
- 16) **meat products** means processed products resulting from meat processing or from further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat;
- 17) **rendered animal fat** means fat derived from rendering fat from meat, including bones, and intended for human consumption;
- 18) **greaves** means the protein-containing residue of rendering, after partial separation of fat and water.
- 19) **gelatine** means natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from animal bones, hides and skins, tendons and sinews;
- 20) **collagen** means the protein-based product derived from animal bones, hides, skins and tendons in accordance with the requirements of this Rulebook;
- 21) **treated stomachs, bladders and intestines** means stomachs, bladders and intestines that have undergone a treatment such as salting, drying or heating after disembowelment and cleaning;
- 22) **slaughterhouse** means an establishment used for slaughtering and treating animals meat of which is intended for human consumption;
- 23) **cutting plant** means an establishment used for boning and/or cutting up meat;
- 24) **game-handling establishment** means an establishment in which game and game meat obtained after hunting are prepared for placing on the market;
- 25) **wholesale establishment** means an establishment for food business that includes several separate units which share common installations and sections where food is sold to the business operators;
- 26) **live bivalve molluscs** (Lamellibranchia class) means filter-feeding molluscs;
- 27) **marine biotoxins** means poisonous substances accumulated by live bivalve molluscs as a result of feeding on toxin-containing plankton;

- 28) **conditioning** means keeping the live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other equipment 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;
- 29) **gatherer** means a company, other legal person, an entrepreneur or a natural person who collects or harvests live bivalve molluscs by any means for the purpose of handling and placing on the market;
- 30) **production area** means a sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or areas used for farming bivalve molluscs, and from which live bivalve molluscs are collected or harvested;
- 31) **relaying area** means a sea, estuarine or lagoon area with boundaries clearly marked by buoys, posts or any other fixed means, used exclusively for the natural purification of live bivalve molluscs;
- 32) **dispatch centre** means any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs intended for human consumption;
- 33) **purification centre** means an establishment equipped with tanks and pools supplied by clean seawater in which live bivalve molluscs are kept until the contamination is reduced so as to make them safe for human consumption;
- 34) **relaying** means the transfer of live bivalve molluscs a relaying area, in which they are kept until the contamination is reduced to make them safe for human consumption, which does not include the specific process of transferring to areas more suitable for further growth or farming;
- 35) **fishery products** means all seawater or freshwater animals (except for live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and mammals, reptiles and frogs) wild or farmed, including all edible forms, parts and products of such animals;
- 36) **factory vessel** means a fishery vessel on board which fishery products undergo one or more operations (filleting, slicing, skinning, shelling mincing or processing) followed by wrapping or packaging and, if necessary, chilling or freezing;
- 37) **freezer vessel** means a fishery vessel on board of which fishery products are frozen, followed by wrapping or packaging, where necessary after preparatory activities (bleeding, de-heading, gutting and removal of fins);
- 38) **mechanically separated fishery product** means a product obtained by removing flesh from fish using mechanical means changing modification of the flesh structure;
- 39) **fresh fishery product** means unprocessed fishery product, whole or prepared, including a product packaged under vacuum or in a controlled atmosphere, that has not undergone any treatment other than chilling;
- 40) **prepared fishery product** means unprocessed fishery product that has undergone a procedure affecting its anatomical wholeness, such as de-heading, gutting, slicing, filleting, and chopping;
- 41) **processed fishery product** means processed product resulting from the processing of fishery products or further processing of such processed fishery products so that the cut surface shows that the product no longer has the characteristics of a fresh fishery product;
- 42) **frogs' legs** means the posterior part of the body of animals of the frog species (*Ranidae*) divided by a transverse cut behind the front limbs, eviscerated and skinned;
- 43) **snails** means terrestrial snails of the species *Helix pomatia* Linné, *Helix aspersa* Muller, *Helix lucorum* and species of the family *Achatinidae*;

- 44) **raw milk** means milk produced by secretion of mammary glands of farmed animals that has not been heated to more than 40°C or undergone any other treatment having an equivalent effect;
- 45) **milk production holding** means an establishment where one or more animals are farmed for production of milk with a view to placing it on the market as food;
- 46) **dairy products** means processed products resulting from processing of raw milk or from further processing of such processed products;
- 47) **eggs** means eggs in shell, other than broken, incubated or cooked eggs, produced by farmed birds and are fit for direct human consumption or for the preparation of egg products;
- 48) **liquid egg** means unprocessed egg contents following removal of the shell;
- 49) **cracked egg** means an egg with damaged shell, but intact membranes;
- 50) **grading and packing establishment** means an establishment where eggs are graded by quality and weight;
- 51) **products of animal origin** means:
- a) food of animal origin, including honey and blood;
 - b) live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods intended for human consumption;
 - c) other animals intended for preparation, for the purpose of being supplied live to the final consumer;
- 52) **tanning** means hardening of hide by tanning plant products, chrome salts or other substances, such as aluminium salts, iron salts, silicon salts, aldehyde, chinons and other synthetic hardeners.

Health and identification marks

Article 4

A business operator may place on the market only a product of animal origin produced and handled in an approved or registered establishment in accordance with the regulation governing the general food requirements, which is:

- 1) a product with a health mark applied in accordance with the regulation governing the method of control of food of animal origin;
- 2) a product marked with an identification mark applied in accordance with the Article 5 of this Rulebook.

The business operator may apply an identification mark to a product of animal origin only if the product has been manufactured in accordance with the provisions of this Rulebook.

The business operator may remove a mark referred to in the paragraph 1 item 1 of this Article only if it cuts, processes or works on it in another manner, in accordance with the regulation governing the method of control of food of animal origin.

Application of the identification mark

Article 5

The business operator referred to in the Article 4 of this Rulebook should ensure that:

- 1) a product of animal origin has an identification mark applied before it is dispatched from the establishment;

2) a product whose wrapping and/or packaging is removed or it is further processed in another establishment, has a new mark applied, which shall indicate the approval number of the establishment where these operations take place;

The identification mark referred to in the paragraph 1 of this Article is not necessary for eggs marked or labelled in accordance with a special regulation.

Form of the identification mark

Article 6

The identification mark referred to in the Article 5 of this Rulebook is of oval shape, it must be legible, clearly displayed, unchangeable and must not be covered by other marks, while its characters must be easily decipherable.

The mark referred to in the paragraph 1 of this Article must indicate the full name of the country in which the establishment is located, or its two-letter code. For an establishment situated in Montenegro, the mark indicating "Montenegro" or "ME" shall be applied.

The mark referred to in the paragraph 1 must indicate the approval number of the establishment, issued by the competent authority.

Marking method

Article 7

Depending on the method of presentation of different products of animal origin, the mark referred to in the Article 5 of this Rulebook may be applied directly to the product, the wrapping or the packaging, be printed on a label affixed to the product, the wrapping or the packaging, and may also be in the form of an irremovable tag made of a resistant material.

In case the wrapping contains cut meat or edible by-products, 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. Where wrapping provides the same protection as packaging, the mark may be applied to the wrapping.

Where products of animal origin are placed in transport containers or large packages for the purpose of further handling, processing, wrapping or packaging in another establishment, the mark may be applied to the external surface of the container or package.

Where products of animal origin are placed in a package intended for supply to the final consumer, it is sufficient to apply the mark to the exterior of that package only.

Where the mark is applied directly to products of animal origin, only the dyes approved in accordance with the regulation governing the use of dyes in food shall be used.

In case liquid, granulated or powdered products of animal origin, including fishery products, are transported in bulk, identification mark is not necessary if the accompanying documentation contains the information specified in Article 6 paragraphs 2, 3 of this Rulebook.

Objectives of procedures based on HACCP system principles

Article 8

The business operator, in establishments where slaughtering of animals is performed (hereinafter referred to as: the slaughterhouse), shall ensure implementation of the procedures put in place in accordance with the Article 5 of the Rulebook on general hygiene requirements for food of animal and plant origin, that the hazard analysis shows to be necessary and the specific requirements listed in paragraph 2 of this Article.

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The specific procedures referred to in the paragraph 1 of this Article include measures ensuring that each animal or, where appropriate, each animal consignment accepted into the slaughterhouse:

- 1) is properly identified;
- 2) is accompanied by the required relevant information on the holding that the animal originates from;
- 3) does not come from a holding or an area for which a movement prohibition or other restriction for reasons of animal or public health has been ordered;
- 4) is clean;
- 5) is healthy, as far as the business operator can judge; and
- 6) is in a satisfactory condition from the animal welfare viewpoint on arrival at the slaughterhouse.

In the event of failure to comply with any of the requirements listed under paragraph 2 of this Article, the business operator shall without delay notify the official veterinarian and take appropriate measures.

Food chain information

Article 9

Prior to accepting the animal into a slaughterhouse, the business operator shall request, receive and check the food chain information for all animals, other than wild game, dispatched or intended to be dispatched to the slaughterhouse.

The business operator may accept to the slaughterhouse premises only animals for which it received appropriate food safety information from the records kept at the holding of origin of the animals concerned, in accordance with the regulation governing the general hygiene requirements for food of animal and plant origin in primary production.

The business operator must be provided with the information referred to in the paragraph 2 of this Article no later than 24 hours before the animals arrive to the slaughterhouse.

The food safety information referred to in paragraph 2 of this Article cover, in particular:

- 1) the status of the holding of origin or the area status in terms of animal health;
- 2) the animals health condition;
- 3) veterinary medicinal products administered to the animals or other treatments the animals have been subjected to within a certain period and with a withdrawal period greater than zero, together with their dates of administration of the medicinal products, or treatments, and withdrawal periods;
- 4) the occurrence of diseases that may affect the safety of meat;
- 5) the results, if relevant to the protection of human and animal health, of all analysis carried out on samples taken from the animals or other samples taken to diagnose diseases that may affect the safety of meat, including the samples taken in the framework of the monitoring and control of zoonoses and residues;
- 6) information from the reports on previous ante- and post-mortem examinations of animals from the same holding of origin including, in particular, the reports from the veterinary inspector;
- 7) information on production of relevance for estimating the presence of a disease; and
- 8) the name and address of the veterinarian responsible for treatment of animals at the holding of origin.

Notwithstanding the paragraph 4 of this Article, the business operator need not be provided with the information referred to in the paragraph 4 item 1, 2. 6 and 7 of this Article if the operator is already aware of this information through a contract on continuous supply or other business arrangement, or if the animal owner gives a statement that there is no information that must be reported from the viewpoint of food safety.

The information referred to in the paragraph 4 of this Article may be supplied in the form of an extract from the records of the holding of origin, through electronic data exchange or in the form of a declaration signed by the animal owner.

The business operator that, after evaluating the relevant food chain information, decides to accept animals into the slaughterhouse shall, without delay make them available to the veterinary inspector. The business operator shall notify the veterinary inspector of any information that gives rise to suspicious regarding the health of an animal before ante-mortem examination.

In case an animal arrives to the slaughterhouse without food chain information, the operator shall without delay notify the veterinary inspector and slaughter of the animal must not take place until the veterinary inspectors approves of it.

Supply of information within the period of less than 24 hours

Article 10

Notwithstanding the Article 9 paragraph 3 of this Rulebook, the food chain information may, with previous approval from the competent authority, accompany the animals to which it relates to the slaughterhouse, in the following cases:

- 1) pigs, poultry or farmed game that have undergone ante-mortem examination at the holding of origin, provided that the consignment is accompanying by a certificate from the veterinarian stating that, following the examination, he found the animals healthy;
- 2) domestic solipeds;
- 3) animals that have undergone emergency slaughter, provided that they are accompanied by a certificate signed by the veterinarian recording the favourable result of the ante-mortem examination;
- 4) animals that are not delivered to the slaughterhouse directly from the holding of origin.

The business operator shall consider the relevant information and in case he accepts the animals for slaughter, he must give the documents mentioned in paragraph 1 items 1 and 3 of this Article to the veterinary inspector.

