

12 Annex - Food safety, veterinary and phytosanitary policy

**48. RULEBOOK ON HYGIENE REQUIREMENTS FOR FOOD
OF ANIMAL OR PLANT ORIGIN**

48. RULEBOOK ON HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL OR PLANT ORIGIN

Pursuant to the Article 43 paragraph 2 and Article 44 paragraph 2 of the Law on Food Safety (Official Gazette of Montenegro 14/07) the Ministry of Agriculture, Forestry and Water Management has adopted

RULEBOOK ON HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL OR PLANT ORIGIN

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GENERAL PROVISIONS

Article 1

This Rulebook lays down in more detail the requirements and methods for meeting the hygiene requirements for business operators dealing with food of animal origin (hereinafter referred to as: business operators) in all production phases as well as in primary production of food of animal and plant origin, together with accompanying activities.

The general hygiene requirements stated under the paragraph 1 of this Article refer to the following:

- 1) requirements for facilities and premises for production of and trade in food;
- 2) transport;
- 3) equipment;
- 4) water supply and wastewater discharge;
- 5) personnel training;
- 6) heat treatment of products;
- 7) food of animal origin (products and raw materials);
- 8) packaging and wrapping;
- 9) waste from food of animal origin.

Definitions

Article 2

For the purposes of this Rulebook the following definitions shall apply:

- 1) Contamination - means the presence or introduction of a hazard into the food;
- 2) Wrapping - means the placing of food in a wrapper or container in direct contact with the food concerned, and the wrapper or container itself;
- 3) Packaging - means the placing of one or more pieces of wrapped food in another packaging or another container, and the packaging or container itself;
- 4) hermetically sealed container - means a container that is designed so as to prevent contamination of the contents of the container;
- 5) unprocessed product - means a product that has not undergone processing, and applies to products that have not been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;
- 6) processed product - means a product resulting from the processing of an unprocessed product, which may also contain ingredients giving it some specific characteristics;

- 7) product of animal origin - means food of animal origin, including blood and honey;
- 8) potable water - means water meeting the prescribed requirements;
- 9) clean seawater - means natural, artificial or purified seawater or salty water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities that may directly or indirectly affect the food safety;
- 10) clean water - means clean seawater and fresh water of a similar quality;
- 11) processing - means action that substantially alters the unprocessed product, including heating, smoking, curing, maturing, fermentation, drying, marinating, extraction, extrusion or a combination of those processes.

II REGISTRATION AND APPROVAL OF ESTABLISHMENTS

Registration of establishments

Article 3

The competent administration authority for veterinary matters and the administration authority for phyto-sanitary matters, as appropriate, shall enter into the register of registered establishments a company, any other legal person, entrepreneur or natural person engaged in production of and trade in food of animal origin, or in primary production of food of animal and plant origin with associated operations, at its request and in compliance with the regulation.

Approval of establishments

Article 4

The competent administration authority for veterinary matters (hereinafter referred to as: the competent authority), shall enter into the register of approved establishments, in compliance with the regulations, a business operator - at its request - referred to in the Article 3 of this Rulebook engaged in production of and trade in: meat of domestic ungulates, poultry, lagomorphs, farmed wild game, wild game, minced meat, meat products, mechanically separated meat, rendered animal fat, greaves, treated stomachs, bladders and intestines, gelatine, collagen, live bivalve molluscs, echinoderms, tunicates and marine gastropods, fishery products, frog legs and snails, milk and dairy products, eggs and egg products.

Hazard Analysis and Critical Control Points (HACCP)

Article 5

A business operator engaged in production of and trade in food of animal origin, not including the primary production with associated operations, shall put in place, maintain and continuously implement the procedures based on the following HACCP principles:

- 1) Identification of a hazard that must be prevented, eliminated or reduced to an acceptable level;
- 2) Identification of the critical control points at the step or steps at which control is essential for prevention or elimination or reduction of an identified hazard;
- 3) Establishing the threshold values at critical control points, separating an acceptable value from an unacceptable one in order to prevent, eliminate or reduce a hazard to an acceptable level;
- 4) Establishing and implementing effective monitoring procedures at critical control points;
- 5) Establishing corrective actions when monitoring indicates that a critical control point is not under control;

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- 6) Establishing procedures, which shall be carried out regularly, in order to check the efficiency of measures outlined in items 1) to 5).
- 7) Setting up of documentation and records, commensurate with the nature and size of the business operation concerned, in order to effectively present the implementation of measures referred to under items 1) to 6) of this paragraph.

In the course of operations, the business operator shall review the procedures put in place and make the changes necessary when a modification is made in the product, to the processing or production procedure.

III HYGIENE REQUIREMENTS IN PRIMARY PRODUCTION OF FOOD OF ANIMAL AND PLANT ORIGIN WITH ASSOCIATED OPERATIONS

General requirements

Article 6

A food business operator engaged in primary production of food of animal and plant origin with associated operations shall ensure protection of primary products, including the procedures applied to primary products in the course of their further treatment.