The animals must not be slaughtered or treated prior to the approval from the veterinary inspector.

The business operator must check the required documents accompanying the domestic solipeds to ensure that the animal is intended for slaughter and its meat intended for human consumption. In case the animal is accepted for slaughter, he must give the documents to the veterinary inspector.

II SPECIFIC REQUIREMENTS FOR MEAT OF DOMESTIC CLEFT FOOTED ANIMALS AND SOLIPEDES

Transport of live animals to the slaughterhouse

Article 11

The business operator transporting live animals (cleft footed animals and solipeds) to slaughterhouses shall:

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- 1) during collection and transport, ensure that the animals are handled carefully in order to avoid unnecessary distress;
- 2) transport the animals showing symptoms of disease or originating from herds known to be contaminated with agents that pose risk to human and animal health to the slaughterhouse only with approval from competent authority.

Requirements for premises or areas for accepting domestic cleft footed animals and solipeds into the slaughterhouse

Article 12

The business operator may carry out the slaughtering of domestic cleft footed animals and solipeds in a slaughterhouse that has the following:

- 1) adequate and hygienic premises for reception and lairage facilities for animals for slaughter or, if the climate permits so, pens for keeping animals before slaughter that are easy to clean and disinfect, with equipment for watering animals and, if necessary, for feeding them, and with the wastewater drainage that must not be a source of contamination.
- 2) separate lockable premises or, if the climate permits so, pens for sick or suspect animals with separate wastewater draining system sited in such a way as to prevent contamination of other animals, unless, during the approval procedure, the competent authority considers that such facilities are not necessary.
- 3) the reception and lairage premises for keeping animals before slaughter size of which ensures protection of animal welfare and constructed so as to facilitate ante-mortem examination, including the identification of the animals or a group of animals.

Requirements for minimum of premises in order to prevent contamination of meat of domestic cleft footed animals and solipeds

Article 13

In order to prevent contamination of meat, the slaughterhouses for slaughter of domestic cleft footed animals and solipeds must:

- 1) have a sufficient number of rooms, appropriate to the operations carried out in them;
- 2) have a separate room for the emptying and cleaning of stomachs and intestines, unless, in the process of approval of the establishment, the competent authority approves of the separation in time of these operations within a slaughterhouse;
- 3) ensure separation in space or time of the following operations:
 - a. stunning and bleeding;
 - b. for slaughter of pigs, scalding, shaving, scraping and singeing;
 - c. evisceration and further treatment;
 - d. handling clean stomachs and intestines;
 - e. preparation and cleaning of other edible by-products, particularly the handling of skinned heads if it does not take place at the slaughter line;
 - f. packaging of edible offal;
 - g. dispatching meat;
- 4) have equipment that prevents contact of meat with the floors, walls, fixtures and constructions and the slaughter line, designed so as to allow, when used, the constant progress of the slaughter process, prevent cross-contamination of different parts of the slaughter line and where more than one slaughter line is operated in the same room, they have to be separately so as to prevent cross-contamination.

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The slaughterhouses must have equipment for washing, cleaning and disinfection of utensils with hot water supplied at not less than 82°C, or another system with the equivalent effect.

The hand-washing facility used by the staff handling unpackaged meat must have taps designed so to prevent the contamination.

The slaughterhouses must have separate lockable rooms, area or equipment with the temperature regime of maintenance, for storage of detained meat, as well as for the meat declared unfit for human consumption.

The slaughterhouse must have a separate area with appropriate equipment for cleaning, washing and disinfection of means of transport for animals.

In case that, during the approval process, the competent authority concludes that the premises and equipment referred to in the paragraph 5 of this Article are not necessary because the business operator concluded a contract on washing, cleaning and disinfection of transport vehicles with a business operator managing the approved establishment in the close vicinity of the slaughterhouse, such premises are not necessary.

The slaughterhouse must have a separate lockable area with equipment reserved for the slaughter of sick and suspect animals, unless the slaughter of these animals takes place in another slaughterhouse approved by the competent authority as a sanitary slaughterhouse or if the slaughter of these animals takes place at the end of the normal slaughter period, with previous approval from the competent authority.

Where content of the digestive tract and manure is stored in the slaughterhouse, there must be a separate area or place for that purpose.

The slaughterhouses must have a separate and equipped room for the use of the veterinary inspectorate.

Hygiene in the process of slaughter of cleft footed animals and solipeds

Article 14

The business operator may slaughter domestic cleft footed animals and solipeds only if it ensures the following:

- 1) that after arrival to the slaughterhouse, the slaughter of the animals is not unduly delayed, unless animals need to be given a resting period before slaughter for animal welfare reasons;
- 2) that only live animals intended for slaughter are delivered to the slaughterhouse with the exception of animals slaughtered outside the slaughterhouse in accordance with the Article 17 of this Rulebook, farmed wild game slaughtered at the place of production in accordance with the Article 30 of this Rulebook and wild game in accordance with the Article 31 of this Rulebook;
- 3) meat from an animal injured as a result of an accident and slaughtered in the slaughterhouse may be placed on the market if the examination finds only the injuries resulting from the accident;
- 4) that only meat of animals slaughtered in the slaughterhouse may be placed on the market.

The animals or consignments of animals sent to the slaughterhouse must be clean and identified so that their origin can be determined.

The business operator referred to in the paragraph 1 of this Article shall provide appropriate conditions for examination of animals before slaughter (ante-mortem examination) in accordance with the regulation governing the control of food of animal origin,

In order to prevent contamination of meat, stunning, bleeding, skinning, evisceration and other dressing procedures must be carried out without undue delay and in the following manner:

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- 1) the trachea and oesophagus must remain intact during bleeding, except in case of slaughter according to religious customs;
- 2) during the skinning the contact between the outside of the skin and the carcass must be prevented while the operators and equipment coming into contact with the outer surface of hide and skin fleece must not touch the meat;
- 3) spillage of digestive tract content during and after evisceration must be prevented and it must be ensured that evisceration is completed as soon as possible, without delay;
- 4) contact of carcass with milk or colostrum during the removal of the udder must be prevented.

The skin of animals slaughtered must be completely taken off the carcass and other parts of the body intended for human consumption, except for pigs, heads of goats and calves, muzzles and labia of cattle, as well as cattle, sheep and goat legs, which must be handled so as to avoid contamination of other meat.

Where pigs are not skinned, the bristles must be removed without delay, minimizing the risk from contamination of the meat with scalding water. Only approved additives may be used for the procedure of bristle removal, after which the pigs must be thoroughly rinsed with potable water.

The carcasses must not be contaminated with faecal matters. Any visible contaminated part must be removed without delay by cutting of or some other manner having an equivalent effect.

Carcases and edible by-products must not come into contact with floors and walls.

Post mortem examination

Article 15

The business operator engaged in slaughtering shall provide appropriate conditions for examination of animals after slaughter (post-mortem examination) in accordance with the regulation governing the control of food of animal origin.

Until completion of the post-mortem examination, the parts of the animal slaughtered must be:

- 1) marked so as that their belonging to the given carcass is visible;
- 2) separated from other carcasses, viscera and edible by-products, including those that have already undergone post-mortem examination.

In case there are no pathological changes, the genitals shall be removed immediately.

Kidneys are separated from the fatty tissue they are covered with, while peri-renal cover (capsule) must be removed in cattle, pigs and solipeds.

If blood or other edible by-products are collected from several animals into the same container before completion of post-mortem examination, the entire content of the container shall be declared unfit for human consumption where the carcass of one of these animals has been declared unfit for human consumption.

Procedure following the post-mortem examination:

Article 16

Following the post-mortem examination:

- 1) tonsils of cattle, pigs and solipeds must be removed hygienically;
- 2) parts unfit for human consumption must be removed immediately from the clean part of the establishment;

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- 3) meat detained or meat declared unfit for human consumption and inedible by-products must be kept separately in order to prevent their contact with meat declared fit for human consumption;
- 4) viscera or parts of viscera remaining in the carcass, except the kidneys, must be removed entirely and immediately, unless the competent authority approves of not removing them.

Following the completion of post-mortem examination, the meat must be stored in accordance with the requirements laid down in Article 20 of this Rulebook.

For further dressing or processing:

- 1) stomachs must be scalded and cleaned;
- 2) intestines must be emptied and cleaned;
- 3) heads and feet must be skinned or scalded and the hair and bristles removed.

Where the establishment is approved for slaughter of different animal species or for handling of carcasses of wild and farmed game, the measures of separation in time or in space of operations carried out on different species must be undertaken in order to prevent cross-contamination.

Separate rooms or areas must be provided for reception and storage of unskinned carcasses of wild and farmed game.

Where the slaughterhouse does not have lockable rooms, areas and equipment dedicated exclusively to slaughter of sick or suspect animals, the rooms, areas and equipment used for slaughter of such animals must be cleaned, washed and disinfected under supervision of a veterinary inspector before the slaughter of other animals begins.

Emergency slaughter of cleft footed animals and solipeds outside the slaughterhouse

Article 17

The business operator engaged in slaughter may place on the market the meat from domestic cleft footed animals and solipeds that have undergone emergency slaughter outside the slaughterhouse only if:

- 1) an animal, injured as a result of an accident that prevented its transport to the slaughterhouse for the purpose of protecting its welfare, is healthy and no deviations in terms of health have been noted with the exception of those resulting from the accident;
- 2) a veterinarian carried out an ante-mortem examination of the animal and issued a certificate on a satisfactory, or where appropriate, regular findings of ante mortem examination, including the date, time and the reason for the emergency slaughter and all treatments administered to the animal concerned;
- 3) the animal slaughtered and bled has been transported to the slaughterhouse hygienically and without undue delay, and viscera may be removed on the spot under the supervision of the veterinary inspector, which are then to be delivered to the slaughterhouse so that their belonging to the carcass concerned is visible;
- 4) where more than two hours are necessary between slaughter and arrival at the slaughterhouse, the animal is actively chilled, unless climatic conditions ensure adequate chilling.
- 5) the animal slaughtered is accompanied by a declaration of the business operator who reared the animal, stating its identity, veterinary medicinal products administered to the animal or other treatments, as well as the dates of administration and withdrawal periods;
- 6) the meat is declared fit for human consumption based on the post-mortem examination in the slaughterhouse.

The business operator referred to in the paragraph 1 of this Article must follow the instructions on use of meat that are issued by the veterinary inspector after the post-mortem examination.

The business operator referred to in the paragraph 1 of this Article may place on the market only the meat of animals that underwent emergency slaughter which has a special health mark which in accordance with the regulation governing the control of food of animal origin or, where appropriate, an identification mark in accordance with the Articles 5, 6 and 7 of this Rulebook.

The meat of animals that underwent emergency slaughter may be placed only on the domestic market.

Requirements for cutting plants for meat of cleft footed animals and solipeds

Article 18

The business operator may engage in cutting meat of cleft footed animals and solipeds only in establishments:

- 1) constructed so as to avoid contamination of meat by allowing constant progress of the operations or by separation of different production batches, lots or lines;
- 2) that have rooms for separate storage of packaged and unpackaged meat, unless stored at different times or in a way ensuring that the packaging material and the manner of storage cannot be a source of contamination for the meat;
- 3) have cutting rooms with equipment that ensures cutting of meat in the manner as laid down in Article 19 of this Rulebook;
- 4) have hand washing facility for use by staff handling unpackaged meat with taps that prevent contamination;
- 5) have facilities for washing, cleaning and disinfection of utensils, supplied with hot water of at least 82°C, or other appropriate system having an equivalent effect.

Hygiene during meat cutting and boning

Article 19

The business operator may carry out the meat cutting and boning only in the following manner:

- 1) carcasses of domestic cleft footed animals and solipeds may be cut in slaughterhouses only into half-carcasses or quarters, and half carcasses into no more than three pieces, while further cutting and boning may be carried out only in a cutting plant;
- 2) meat dressing is to be organised in such a way as to prevent or minimise contamination, so that:
 - a. meat intended for cutting is delivered into the rooms for dressing gradually and as needed;
 - b. during cutting, boning, slicing or in other dressing phases, wrapping and packaging the meat temperature is maintained at not more than 3°C for edible by-products and 7°C for other meat, by keeping the ambient temperature at no more than 12°C, or by some other appropriate system having an equivalent effect;
 - c. in the establishment where meat of different animal species is cut, the measures of precaution are to be taken to prevent cross-contamination by separation in time or in space of the operations on different animal species.

Notwithstanding the paragraph 1 item 2 sub-item b) of this Article, meat may be cut and boned before the temperatures said are achieved, in accordance with the Article 20, paragraph 1, item 1 of this Rulebook.

Meat may also be cut and boned prior to achieving the temperature referred to in the paragraph 1 item 2, sub-item b) of this Article where the cutting plant is on the same site as the slaughterhouse. In that case, the meat may be delivered directly from the slaughterhouse or after

chilling in the chilling or refrigerating room. Immediately after cutting and, where necessary, packaging, the meat must be chilled and maintained at the temperature referred to in the paragraph 1 item 2 sub-item b) of this Article.

Temperature requirements for storage and transport of meat of cleft footed animals and solipeds

Article 20

The business operator may engage in storage and transport of meat of domestic cleft footed animals and solipeds only if the following requirements are met:

- 1) after the post-mortem examination, the meat in the slaughterhouse must be chilled so as to ensure a temperature not more than 3°C in all parts of the meat for edible by-products and 7°C for other meat, but meat may be cut and boned during chilling in accordance with the Article 19 paragraph 3 of this Rulebook with adequate ventilation in order to prevent condensation on the meat surface;
- 2) meat must be chilled and achieve the temperature referred to in item 1 of this paragraph and maintained at the temperature during storage;
- 3) meat must be chilled and achieve the temperature referred to in item 1 of this paragraph before transport and maintained at the temperature during transport.

Notwithstanding the paragraph 1 item 3 of this Article, for production of specific products, transport may take place with previous approval from the competent authority, provided that:

- 1) it takes place in accordance with the requirements set by the competent authority with respect to the transport from one establishment to another;
- 2) the meat immediately leaves the slaughterhouse, or a cutting and boning plant on the same site as the slaughterhouse, and transport takes no more than two hours.

Meat intended for freezing must be frozen without undue delay following the stabilization period, where necessary.

Unpackaged meat must be stored and transported separately from packaged meat, unless storage and transport take place at different times or in such a way that the packaging material and the manner of storage cannot be a source of meat contamination.

III: SPECIAL REQUIREMENTS FOR POULTRY AND LAGOMORPH MEAT

Requirements for transport of live animals to the slaughterhouse

Article 21

The business operator engaged in transport of live animals (poultry and lagomorphs) to slaughterhouse shall:

- 1) during collection and transport of animals, ensure careful handling of animals in order to avoid unnecessary distress;
- 2) animals showing symptoms of disease or originating from flocks known to be contaminated with agents that pose risk to human and animal health are transported to the slaughterhouse only with previous approval from the competent authority;
- 3) ensures that crates in which animals are delivered to the slaughterhouse are made of corrosion-resistant material, easy to clean and disinfect.

Immediately after emptying, before it is used again, all equipment used for collecting and delivery of live animals must be cleaned, washed and disinfected.

Requirements for premises or areas for reception of poultry and lagomorphs

Article 22

The business operator may engaged in slaughter of poultry, hares and rabbits only in a slaughterhouse that:

- 1) has appropriate and hygiene premises for the reception of animals and examination before slaughter;
- 2) a room for reception and temporary accommodation of animals before slaughter which, by its size, ensures protection of animal welfare and constructed in the way that facilitates ante-mortem examination, including the identification of animals or a group of animals.

Minimum number of rooms in order to prevent contamination of meat of poultry and lagomorphs

Article 23

In order to avoid contamination of meat, the slaughterhouses for poultry and lagomorphs must have:

- 1) a sufficient number of rooms, appropriate for the operations carried out in them;
- 2) a separate room for emptying and cleaning of stomachs and intestines and further dressing, including the addition of seasonings to whole poultry carcasses, unless the competent authority, in the approval procedure, authorises separation in time of these operations;
- 3) ensure separation in space or time of the following operations:
 - a. stunning and bleeding;
 - b. plucking, skinning or scalding;
 - c. dispatching meat;
- 4) equipment that prevents contact of the meat and the floors, walls, fixtures and constructions and slaughter lines that are designed so as to allow, when operated, a constant progress of the slaughter process, prevent cross-contamination of different parts of the slaughter line and where more than one slaughter line is operated in the same room, they must be separated so as to prevent cross-contamination.

The slaughterhouses must have equipment for washing, cleaning and disinfection of utensils and tools supplied with hot water of not less than 82°C, or other appropriate system having an equivalent effect.

The hand washing facility used by the staff handling unpackaged meat must have taps designed so as to prevent the contamination.

The slaughterhouses must have separate lockable rooms, area or equipment with the temperature regime of maintenance, for storage of detained meat, as well as for the meat declared unfit for human consumption.

The slaughterhouse must have a separate area with appropriate equipment for cleaning, washing and disinfection of equipment in which the animals are transported (crates) and means for transport of animals.

In case that, during the approval process, the competent authority concludes that the premises and equipment referred to in the paragraph 5 of this Article are not necessary because the business operator concluded a contract on washing, cleaning and disinfection of means of transport with a business operator managing the approved establishment in the close vicinity of the slaughterhouse, such premises are not necessary.

The slaughterhouses must have a separate and equipped room for the use of the veterinary inspectorate.

Hygiene in the process of slaughter of poultry and lagomorphs

Article 24

The business operator may carry out the slaughter of poultry, hares and rabbits only if it ensures the following:

- 1) that following the delivery to the slaughterhouse the slaughter of animals is not unduly delayed;
- 2) that only meat of animals slaughtered in the slaughterhouse is placed on the market;
- 3) that only live animals intended for slaughter are brought to the slaughterhouse, with the exception of:
 - a. delayed eviscerated poultry, geese and ducks reared for the production of "foie gras" and birds that are not considered domestic but which are farmed as domestic animals on a holding, if slaughtered on the holding in accordance with the Article 26 of this Rulebook;
 - b. farmed game slaughtered at the place of production in accordance with the Article 30 of this Rulebook;
 - c. small wild game hunted in accordance with the Article 33 of this Rulebook.

The business operator referred to in the paragraph 1 of this Article shall provide appropriate conditions for examination of animals before slaughter (ante-mortem examination) in accordance with the regulation governing the control of food of animal origin.

In order to prevent contamination of meat, stunning, bleeding, plucking, skinning or scalding, evisceration and other dressing operations shall be carried out without undue delay, undertaking the measures to prevent the spillage of digestive tract contents during and after evisceration.

The business operator engaged in slaughter shall ensure adequate conditions for examination of animals after the slaughter (post-mortem examination) in accordance with the regulation governing the control of food of animal origin.

Where the establishment is approved for the slaughter of different animal species or for dressing of carcasses of farmed ratites slaughtered on the holding and small farmed wild game, as a measure of precaution the separation either in time or in space of the operations carried out on the different species must be taken in order to prevent cross contamination. In slaughterhouses referred to in the paragraph 1 of this Article, separate rooms or areas for reception and storage of carcasses of farmed ratites slaughtered on the holding and small farmed wild game must be provided.

Procedure after post-mortem examination

Article 25

Following the post-mortem examination:

- 1) parts unfit for human consumption must be removed immediately from the clean part of the establishment;
- 2) meat detained or meat declared unfit for human consumption and inedible by-products must be kept separately in order to prevent their contact with the meat declared fit for human consumption;
- 3) viscera or parts of viscera remaining in the carcass, except for the kidneys, must be removed entirely and immediately, unless otherwise authorised by the competent authority.

Following the inspection and evisceration, animals slaughtered must be cleaned without delay and chilled at the temperature of not more than 4°C, unless the meat is cut while it is still warm.

When carcasses are chilled by immersion in water, the following must be done:

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- 1) all measures of precaution must be taken in order to prevent contamination of carcasses, taking into account parameters such as: carcass weight, water temperature, volume and direction of water flow and chilling time, and
- 2) equipment or pools, as appropriate, must be entirely emptied, cleaned and disinfected at least once a day, but several times when necessary.

Sick or suspect animals slaughtered under disease eradication or control program must not be slaughtered in the establishment, except with previous approval from the competent authority.

In cases referred to in the paragraph 3 of this Article, slaughter may be performed only under the supervision of a veterinary inspector and all measures of precaution to prevent contamination must be taken, while the rooms, areas and equipment used for slaughter of such animals must be cleaned, washed and disinfected under the supervision of a veterinary inspector before commencing slaughter of other animals.

Slaughter on the holding

Article 26

The business operator may slaughter delayed eviscerated poultry, geese and ducks reared for the production of "foie gras" and birds that are not considered domestic but which are farmed as domestic animals on a holding, only with previous approval from the competent authority and under the following conditions:

- 1) that the farm has undergone regular veterinary controls;
- 2) that the business operator has informed the competent authority in advance of the place, date and time of slaughter;
- 3) that the holding has adequate premises for collecting the birds for ante-mortem examination of poultry;
- 4) that the holding has premises suitable for hygienic slaughter and further handling of the poultry;
- 5) that animal welfare requirements are complied with;
- 6) that the slaughtered poultry is accompanied to the slaughterhouse by a written declaration from the business operator who reared the poultry indicating any veterinary medicinal products administered to the animal, dates of administration of the treatment and withdrawal periods, information on nutrition, the place, date and time of slaughter;
- 7) that the slaughtered poultry is accompanied to the slaughterhouse by written documentation issued by a veterinary inspector;
- 8) that evisceration is carried out within 24 hours from the moment of slaughter under the supervision of a veterinary inspector and that the eviscerated poultry is, without delay, chilled and transported to the slaughterhouse or the cutting plant.

The delayed eviscerated poultry slaughtered on the holding of production may be kept for up to 15 days at a temperature of not more than 4°C. The evisceration must be carried out in a slaughterhouse or in a cutting plant.

Requirements for cutting plants for meat of poultry and lagomorphs

Article 27

The business operator may engage in cutting of meat of poultry and lagomorphs only in establishments that:

- 1) are constructed so as to avoid contamination of meat, in particular by allowing a continuous progress of the operations or by separation of the different production batches, lots or lines;

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- 2) have rooms for separate storage of packaged and unpackaged meat, unless stored at different times or in a way that ensures that the packaging material and the manner of storage cannot be a source of contamination for the meat;
- 3) have cutting rooms with equipment that ensures compliance with the requirements for meat cutting laid down by the Article 28 of this Rulebook;
- 4) have equipment for washing, cleaning and disinfection of tools with hot water supplied at not less than 82°C, or an alternative system having an equivalent effect;
- 5) have hand-washing facility used by staff handling unpackaged meat with taps designed so as to prevent the contamination.

Where a plant for cutting the meat of poultry, hares and rabbits also eviscerates geese and ducks reared for the production of "foie gras", which have been stunned, bled and plucked on the holding of production, or the evisceration of delayed eviscerated poultry, the business operator shall ensure that separate rooms are available for that purpose.

Hygiene during and after cutting and boning

Article 28

The business operator may engage in cutting and boning of meat of poultry and lagomorphs only in the following manner:

- 1) to organize the work on meat in such a way as to prevent or minimise contamination, so that:
 - a. the meat intended for cutting is delivered into the workrooms progressively and as needed;
 - b. during cutting, boning, slicing or in other dressing phases, wrapping and packaging the meat temperature is maintained at not more than 4°C by means of maintaining the ambient temperature at not more than 12°C or by some other appropriate system having an equivalent effect;
 - c. in the cutting plant where cutting of meat of different animal species takes place, the measures of precaution are taken to prevent cross-contamination, by separation in space or time of the operations on the different species.

Meat may be cut and boned prior to reaching the temperature referred to in the paragraph 1 item 1 sub-item b) of this Article where the cutting plant is on the same site as the slaughterhouse. In that case, the meat may be delivered directly from the slaughterhouse or after chilling in a chilling or refrigerating room.

Following the cutting, and where appropriate, packaging, the meat must be chilled to the temperature referred to in paragraph 1 item 1 sub-item b) of this Article.

Unpackaged meat must be stored and transported separately from the packaged meat, unless storage and transport take place at different times or in such a way that the packaging material and the manner of storage cannot be a source of meat contamination.

Water-binding substances

Article 29

The business operator shall ensure that meat treated by substances facilitating the binding of water is not placed on the market as fresh meat, but as a meat product or meat preparations, or that it is used for production of meat products or meat preparations.

IV SPECIAL REQUIREMENTS FOR MEAT OF FARMED GAME

Article 30

Production and placing on the market of meat of farmed wild game (*Cervidae* and *suidae*), shall be done in accordance with Articles 11, 12, 13, 14, 15, 16, 17, 18, 19 and 20 of this Rulebook, unless otherwise decided by the competent authority in the process of issuing approval.

Production and placing on the market of meat from ratites shall be done in accordance with Articles 21, 22, 23, 24, 25, 26, 27 and 28 of this Rulebook in appropriate premises adapted to the size of the animals.

Where the competent authority finds it appropriate in the process of issuing the approval for production and placing on the market of meat referred to in the paragraph 2 of this Article, it may also order application of provisions of Articles 11, 12, 13, 14, 15, 16, 17, 18, 18 and 20 of this Rulebook.

Notwithstanding paragraphs 1 and 2 of this Article, the business operator may, with previous approval from the competent authority, slaughter farmed domestic cleft footed animals and solipeds or farmed ratites at the place of origin in case:

- 1) transit of animals could pose the risk to the handler or would risk the welfare of the animals;
- 2) the herd undergoes regular veterinary examinations;
- 3) the owner of the animals submits a request for slaughter;
- 4) the competent authority has been informed in advance of the place, date and time of slaughter of the animals;
- 5) the holding has the procedures in place for collecting the animals to allow ante-mortem examination of the group of animals;
- 6) the holding has adequate premises and equipment for slaughter and bleeding and, where ratites must be plucked, the plucking equipment as well;
- 7) animal welfare requirements are complied with;
- 8) slaughtered and bled animals are transported to the slaughterhouse hygienically and without delay and in case transport takes more than two hours, the animals are, if necessary, kept in refrigeration facilities, while evisceration may take place on the spot, under the supervision of a veterinarian;
- 9) animal slaughter is accompanied to the slaughterhouse by a written declaration of the business operator who reared the animals, stating its identity, information on feed, veterinary medicinal products administered to the animal or other treatments, dates of administration and withdrawal periods;
- 10) a veterinarian carried out ante-mortem examination of animals and issued a certificate on a favourable or regular result of the ante-mortem examination, with the date, time and reason for the emergency slaughter and treatments that the veterinarian administered to the animal.

Notwithstanding the paragraph 4 of this Article, the business operator may carry out slaughter of bison on the holding, with previous approval from the competent authority.

V SPECIAL REQUIREMENTS FOR WILD GAME MEAT

Training of hunters on wild game health and hygiene

Article 31

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, in order to be able to undertake an initial examination of wild game on the spot.

Where a team was formed for hunting purposes, at least one person from it should have the knowledge referred to in paragraph 1 of this Article (hereinafter referred to as; the trained person).

The trained person is considered to be the gamekeeper or the hunting grounds' manager if he/she is part of the hunting team or is located in the immediate vicinity of the hunting place, who undertook the initial examination of the wild game hunted and who was informed of any potential abnormal behaviour of the wild game observed before killing.

The trained person referred to in paragraphs 1, 2 and 3 of this Article, in lien with the training curriculum set by a relevant regulation, should also have basic knowledge on the following:

- 1) anatomy, physiology and behaviour of wild game;
- 2) pathological changes in wild game caused by diseases, environmental contamination or other factors that may affect human health after consumption of the meat of such wild game;
- 3) the hygiene rules and proper handling, evisceration, transportation and other procedures of wild game after killing;
- 4) legislation on animal and public health and hygiene requirements governing the placing on the market of wild game.

Handling large wild game

Article 32

After killing, stomachs and intestines of large wild game must be removed without delay and if necessary, be bled.

The trained person must carry out examination of the body and of any viscera removed as soon as possible after killing in order to identify any signs that may indicate that the meat presents a human health risk.

The meat of large wild game may be placed on the market only if the body of the animal killed is transported to a game-handling establishment as soon as possible after the examination. The viscera must accompany the body and must be identified in order to establish the belonging to a given body.

If no signs of disease are found during the examination referred to in paragraph 2, no abnormal behaviour was observed before killing, and there is no suspicion of environmental contamination, the trained person must attach with the animal body a declaration stating the date, time and place of killing. In this case, the head and the viscera need not be send together with the body, except for species susceptible to Trichinosis (porcine animals, solipeds and others), whose head (except for tusks) and diaphragm must be sent together with the body. The hunters must comply with any other additional requirements imposed.

In case a disease is suspected, the head (except for tusks, antlers and horns) and all the viscera except for the stomach and intestines must be sent together with the body. The trained person who carried out the examination must inform the competent authority of the any signs of disease, abnormal behaviour or suspicion of environmental contamination that prevented him/her from making a declaration in accordance with the paragraph 4 of this Article.

If in a particular case there is no trained person available to carry out the examination referred to in paragraph 2 of this Article, the head (except for tusks, antlers and horns) and all the viscera, except for the stomach and the intestines, must be sent together with the body.

Chilling wild game meat must begin as soon as possible after killing so as to achieve a temperature throughout the meat of not more than 7°C, unless the climatic conditions permit appropriate natural chilling.

During transport to the game-handling establishment, heaping of wild game must be avoided.

Large wild game delivered to a game-handling establishment must be presented to the veterinary inspector for examination.

Unskinned large wild game may be skinned and placed on the market as such if:

- 1) before skinning, the wild game is stored and handled separately from other food;
- 2) the wild game was not frozen;
- 3) after skinning, an examination is undertaken in accordance with the regulation governing the control of food of animal origin.

Cutting and boning of large wild game meat is done in accordance with the Article 19 of this Rulebook.

Handling small wild game

Article 33

The trained person must carry out examination of wild game as soon as possible after killing in order to identify any signs that may indicate that the meat presents a human health risk.

In case the signs of disease are found during the examination, abnormal behaviour was observed, or environmental contamination is suspected, the trained person must inform the veterinary inspectorate without delay.

Meat of small wild game may be placed on the market only if the body has been transported to a game-handling establishment without delay, after the examination referred to in point 1 of this Article.

Chilling of wild game meat must begin as soon as possible after killing so as to achieve a temperature throughout the meat of not more than 4°C, unless the climatic conditions provide appropriate natural chilling.

Evisceration must be carried out without delay upon arrival at the game-handling establishment.

Small wild game delivered to a game-handling establishment must be presented to the veterinary inspector for examination.

Cutting and boning of small wild game meat is done in accordance with the Article 19 of this Rulebook.

VI SPECIAL REQUIREMENTS FOR MINCED MEAT, MEAT PREPARATIONS AND MECHANICALLY SEPARATED MEAT

Requirements for production establishments

Article 34

The business operator may produce minced meat, meat preparations or mechanically separated meat (hereinafter referred to as: MSM) only in establishments that:

- 1) are constructed so as to avoid contamination of meat and products, allowing continuous progress of the operations or ensuring separation between the different production batches, lots or lines;
- 2) have rooms for separate storage of packaged and unpackaged 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 in the manner that ensures compliance with the temperature requirements laid down in Article 36 of this Rulebook;
- 4) have equipment for washing, cleaning and disinfection of utensils and tools supplied with hot water of not less than 82°C, or other appropriate system having an equivalent effect

- 5) have hand washing facilities to be used by staff handling unpackaged meat or products with taps designed so as to prevent the contamination.

Requirements for raw material

Article 35

The business operator engaged in operations referred to in Article 34 of this Rulebook may use for the production only the following:

1) raw material used for production of minced meat:

- a. that comply with the requirements for fresh meat;
- b. that derive from skeletal muscle, including adherent fatty tissues;
- c. that do not derive from scrap cuttings and scrap trimmings (other than whole muscle cuttings), MSM, meat containing bone fragments or skin, 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) raw material used for production of meat preparations:

- a. that comply with requirements from item 1 sub-items a) and b) of this paragraph;
- b. for production of meat preparations for human consumption only with previous heat treatment may be used in addition to raw material that meets the requirements referred to in item 1 sub-items a) and b) of this paragraph and the meat derived from mincing or fragmentation of meat, unless derived from scrap trimmings (other than whole muscle cuttings);
- c. and MSM meeting the requirements of Article 36 paragraph 6 of this Rulebook;

3) the raw material used to produce MSM must:

- a. comply with the requirements referred to in item 1 sub-item a) of this paragraph;
- b. be raw material that not derived from poultry feet, neckskin and head and for other animals, the bones of the head, feet, tails, femur (tibia, fibula, humerus, radius and ulna).

Hygiene during and after production

Article 36

The business operator producing minced meat, meat preparations or MSM should organize work on meat in such a way as to prevent or minimise the meat contamination, and that only the following meat is used for production:

- 1) maintained at a temperature of not more than 4°C for poultry, 3°C for edible by-products and 7°C for other meat;
- 2) delivered into the workrooms gradually and as needed.

For production of minced meat and meat preparations only the following may be used:

- 1) frozen or deep-frozen meat which is boned before freezing, unless the competent authority previously authorized boning immediately before mincing, and which may be stored only for a limited period of time;
- 2) chilled meat, where minced meat obtained from it must be prepared:
 - a. no more than 3 days from slaughter of poultry;
 - b. no more than 6 days from slaughter of other animals;

- c. within 15 days from the slaughter of the animals in the case boned, vacuum-packed beef and veal is used.

Immediately after production, minced meat and meat preparations must be wrapped or packaged and be chilled to a temperature of not more than 2°C for minced meat and 4°C for meat preparations or frozen to a temperature of not more than -18°C. These temperature conditions must be maintained also during storage and transport.

For the production and use of MSM using the techniques that do not alter the structure of the bones where calcium content is not significantly higher than that of minced meat, only the following may be used:

- 1) raw material for deboning no more than 5 days old, and if they come from a slaughterhouse on the same site, the raw material must be no more than 7 days old, while poultry carcasses must be no more than 3 days old.
- 2) mechanically separated parts obtained immediately after deboning.

If not used immediately after being obtained, MSM referred to in paragraph 4 of this Article must be wrapped or packaged and chilled to a temperature of not more than 2°C or frozen to a temperature of not more than -18°C. These temperature requirements must be maintained also during storage and transport.

If the business operator carried out an analysis demonstrating that MSM complies with the microbiological criteria for minced meat, the MSM may be used in meat preparations not intended to be consumed without first undergoing heat treatment and in meat products.

MSM for which analysis shows that it fails to comply with the microbiological criteria for minced meat may be used only for production of heat-treated meat products in approved establishments.

Notwithstanding the paragraph 4 of this Article, for production and use of MSM produced using other techniques only the following may be used:

- 1) raw material for deboning no more than 5 days old, and if they come from a slaughterhouse on the same site, the raw material must be no more than 7 days old, while poultry carcasses must be no more than 3 days old.
- 2) bones, from which meat has not been separated mechanically without delay, and which have been stored and transported at a temperature of not more than 2°C or, if frozen, at a temperature of not more than -18°C.
- 3) flesh bearing bones, obtained from frozen carcasses and which have not been refrozen.

If not used within one hour of being obtained, MSM referred to in paragraph 8 of this Article must be chilled immediately to a temperature of not more than 2°C.

If, after chilling, MSM referred to in paragraph 8 of this Article 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.

Frozen MSM referred to in paragraphs 4 and 8 of this Article must be wrapped or packaged before storage or transport. Frozen MSM 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.

MSM may be used only for production of heat-treated meat products in approved establishments.

Once thawed, minced meat, meat preparations and MSM must not be re-frozen.

Marking

Article 37

In addition to the labelling and marking requirements for food of animal origin the business operator shall clearly and legibly indicate on the mark of the product intended for supply to the final

consumer containing minced meat from poultry or solipeds or meat preparations containing MSM that such a product must be cooked, i.e. that it must undergo heat treatment before consumption.

VII SPECIAL REQUIREMENTS FOR MEAT PRODUCTS

Requirements for raw material

Article 38

The business operator producing and preparing meat products may use only the meat that does not contain:

- 1) genital organs of either female or male animals, except testicles;
- 2) urinary organs, except the kidneys and the bladder;
- 3) the cartilage of the larynx, the trachea and the extra-lobular bronchi;
- 4) eyes and eyelids;
- 5) the external auditory meatus;
- 6) horn tissue;
- 7) in poultry, the head, the crop, the intestines and the genital organs.

The meat, including minced meat and meat preparations, used for production of meat product must meet the requirements set for fresh meat.

Minced meat and meat preparations used for production of meat products need not comply with other specific requirements from Articles 34, 35, 36 and 37 of this Rulebook.

VIII SPECIAL REQUIREMENTS FOR RENDERED ANIMAL FAT AND GREAVES

Requirements for establishments for collecting or processing of raw material

Article 39

The business operator may collect or process the raw materials for production of rendered animal fats and greaves only in an establishment having:

- 1) a centre for collection of raw materials and their further transport to the processing establishment, and which also has adequate premises and equipment for storage of the raw materials at a temperature of not more than 7°C;
- 2) a processing establishment which has:
 - a. refrigeration facilities;
 - b. a dispatch room, unless the establishment dispatches rendered animal fat in tankers only;
 - c. appropriate equipment for preparation of products consisting of rendered animal fats mixed with other foodstuffs or seasonings.

The refrigeration facilities referred to under the paragraph 1 items 1 and 2 sub-item a) of this Article are not necessary if the system of supply raw materials is organized so that their storage or transport is not necessary.

Hygiene requirements for preparation of rendered animal fat and greaves

Article 40

The business operator producing rendered animal fats and greaves may use only the raw materials that:

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- 1) derive from animals slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem examination;
- 2) consist of adipose tissues or bones, containing the least possible quantity of blood and impurities;
- 3) come from approved establishments;
- 4) are, until rendering, transported and stored in hygienic conditions and at an temperature of not more than 7 °C, or are stored and transported without active refrigeration if rendered within 12 hours from the moment they were obtained.

Solvents must not be used during the rendering of raw materials referred to in the paragraph 1 of this Article.

When the fat for rendering meets the standards referred to in paragraph 4 of this Article, the rendered animal fat referred to in paragraphs 1 and 2 of this Article may be rendered in the same establishment or in another establishment with a view to improving its physico-chemical characteristics.

Rendered animal fat, depending on type, must meet the following standards:

	Ruminants			Pigs			Other animal fat	
	Edible tallow			Edible fat		Lard and other fat for refining	Edible	For refining
	Premier jus (1)	Other	Tallow for refining	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 fresh adipose tissue of heart, caul, kidneys and mesentery of cattle and fat from cutting establishment.								
(2) Rendered animal fat obtained from the adipose tissues of pigs.								

Greaves intended for human consumption must be stored in accordance with the following temperature requirements:

- 1) if greaves are rendered at a temperature of not more than 70°C, they must be stored at a temperature of not more than 7°C for a period not exceeding 24 hours or at a temperature of not more than -18°C, as appropriate;
- 2) if 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 at a temperature of not more than 7°C for a period not exceeding 48 hours or a temperature of not more than -18°C, as appropriate;
- 3) If 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 temperature requirements.

IX SPECIAL REQUIREMENTS FOR TREATED STOMACHS, BLADDERS AND INTESTINES

Requirements for placing on the market

Article 41

The business operator treating stomachs, bladders and intestines may place animal stomachs, bladders and intestines on the market only if:

- 1) derived from animals slaughtered in a slaughterhouse, and which have been found fit for human consumption following ante-mortem and post-mortem inspection;
- 2) they are salted, heat-treated or dried;

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- 3) after the heat-treatment referred to in item 2) of this Article, effective measures are taken to prevent subsequent contamination;
- 4) treated stomachs, bladders and intestines that cannot be kept at ambient temperature are stored in chilling facilities pending their dispatch;
- 5) products that are not salted or dried are kept at a temperature of not more than 3°C.

X SPECIAL REQUIREMENTS FOR GELATINE

Requirements for raw material

Article 42

The business operator for production of gelatine may use only the following raw materials:

- 1) bones;
- 2) hides and skins of farmed ruminants;
- 3) pig skins;
- 4) poultry skin;
- 5) tendons;
- 6) wild game hides and skins;
- 7) fish skin and bones.

Hides and skins that underwent any tanning process must not be used for gelatine production.

Raw materials referred to in paragraph 1, items 1) to 5) of this Article must be derived from animals slaughtered in a slaughterhouse and 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.

Raw materials referred to in paragraph 1 of this Article must come from approved establishments.

The establishment for collecting and tanning of skin and hide may supply raw material for the production of gelatine intended for human consumption only if approved and if it complies with the following requirements:

- 1) Has appropriate rooms for storage, with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.
- 2) Keeps storage rooms clean and in good repair so that they do not constitute a source of contamination for the raw materials.
- 3) If raw material not meeting the requirements of this Article are stored or processed in storage premises, the raw material must be separated from raw material that meets the requirements of this Article in the period of receipt, storage, processing and dispatch.

Transport and storage of raw materials

Article 43

In place of the identification marks prescribed, a document indicating the establishment of origin and containing the information set out in the Form printed in the Annex 1 of this Rulebook that it is integral part of must accompany raw materials during transport to an establishment for collecting and treatment and the establishment for gelatine production.

Raw materials must be stored and transported chilled or frozen, unless they are to be processed within 24 hours after the beginning of the transport.

45. RULEBOOK ON SPECIAL HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL ORIGIN

Degreased and dried bones or bone tissues, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored without any particular temperature regime.

Requirements for gelatine production

Article 44

In the gelatine production process, the following must be ensured:

- 1) That all ruminant bone material comes from animals born, reared or slaughtered in countries or regions included in the list of countries having a low incidence of bovine spongiform encephalopathy (BSE), subjected to a process ensuring that all bone material is finely crushed and degreased with hot water and treated with diluted 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°C to 140°C during 4 seconds or by some other approved process having the equivalent effect;
- 2) That other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses where pH must be adjusted subsequently. Gelatine must be extracted by one or several successive heating rounds, followed by purification by filtration or sterilisation.

The business operator that complies with the requirements for production of gelatine intended for human consumption may produce and store in the same establishment also the gelatine not intended for human consumption.

Requirements for finished products

Article 45

The business operator producing gelatine complies shall produce the gelatine in line 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 ₂ O ₂ (European Pharmacopoeia 1986 (V2O2))	10 ppm

XI SPECIAL REQUIREMENTS FOR COLLAGEN

Requirements for raw materials

Article 46

For production of collagen intended for use in food, the following raw materials may be used:

- 1) hides and skins of farmed ruminant animals;
- 2) pig skins and bones;
- 3) poultry skin and bones;
- 4) tendons;
- 5) wild game hides and skins; and
- 6) fish skin and bones.

Hides and skins that underwent any tanning process must not be used for gelatine production.

45. RULEBOOK ON SPECIAL HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL ORIGIN

Raw materials referred to in paragraph 1, items 1) to 4) of this Article must be derived from animals slaughtered in a slaughterhouse and 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.

Raw materials referred to in paragraph 1 of this Article must come from approved establishments.

The establishment for collecting and tanning of skin and hide may supply raw material for the production of gelatine intended for human consumption only if approved and if it complies with the following requirements:

- 1) Has appropriate rooms for storage, with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.
- 2) Keeps storage rooms clean and in good repair so that they do not constitute a source of contamination for the raw materials.
- 3) If raw material not meeting the requirements of this Article are stored or processed in storage premises, the raw material must be separated from raw material that meets the requirements of this Article in the period of receipt, storage, processing and dispatch.

Transport and storage of raw materials

Article 47

In place of the identification marks prescribed, a document indicating the establishment of origin and containing the information set out in the Annex 1 of this Rulebook must accompany raw materials during transport to an establishment for collecting and treatment and the establishment for collagen production.

Raw materials must be stored and transported chilled or frozen, unless they are to be processed within 24 hours after the beginning of the transport.

Degreased and dried bones or bone tissues, salted, dried and limed hides, and hides and skins treated with alkali or acid may be transported and stored without any particular temperature regime.

Requirements for collagen production

Article 48

Collagen must be produced by a process where 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 another approved process having an equivalent effect.

After the implementation of the process referred to in paragraph 1 of this Article, collagen may undergo a drying process.

The business operator that complies with the requirements for production of collagen intended for human consumption may store and produce in the same establishment also the collagen not intended for human consumption.

Requirements for finished products

Article 49

The business operator producing collagen shall produce collagen in line with the residue limits set out in the following table:

Residue	Limit
As	1 ppm
Pb	5 ppm
Cd	0.5 ppm

45. RULEBOOK ON SPECIAL HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL ORIGIN

Hg	0.15 ppm
Cr	10 ppm
Cu	30 ppm
Zn	50 ppm
SO ₂ (Reith Williams)	50 ppm
H ₂ O ₂ (European Pharmacopoeia 1986 (V2O2))	10 ppm

Marking

Article 50

Wrapping and packaging containing collagen, or gelatine, must bear the words “collagen fit for human consumption” and “gelatine fit for human consumption” respectively, as well as the date of production.

XII SPECIAL REQUIREMENTS FOR PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS

General requirements for placing live bivalve molluscs on the market

Article 51

Live bivalve molluscs may be placed on the market for retail sale only when delivered from a dispatch centre, where an identification marking has been applied in accordance with Articles 5, 6 and 7 of this Rulebook..

The business operator may accept into the establishment for the purpose of placing on the market only batches of live bivalve molluscs accompanied by documentation set out in Article 52 of this Rulebook.

When moving a batch of live bivalve molluscs between establishments, until delivery to a dispatch centre or a processing establishment, the prescribed documents must accompany each batch.

Documents to accompany live bivalve molluscs

Article 52

Where the establishment receiving a batch of live bivalve molluscs is situated beyond the territory of Montenegro, the accompanying documents must also be written in at least one official language of the state in which the receiving establishment is located.

The accompanying documents referred to in the paragraph 1 of this Article must include the following information:

- 1) For a batch of live bivalve molluscs delivered from the production area:
 - a. Name and address of the gatherer;
 - b. the date of collecting or harvesting;
 - c. the location of the production area described in as much detail as possible or by a code number;
 - d. the health status of the production area;
 - e. the shellfish species and quantity;
 - f. the destination of the batch.
- 2) For a batch of live bivalve molluscs dispatched from a relaying area, in addition to the information referred to in the paragraph 1 item 1 of this Article, also:
 - a. the location of the relaying area;
 - b. the duration of relaying.

- 3) For a batch of live bivalve molluscs dispatched from a purification centre, in addition to the information referred to in the paragraph 1 item 1 of this Article, also:
- a. the address of the purification centre;
 - b. the duration of purification;
 - c. the dates on which the batch was dispatched to and from the purification centre.

The business operator dispatching batches of live bivalve molluscs shall complete the accompanying documents so that they are easy to read and cannot be altered.

The business operator receiving batches of live bivalve molluscs must write in the date of the receipt and stamp the document or record the date of receipt in another manner.

The business operator dispatching, or receiving the batches of live bivalve molluscs shall keep a copy of the required accompanying documents for each batch sent and received for at least twelve months after its dispatch or receipt.

Notwithstanding the paragraphs 1 to 5 of this Article, in case that the business operator gathering or harvesting live bivalve molluscs also operates the dispatch centre, purification centre, relaying area or processing establishment, accompanying documents are not necessary in case the competent authority deems it appropriate in the process of issuing approvals.

Requirements for production areas

Article 53

A gatherer may harvest live bivalve molluscs only from production areas with locations and boundaries set by the competent authority in accordance with the relevant regulation and classified as production areas of class A, B or C, in accordance with the regulation governing the control of food of animal origin.

A business operator may place on the market for direct human consumption only the live bivalve molluscs collected or harvested from class A production area that meet the health requirements from the Article 59 of this Rulebook.

A business operator may place on the market live bivalve molluscs collected or harvested from class B production areas for direct human consumption only after treatment in a purification centre or after relaying.

A business operator may place on the market live bivalve molluscs collected or harvested from class C production areas for direct human consumption only after relaying over a long period in accordance with the Article 55 of this Rulebook.

After purification or relaying, live bivalve molluscs from class B or C production areas must meet the health requirements of Article 59 of this Rulebook.

Where live bivalve molluscs from class B or C production areas have not undergone purification or relaying, these may be sent to a processing establishment, where, after removal of sand, mud or slime in the same or another establishment, they must be processed in order to eliminate pathogenic microorganisms using the following approved methods:

- 1) sterilisation in hermetically sealed containers;
- 2) heat treatments involving:
 - a. 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 the temperature for a period of not less than 90 seconds;
 - b. cooking for three to five minutes in an enclosed space where the temperature is between 120°C and 160°C and the pressure is between 25 kg/cm² and 5 kg/cm², followed by shelling and freezing of the flesh to a core temperature of -20°C;

- c. steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh referred to in paragraph 6 item 2 sub-item a) of this Article, where procedures based on the HACCP principles must be applied in order to ensure the uniform distribution of heat.

The business operator producing or harvesting live bivalve molluscs must not produce, collect or harvest live bivalve molluscs from areas that the competent authority has set or classified, and which do not meet the health requirements referred to in Article 59 of this Rulebook.

The business operator producing or harvesting live bivalve molluscs shall take care of all important information concerning the areas' safety of production and harvesting, obtained from its own checks or from the competent authority on weather conditions and the environment, in order to determine the appropriate treatment to be applied to each harvested batche.

Requirements for harvesting and handling live bivalve molluscs following harvesting

Article 54

The business operator harvesting live bivalve molluscs or handling live bivalve molluscs immediately after harvesting shall:

- 1) apply harvesting and handling techniques that do not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes that may affect their purification, processing or relaying;
- 2) adequately protect live bivalve molluscs from crushing, abrasion or vibration;
- 3) adequately protect live bivalve molluscs from exposure to high temperatures;
- 4) not re-immerses live bivalve molluscs in water that may cause additional contamination;
- 5) use only areas that the competent authority has classified as class A if carrying out conditioning in natural sites.

Means of transport for transport of harvested live bivalve molluscs must have adequate equipment ensuring their survival and efficient protection against contamination, as well as adequate drainage for wastewaters.

Requirements for relaying live bivalve molluscs

Article 55

The business operator relaying live bivalve molluscs shall:

- 1) use only the areas that the competent authority has approved for relaying live bivalve molluscs, with boundaries clearly marked with buoys, poles or other fixed means. In order to prevent the risk from spread of contamination among relaying areas and production areas, there must be a minimum distance between relaying areas, and also between relaying areas and production areas;
- 2) apply techniques for handling live bivalve molluscs to be relayed that permit the resumption of filter-feeding activity after immersion in natural waters;
- 3) relay live bivalve molluscs in a manner that ensures efficient purification;
- 4) keep the live bivalve molluscs immersed in seawater at the relaying area for a specific period of time set depending on the water temperature, where that period must be at least two months;
- 5) ensure sufficient distance between certain sites in a relaying area in order to prevent mixing of batches by the system "all in, all out", so that a new batch cannot be brought in before the whole of the previous batch has been removed.

The business operator shall keep permanent records of the source of live bivalve molluscs, relaying periods and relaying areas, relaying areas used and the subsequent destination of the batch after relaying.

Requirements for construction and organization of purification and dispatch centres

Article 56

The purification and dispatch centre must be located on a site that is not at risk from flooding as a result of high tides or run-off from surrounding areas.

Tanks and water containers in establishments referred to in the paragraph 1 of this Article must:

- 1) have smooth, durable, impermeable internal surfaces, easy to clean;
- 2) be constructed so as to allow complete draining of water;
- 3) have water supply positioned so as to avoid contamination of the water;
- 4) be suitable for the volume and type of products purified.

Hygiene requirements for purification centre

Article 57

The business operator purifying live bivalve molluscs shall:

- 1) wash live bivalve molluscs from mud and accumulated debris using clean water, before purification;
- 2) have in place a purification system that:
 - a. allows live bivalve molluscs to promptly resume filter-feeding;
 - b. ensures efficient secretion of contaminants from wastewaters;
 - c. prevent re-contamination, and
 - d. ensure that, following the purification, the live bivalve molluscs remain alive and in a suitable condition for wrapping, storage and transport before being placed on the market;
- 3) ensure that the quantity of live bivalve molluscs to be purified is not above the capacity of the purification centre. The process of purification of live bivalve molluscs must go on without interruption for as long as the health requirements referred to in the Article 59 of this Rulebook and the microbiology criteria set are complied with;
- 4) ensure that, in case the purification pool or tank contains several batches of live bivalve molluscs, they belong to the same species and the length of the purification procedure must be set according to the batch needing the longest purification period;
- 5) ensure that containers or pools used to hold live bivalve molluscs in the purification system are constructed so as to allow clean seawater to flow through, where the depth of layers of live bivalve molluscs must not impede the opening of shells during purification;
- 6) keep no fishery products or other marine species in a purification tank in which live bivalve molluscs are undergoing purification;
- 7) ensure that every package of purified live bivalve molluscs sent to a dispatch centre must have a mark certifying that all live bivalve molluscs have been purified.

Hygiene requirements for dispatch centre

Article 58

The business operator in a dispatch centre shall:

- 1) Handle live bivalve molluscs, particularly the maintaining, calibration, wrapping and packing in the manner that prevents contamination of the product and effect on the viability of the live bivalve molluscs;
- 2) Before dispatch, thoroughly wash the live bivalve molluscs with clean water;
- 3) Ensure that live bivalve molluscs come from:
 - a. a class A production area;
 - b. a relaying area;
 - c. a purification centre or
 - d. another dispatch centre.

The requirements referred to in paragraph 1 items 1) and 2) of this Article also apply to dispatch centres situated on board vessels. Live bivalve molluscs handled in such centres must come from a class A production area or a relaying area.

Health requirements for live bivalve molluscs

Article 59

The business operator may place on the market for direct human consumption only the bivalve molluscs that, in addition to the microbiological criteria set, meet also the following requirements:

- 1) that they have organoleptic characteristics inherent to live and viable bivalve molluscs, a clean shell (free from weed and impurities), undamaged edges that, when touched, close completely and that have normal amounts of intravalvular liquid;
- 2) that they do not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:
 - a. for the biotoxin causing paralysis, the Paralytic Shellfish Poison (PSP), 800 micrograms per kilogram;
 - b. for the biotoxin causing loss of memory, the 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.

Wrapping and packaging of live bivalve molluscs

Article 60

Individual packages of live bivalve molluscs intended for direct human consumption must be closed and remain closed after leaving the dispatch centre and until sold to the final consumer.

Oysters must be wrapped or packaged so that the concave shell faces downwards.

Identification marking and labelling of live bivalve molluscs

Article 61

The label, including the identification mark, must be waterproof.

In addition to the requirements for identification marks referred to in Articles 5, 6 and 7 of this Rulebook, the label must contain the following information:

- the species of bivalve mollusc (common name and scientific name);
- the date of packaging, with mandatory stating of the day and the month.

Notwithstanding the requirements for labelling and marking of food of animal origin, the date to be used by may be replaced by the entry “these animals must be alive at the moment of sale”.

The business operator in retail sale of live bivalve molluscs shall keep the label attached to the packaging of live bivalve molluscs that are not in individual packages for at least 60 days after splitting up the contents of the packaging.

Other requirements for live bivalve molluscs

Article 62

The business operator storing and transporting live bivalve molluscs shall ensure temperature conditions during storage and transport in order to preserve the safety or viability of live bivalve molluscs.

If live bivalve molluscs are packaged for retail sale and delivered from a dispatch centre must not be re-immersed in water or sprayed with water.

Specific requirements for pectinidae harvested outside the classified production areas

Article 63

The business operator may collect or harvest and handle pectinidae outside the classified production areas if it complies with the following requirements:

- 1) Pectinidae may not be placed on the market unless during harvesting and handling the requirements from Articles 54 and 59 of this Rulebook are met, which is established on the basis of data from the own-check systems in place;
- 2) where data from monitoring regarding the compliance of certain production areas enable the competent authority to classify production grounds, where appropriate in cooperation with the business operators, in accordance with the Article 53 of this Rulebook, the provisions of shall apply by analogy to pectinidae as well;
- 3) Pectinidae may be placed on the market for direct human consumption only through a dispatch centre, a processing establishment or a fish auction.

The business operator operating the establishment for fish auction, dispatch centre or a processing establishment must inform the competent authority of placing pectinidae on the market through that establishment, while the dispatch centres must meet the requirements from Articles 54 and 56 of this Rulebook.

In addition to requirements referred to in the paragraph 1 of this Article, the business operator handling pectinidae must comply with the requirements related to accompanying documents referred to in Article 52 of this Rulebook. The accompanying documents must clearly indicate the location of the area where the pectinidae were harvested.

The business operator handling packaged or wrapped pectinidae must meet the requirements on identification mark and label referred to in Article 61 of this Rulebook.

XIII FISHERY PRODUCTS

Requirements for fishery vessels

Article 64

The business operator shall ensure that:

- 1) Fishery vessels (hereinafter referred to as: vessels) used for collecting or harvesting fishery products from their natural environment, or for handling or processing them after collecting or harvesting, comply with the requirements laid down in Article 65 as regards construction and equipment;
- 2) operations carried out on board vessels take place in accordance with the requirements laid down in Article 69 of this Rulebook.

Requirements as regards construction and equipment for all vessels

Article 65

The vessels must be designed and constructed so as to prevent contamination of the fishery products with bilge-water, wastewaters, smoke, fuel, oil, grease or other undesirable substances.

Surfaces with which fishery products come into contact must be of suitable smooth material, corrosion-resistant, easy to clean, with surface coatings that must be durable and non-toxic.

Equipment and material used for working on fishery products must be made of corrosion-resistant material that is easy to clean and disinfect.

Where a vessel have a water intake for water used with fishery products, it must be situated in a position that avoids contamination of the water.

Requirements as regards construction and equipment for vessels for preserving fresh fishery products for more than 24 hours

Article 66

The vessel designed and equipped to preserve fresh fishery products for more than 24 hours must be equipped with holds, tanks and containers for the storage of fishery products at the temperatures laid down in Article 78 of this Rulebook.

Holds for fishery products must be separated from the engine compartments of the vessel and from the crew quarters by partitions sufficient to prevent any contamination of the products stored.

Holds and containers used for the storage of fishery products must ensure their preservation under satisfactory hygiene conditions and, where necessary, ensure that water from melt ice does not remain in contact with the products.

In vessels equipped for chilling fishery products in cooled clean seawater, tanks must incorporate devices for achieving and maintaining a uniform temperature throughout the tanks. Such devices must achieve a chilling rate that ensures that the mix of fishery products and clean seawater reaches not more than 3°C 6 hours after loading and not more than 0 °C after 16 hours, and allow the monitoring and, where necessary, recording of temperatures.

Requirements as regards construction and equipment for freezer vessels

Article 67

A freezer vessels must:

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- 1) have freezing equipment with sufficient capacity to lower the temperature rapidly and to achieve core temperatures of not more than -18°C;
- 2) have refrigeration equipment with sufficient capacity to maintain fishery products in the storage holds at temperature of not more than -18°C. Storage holds must be equipped with a temperature-recording device in a place where it can be easily read, with the temperature sensor of the reader situated in the area where the temperature in the hold is the highest;
- 3) meet the requirements laid down in Article 66 paragraph 2 of this Rulebook.

Requirements as regards construction and equipment for factory vessels

Article 68

A factory vessels must have:

- 1) a receiving area for fishery products constructed so as to allow each successive catch to be separated from the previous one, which is easy to wash and clean and that fishery products are protected from the sun, bad weather and contamination sources;
- 2) a hygienic system for conveying fishery products from the receiving area to the work area;
- 3) work areas or rooms for preparation and processing of fishery products in a hygienic manner, that are large enough, easy to clean and constructed and distributed so as to prevent contamination of the products;
- 4) areas or rooms for storage of treated fishery products that are large enough and constructed so that they are easy to clean. If waste is processed on board, a separate hold must be provided on the vessel for storage of such waste;
- 5) a place for storing packaging and wrapping materials that is separate from the preparation and processing areas for fishery products;
- 6) special equipment for discharge of waste or fishery products unfit for human consumption directly into the sea or, where circumstances so require, into watertight tanks intended only for that purpose. If waste is temporarily stored and processed on board with a view to its sanitation, separate area must be allocated for that purpose;
- 7) a water intake situated in a position that prevents contamination of the water;
- 8) hand-washing facility for use by the staff handling unpackaged fishery products with taps designed so to prevent the contamination of products.

The factory vessel on board which crustaceans and molluscs are cooked, chilled and wrapped, need not meet the requirements of paragraph 1 of this Article.

The factory vessel that freeze fishery products on board must have equipment meeting the requirements for freezer vessels laid down in Article 67 of this Rulebook.

Hygiene requirements

Article 69

When in use, the parts of vessels, tanks or containers used for the storage of fishery products must be kept clean and maintained in good repair and condition.

As soon as possible after they are taken on board, fishery products must be protected from contamination, sun and other sources of heat. Only potable water, or where appropriate, clean water may be used for washing of fishery products.

Fishery products must be handled and stored so as to prevent damaging. Persons handling the fishery products may use spiked instruments to move large fish or fish which might injure them, provided that the flesh of the products is not damaged.

Fishery products other than those kept alive must undergo chilling as soon as possible after harvesting or loading. If chilling is not possible, fishery products must be landed as soon as possible.

Ice used to chill fishery products must be made from potable water or clean water.

Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after catching, and the products must be washed immediately and thoroughly with potable water or clean water. The heads and viscera removed and parts that may constitute a hazard to public health must be removed without delay and kept separately from products intended for human consumption. Livers and roes intended for human consumption must be kept on ice, at a temperature approaching that of melting ice, or be frozen.

Freezing in brine of whole fish intended for canning must be done at a temperature of the product of not more than -9 °C. The brine must not be a source of contamination for the fishery products.

Requirements to be met during and after landing

Article 70

The business operator unloading fishery products from the vessel to the land must:

- 1) ensure that unloading 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;
- 2) avoid contamination of fishery products during unloading, so that:
 - a. unloading takes place rapidly;
 - b. fishery products are stored without delay in an appropriate space at the temperature laid down in Article 78 of this Rulebook;
 - c. equipment and practices that cause unnecessary damage to the edible parts of the fishery products are not used.

The business operator running the wholesale and retail sale of fishery products through fish auction, wholesale and retail sale markets or establishments must ensure the following conditions:

- 1) separate lockable facilities and equipment for the refrigerated storage of detained fishery products and for the storage of fishery products unfit for human consumption;
- 2) equipped separate room for the veterinary inspectorate;
- 3) at the time of storage or display of fishery products:
 - a. the premises referred to in paragraph 2 item 1) of this Article must not be used for other purposes;
 - b. vehicles emitting exhaust fumes that might have a negative effect on safety of fishery products must not have access to the premises;
 - c. persons having access to the premises must not introduce other animals;
 - d. the premises must be well lit to facilitate efficient controls.

When chilling is not possible on board, the fresh fishery products, other than those kept alive, must undergo chilling without delay after landing and be stored at a temperature of melting ice.

The business operator shall notify the competent authority of the time and place of landing of fishery products in accordance with the regulation governing the control of food of animal origin.

Requirements for fresh fishery products

Article 71

The business operator must ensure that in establishments handling fishery products the following requirements are complied with:

- 1) Where chilled, unpackaged fishery products are not distributed, dispatched, prepared or processed immediately after delivery into an establishment on land, they must be stored under ice in appropriate facilities. Re-icing must be carried out as often as necessary, while 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, and where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after catching or landing the products and the products must be washed thoroughly with potable water or, on board vessels, by clean water;
- 3) Operations such as filleting and cutting must be carried out so as to prevent contamination or spoilage of fillets and slices, where fillets and slices must not remain on the worktables beyond the time necessary for their preparation and must be wrapped and, where necessary, packaged and 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 only in cooled water on board vessels and after landing, they may be transported in cooled water and be transported from aquaculture establishments, until they arrive at the first establishment on land carrying out any activity other than transport or classification.

Requirements for frozen products

Article 72

Establishments on land that freeze fishery products must have equipment that satisfies the requirements laid down for freezer vessels in Article 67 paragraphs 1 and 2 of this Rulebook.

Requirements for mechanically separated fishery products

Article 73

The business operator producing mechanically separated fishery products must ensure compliance with the following requirements:

- 1) only whole fish and bones after filleting may be used to produce mechanically separated fishery products and raw materials must be gutted;
- 2) the production procedure must be done in the following manner:
 - a. mechanical separation must take place immediately after filleting, without delay;
 - 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 stabilization.

Requirements regarding the parasites

Article 74

The fishery products (finished products or raw materials) which must be frozen at a temperature of not more than -20 °C in all parts of the product in not less than 24 hours are:

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- 1) fishery products to be consumed raw or almost raw;
- 2) fishery products from the following species, if they are to undergo a smoking process in which the internal temperature of the fishery product is not more than 60 °C:
 - a. herring;
 - b. mackerel;
 - c. sprat;
 - d. (wild) Atlantic and Pacific salmon;
- 3) marinated and/or salted fishery products, if the processing is insufficient to destroy nematode larvae.

The business operator need not carry out the operation referred to in paragraph 1 of this Article if:

- 1) epidemiological data are available indicating that the fishing grounds of origin do not present a health hazard with regard to the presence of parasites;
- 2) the competent authority so authorises.

A document in which the producer indicates the type of process the products have undergone, must accompany fishery products referred to in paragraph 1 of this Article when placed on the market, except when supplied to the final consumer.

Requirements for fish oil for human consumption

Article 75

The business operator must ensure that raw material used for production of fish oil for human consumption meets the following requirements:

- 1) that they originate from fishery products declared fit for human consumption;
- 2) that they originate from approved establishments, including vessels;
- 3) that they are hygienically transported and stored by production.

Requirements for processed fishery products

Article 76

The business operator cooking crustaceans and molluscs must ensure compliance with the following requirements:

- 1) products must be cooled rapidly after cooking. Water used for this purpose must be potable water or, on board vessels, clean water and if no other method of preservation or keeping is used, cooling must continue until a temperature approaching that of melting ice is achieved;
- 2) shelling or shucking must be carried out hygienically, avoiding contamination of the product and where such operations are done by hand, the staff 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 Article 79 of this Rulebook.
- 4) in establishments on land, clean water may be used for cooling crustaceans and molluscs after cooking.

Health requirements for fishery products

Article 77

The business operator may place on the market for human consumption only those fishery products that, in addition to microbiological criteria set, depending on the nature and type of the product, the following requirements as well:

- 1) that an organoleptic examination of fishery products was carried out in order to establish whether the products comply with the freshness criteria;
- 2) that the histamine quantity does not exceed the limits set;
- 3) that the unprocessed fishery products are not placed on the market unless chemical tests reveal that the limits with regard to TVB-N (Total Volatile basic Nitrogen) or TMA-N (Trimethylamine Nitrogen) have not been exceeded.
- 4) that fishery products have been subjected to a visual examination for the purpose of detecting visible parasites before placing on the market;
- 5) that fishery products obviously contaminated with parasites must not be placed on the market;
- 6) that fishery products derived from poisonous fish of the following families must not be placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*.
- 7) that fishery products containing biotoxins such as ciguatoxin or muscle-paralysing toxins must not be placed on the market.
- 8) fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market only if they comply with the requirements laid down by Article 59 paragraph 1 item 2) of this Rulebook.

Requirements for wrapping and packaging of fishery products

Article 78

Receptacles, containers or tanks in which fresh fishery products are kept under ice must be water-resistant and ensure that ice melt water does not remain in contact with the products.

Frozen blocks prepared on board vessels must be adequately wrapped before landing.

When fishery products are wrapped on board fishing vessels, the business operator must ensure that wrapping material:

- 1) is not a source of contamination;
- 2) is stored in such a manner that it is not exposed to a risk of contamination;
- 3) if intended for re-use, is easy to clean and, where necessary, to disinfect.

Requirements for storage of fishery products

Article 79

The business operator storing fishery products must ensure compliance with the following requirements:

- 1) Fresh fishery products, thawed unprocessed fishery products, 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 production of canned food may be kept at a temperature of not more than -9°C;

- 3) Fishery products kept alive must be maintained at a temperature and in a manner that does not adversely affect food safety or product viability.

Requirements for transport of fishery products

Article 80

The business operator transporting fishery products must ensure compliance with the following requirements:

- 1) during transport, fishery products must be maintained at the following temperatures:
- 2) the business operator need not comply with paragraph 1 item 1 sub-item b) of this Article when frozen fishery products are transported from a cold store to an approved establishment where they would be thawed on arrival for the purposes of preparation and/or processing, if the journey is short or if previously approved by the competent authority;
- 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 a way that does not have an adverse effect on food safety or product viability.

XIV SPECIAL REQUIREMENTS FOR FROGS' LEGS AND SNAILS

Frogs' legs and snails

Article 81

The business operator 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 intended solely for the storage and washing of live frogs, and for their slaughter and bleeding, 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 or laboratory examination, and in case that the examination indicates that they might present a hazard to human health they must not be used for human consumption;
- 5) immediately following preparation, frogs' legs must be thoroughly rinsed 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 be removed if it might present a hazard, and must not be used for human consumption.

Article 82

With regard to fishery products, the primary production includes farming, harvesting and collecting of live fishery products in order to place them on the market.

Accompanying operations, when performed on board, such as killing, bleeding, heading, gutting, finning, chilling and wrapping include also:

- 1) the transport and storage of fishery products character of which has not been changed in its essence, including live fish, in fish farms or on land;

- 2) the transport of fishery products character of which has not been changed in its essence, including live fish, from the place of production till the first establishment of the destination.

XV SPECIAL REQUIREMENTS FOR MILK AND DAIRY PRODUCTS

Health requirements for raw milk production

Article 83

The business operator producing or collecting raw milk (primary production) must comply with the following requirements:

- 1) Raw milk must come from animals:
 - a. that do not show any symptoms of infectious diseases transmissible to humans through milk;
 - b. that are in a good general state of health, show no sign of disease that might result in the contamination of milk and are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or udder inflammation;
 - c. that do not have any udder wounds likely to affect the milk;
 - d. to which no unauthorised substances or products have been administered and that have not undergone illegal treatment in accordance with the regulation laying down monitoring of residues in live animals and products of animal origin;
 - e. where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.
- 2) as regards prevention of brucellosis, raw milk must come from:
 - a. cows belonging to a herd free or officially free from brucellosis;
 - b. sheep or goats belonging to a holding officially free or free from brucellosis, or
 - c. females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under the operational programme of health protection.
- 3) as regards prevention of tuberculosis, raw milk must come from:
 - a. cows belonging to a herd which is free or officially free from tuberculosis;
 - b. females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under the operational programme of health protection.
- 4) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.

Raw milk from animals that do not meet the requirements from paragraph 1 item 2 of this Article may be used with previous approval from the competent authority:

- 1) in the case of cows that do not show a positive reaction to tests for tuberculosis or brucellosis, nor show any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the phosphatase test;
- 2) 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 under the operational programme of health protection, and which do not show any symptom of that disease:
 - a. for production of cheese with a maturation period of at least two months or
 - b. after having undergone heat treatment such as to show a negative reaction to the phosphatase test;
- 3) if treated to ensure its safety, 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 paragraph 1 item 2 sub-item c) or item 3 sub-item b) of this Article.

Raw milk from an animal not complying with the requirements from the paragraph 1 of this Article and in particular any animal showing individually a positive reaction to the prophylactic tests for tuberculosis or brucellosis as laid down by regulations governing the control and eradication of brucellosis or tuberculosis, must not be used for human consumption.

Infected animals, or animals suspected of being infected with any of the diseases referred to in paragraph 1 of this Article must be isolated in order to avoid adverse effect on other animals' milk.

Hygiene on milk production holdings and requirements as regards premises and equipment

Article 84

Milking equipment, and premises where milk is stored, handled or cooled must be located and constructed so as to prevent milk contamination.

Premises for the storage of milk must be protected against pests and be adequately separated from the premises where animals are housed and, where necessary to meet the requirements laid down in Article 85 of this Rulebook, have suitable refrigeration equipment.

Surfaces of equipment that come or may come into contact with milk (utensils, containers, tanks intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and be maintained in good condition, and smooth, washable and non-toxic materials must be used in their production.

After use, surfaces of equipment referred to in paragraph 3 of this Article must be cleaned and, where necessary, disinfected. In case the period of time between unloading and the following leading is very short, after each journey, or after each series of journeys they must be cleaned and disinfected 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.

Hygiene during milking, collection and transport

Article 85

Milking must be carried out hygienically, and the following must be ensured:

- 1) that, before milking starts, the teats, udder and adjacent parts are clean;
- 2) that milk from each animal is checked for organoleptic or physico-chemical abnormalities by either the milker or by a method achieving similar results and that milk presenting such abnormalities is not used for human consumption;
- 3) that milk from animals showing clinical signs of udder disease is used for human consumption only in accordance with the instructions of a veterinarian;
- 4) that animals undergoing medical treatment likely to transfer residues to the milk are identified, and that milk obtained from such animals before the end of the prescribed withdrawal period is not used for human consumption;
- 5) that products in which tits are immersed or washed are used only with previous approval from the competent authority in accordance with the relevant regulation.

Immediately after milking, milk must be held in a clean place designed and equipped so to avoid contamination.

In case of daily collection, milk must be cooled immediately to a temperature of not more than 8 °C, or not more than 6 °C if collection is not daily.

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.

45. RULEBOOK ON SPECIAL HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL ORIGIN

The business operator need not comply with the temperature requirements laid down in paragraphs 2 and 3 of this Article if the milk meets the criteria laid down by Article 85 of this Rulebook and if:

- 1) the milk is processed within 2 hours of milking; or
- 2) a higher temperature is necessary for technological reasons related to the production of certain dairy products and with previous approval from the competent authority.

Staff hygiene

Article 86

Persons performing milking and/or handling raw milk must wear suitable clean clothes.

Persons performing milking must maintain a high degree of personal hygiene.

Suitable hand-washing facilities must be available near the place of milking to enable persons performing milking and handling raw milk to wash their hands.

Criteria for raw milk

Article 87

The following criteria for raw milk apply, unless otherwise provided for by relevant regulation on quality of milk and dairy products:

- 1) compliance with requirements from paragraphs 2 and 3 of this Article for raw milk must be checked on a representative number of samples of raw milk collected from milk production holdings taken by random sampling. The checks are carried out by, or on behalf of:
 - a. the business operator producing the milk;
 - b. the business operator collecting or processing the milk;
 - c. association/co-operative of the business operator, or
 - d. under the program of control in place.

The business operator must ensure that raw milk meets the following criteria:

- 1) 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.	

- 2) 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.	

If raw milk is derived from species other than cows and is intended for the production of products made from raw milk by a process that does not involve any heat treatment, the business operator must take steps to ensure that the raw milk used meets the following requirements:

Plate count at 30 °C (per ml)	≤ 500 000 (*)
(*) Rolling geometric average over a two-month period, with at least two samples per month.	

The business operator must apply procedures to ensure that raw milk is not placed on the market if either:

- 1) it contains antibiotic residues in a quantity that exceeds the levels permitted under the relevant regulation, or

- 2) the combined total of residues of antibiotic substances exceeds any maximum permitted value.

When raw milk fails to comply with requirements from paragraphs 2, 3 or 4 of this Article, the business operator must inform the veterinary inspectorate of it and take measures to correct the situation without delay.

Criteria for raw cows' milk

Article 88

The business operator producing dairy products from milk must apply procedures that ensure that, immediately before processing:

- 1) raw cows' milk used to prepare dairy products has a plate count at 30°C of less than 300 000 per ml; and
- 2) processed cows' milk used to prepare dairy products has a plate count at 30°C of less than 100 000 per ml.

Where milk fails to meet the criteria laid down in paragraph 1 of this Article, the business operator must inform the veterinary inspector of it and take measures to correct the situation without delay.

Requirements for dairy products

Article 89

The business operator 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.

The business operator may keep milk at a higher temperature if:

- 1) processing begins immediately after milking, or within 4 hours from acceptance at the processing establishment; or
- 2) the competent authority authorises a higher temperature for technological reasons concerning the production of certain dairy products.

Requirements for heat treatment

Article 90

When raw milk and dairy products undergo heat treatment, the business operator must ensure that the processing takes place in accordance with the regulation governing the hygiene of food of animal origin and in particular it must ensure that in subsequent production operations the following requirements are complied with:

- 1) for pasteurisation procedure:
 - a. high temperature over a short period of time (at least 72°C over 15 seconds);
 - b. low temperature over a longer period of time (at least 63°C over 30 minutes);
 - c. some other combination of time and temperatures having the equivalent effect so that the products, where applicable, show a negative reaction to a phosphatase test immediately after application of such a treatment operation;
- 2) for ultra high temperature treatment (UHT):
 - a. which includes continuous flow of the procedure at a high temperature over a short period of time (no less than 135°C in combination with an appropriate time of keeping) so that there are no microorganisms or spores surviving, which

might grow in the treated product if kept in aseptic closed containers on ambient temperature;

- b. which ensures that the product remains microbiologically stable following a 15-day incubation at a temperature of 30°C in a closed container or 7 days at 55°C in a closed container, or after some other method showing that the treatment process applied is an appropriate one.

When choosing the method of heat treatment of raw material, the business operator must:

- 1) take into account the procedures set in line with the HACCP principles in accordance with the regulation governing the control of food of animal origin, and
- 2) comply with all the requirements set by the competent authority in that regard when approving establishments or when checking them in accordance with the regulation governing the control of food of animal origin.

Wrapping and packaging requirements

Article 91

Packages intended for consumer must be sealed 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 such that, after opening, the evidence of its opening remains clear and easy to check.

Marking requirements

Article 92

In addition to the requirements laid down by the regulation on marking and labelling of food, the label must clearly indicate the words:

- 1) “raw milk” in the case of raw milk intended for direct human consumption;
- 2) “made with raw milk” in the case of products made with raw milk.

The requirements of paragraph 1 of this Article apply to products destined for retail trade.

Identification marking requirements

Article 93

Notwithstanding the Article 5 of this Rulebook:

- 1) Instead of indicating the approval number of the establishment, the identification mark may include a reference to the establishment 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 code of the country the milk is supplied from and the approval number of the establishment.

XVI SPECIAL REQUIREMENTS FOR EGGS AND EGG PRODUCTS

Requirements for eggs

Article 94

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.

Eggs must be stored and transported at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties.

Eggs must be delivered to the consumer within a maximum time limit of 21 days of laying.

Requirements for establishments for production of egg products

Article 95

The business operator must ensure that establishments for production 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 items 1 and 2 of this Article.

Raw materials for production of egg products

Article 96

The business operator must ensure that raw materials used for production of egg products comply with the following requirements:

- 1) The shells of eggs used in production of egg products must be fully developed and contain no breaks. Cracked eggs may be used for production of egg products if the establishment of production or a packing centre delivers them directly to a processing establishment, where they must be broken without delay;
- 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 Article 97, items 1, 2, 3, 4 and 7 of this Rulebook.

Hygiene requirements for production of egg products

Article 97

The business operator must ensure that all operations are carried out in such a way as to prevent contamination during production, handling and storage of egg products, in particular by complying 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 without delay;
- 3) Eggs other than those of hens, turkeys or geese must be handled and processed separately. All equipment must be cleaned and disinfected before processing of hens', turkeys' and geese eggs is resumed;
- 4) Egg contents must 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 liquid egg must be processed without delay in order to eliminate or reduce microbiological hazards. 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 production of dried or crystallised albumin destined 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. These requirements do not apply to products to be de-sugared, if de-sugaring process is performed without delay;
- 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.

Analytical specifications

Article 98

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 for production of egg products must not exceed 1 g/kg of dry matter. For fermented products, this value must be the one recorded before the fermentation process.
3. The quantity of eggshell remains, egg membranes and other particles in the processed egg product must not exceed 100 mg/kg of egg product.

Label and identification mark

Article 99

In addition to the requirements for identification marking laid down in Article 5 of this Rulebook, the consignments of egg products destined not for retail but for use as an ingredient in the production of another product, must have a label indicating the temperature at which the egg products must be maintained and the period during which conservation may thus be assured.

In the case of liquid eggs, the label referred to in paragraph 1 of this Article must also bear the words: "non-pasteurised egg products - to be treated at place of destination" and indicate the date and hour of breaking.

Article 100

The day this Rulebook enters into force the provisions of the Rulebook on detailed requirements for issuing approvals for consignments of animals, foodstuffs, raw materials, products, feedstuffs and waste of animal origin, veterinary-sanitary requirements to be met by the consignment, the pace and the means of transport in loading, re-loading and unloading in national and international trade (Official Gazette of the Republic of Montenegro 13/06) and provisions of Article 1 to 22 of the Rulebook on minimum hygiene requirements to be met by vehicles for sea fish harvesting, method of performing veterinary-sanitary examination and control and special requirements with regard to hygiene of fresh sea fish intended for exports (Official Gazette of the Republic of Montenegro 41/03) shall be repealed.

Article 101

This Rulebook shall enter into force on the eighth day from the day of its publishing in the Official Gazette of Montenegro.

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Podgorica, February 16, 2009

Ministry of Agriculture, Forestry and Water Management

Minister

Milutin Simovic, MSc

ANNEX I

**MODEL DOCUMENT THAT MUST ACCOMPANY RAW MATERIAL
INTENDED FOR 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:.....