In addition to the protection referred to in the paragraph 1 of this Article, the food business operator shall also implement the measures as laid down by the relevant regulations with regard to the control of hazards in primary production and associated operations, and in particular the following:

- 1) control of contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and during the storage, handling and disposal of waste;
- 2) control of animal health and welfare, plant health protection of relevance for human health, including the measures as laid down by the programmes for the monitoring and control of zoonoses and zoonotic agents.

A food business operator rearing, harvesting or hunting animals or in production of primary products of animal origin shall also take the following measures, as appropriate:

- 1) to keep clean the establishments and premises used in primary production and associated operations, including the establishments and premises used for storage and handling of feed, and, where necessary after cleaning, to disinfect them in an appropriate manner;
- 2) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, conveyances and fishery vessels;
- 3) to ensure, as far as possible, the cleanliness of animals going to slaughter;
- 4) to use potable water or clean water, to prevent contamination of primary products;
- 5) to ensure that staff handling primary products receives training on the general food hygiene;
- 6) to prevent contamination from animals and pests;
- 7) to selectively collect waste and hazardous substances and provide temporary storage in line with relevant regulations, so as to prevent contamination;
- 8) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including the taking of precautionary measures when introducing new animals and reporting the suspected outbreaks of such diseases to the competent authority;
- 9) to keep records on the results of analyses carried out on samples taken from animals or other samples of relevance for human health;
- 10) to use feed additives and veterinary medicinal products correctly, in compliance with the relevant legislation.

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A food business operator producing or harvesting plant products shall take the measures that are in line with the type of activity, including the following:

- 1) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner the equipment, containers, crates and conveyances;
- 2) to ensure, where necessary, hygienic production, transport and storage conditions for the plant products;
- 3) to use potable water, or clean water, to prevent contamination of primary products;
- 4) to ensure that staff handling primary products receives training on the general food hygiene;
- 5) to prevent contamination from animals and pests;
- 6) to selectively collect waste and hazardous substances and provide temporary storage in compliance with relevant regulations, so as to prevent contamination;
- 7) to keep records on the results of analyses carried out on samples taken from plants or other samples of relevance for human health;
- 8) to use plant protection products and biocides correctly, in compliance with the relevant legislation.

Record keeping

Article 7

A food business operator shall keep and retain the records on the measures undertaken in order to control and monitor the hazards, in an appropriate manner and for a specific period of time, commensurate with the nature and volume of the business operations and make the relevant information from the records available to the business operator it delivers the products to.

A food business operator rearing animals for production of food or producing primary products of animal origin shall keep records on:

- 1) the nature and origin of feed fed to the animals;
- 2) the veterinary medicinal products or other treatments administered to the animals, administration dates, dates when the treatment ended and withdrawal periods;
- 3) the occurrence of diseases that may affect the safety of food of animal origin;
- 4) the results of any analyses carried out on samples taken from animals taken for diagnostic purposes, that are of relevance for human health;
- 5) the reports on checks carried out on animals or products of animal origin.

A food business operator producing or harvesting plant products shall, in particular, keep and retain records on the following:

- 1) any use of plant protection and nutrition products and biocides;
- 2) any occurrence of pests or diseases that may affect the safety of products of plant origin;
- 3) the results of analyses carried out on samples taken from plants or other samples of relevance for human health.

INSTRUCTIONS FOR GOOD HYGIENE PRACTICE IN PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

Article 8

The good hygiene practice in primary production of food of animal and plant origin and associated operations may be implemented in line with instructions, guides and manuals.

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The instructions, guides and manuals referred to in the paragraph 1 of this Article should contain at least the information on hazards that may arise in primary production of food of animal or plant origin, as appropriate, and associated operations, including the following:

- 1) the control of contamination, such as mycotoxins, heavy metals and radioactive material;
- 2) the use of water, organic waste and fertilisers;
- 3) the use of plant protection products and biocides and their traceability;
- 4) the use of veterinary medicinal products and feed additives and their traceability in an appropriate manner;
- 5) the preparation, storage, use and traceability of feed;
- 6) the disposal of dead animals and waste;
- 7) the protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and the obligation to notify the competent authority;
- 8) the procedures and methods to ensure that primary products of animal and plant origin are produced, packed, stored and transported in compliance with the hygiene requirements, including the effective cleaning and pest-control;
- 9) the measures relating to the cleanliness of animals for slaughter and production;
- 10) the measures relating to record-keeping.

IV HYGIENE REQUIREMENTS FOR CONSTRUCTION AND DESIGN OF ESTABLISHMENTS FOR PRODUCTION AND TRADE IN FOOD OF ANIMAL ORIGIN FOLLOWING THE PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

Site

Article 9

An establishment for production and trade in food of animal origin referred to in the Article 4 of this Rulebook may be constructed in sites that the appropriate planning documents identify as sites for such establishment type.

Establishment Area

Article 10

The area of the establishment referred to in the Article 4 of this Rulebook consists of the land, buildings and accompanying facilities used for regular purposes of an establishment for production and trade in food of animal origin.

The land area shall be proportionate with the capacity, number and size of the buildings in order to ensure functional connection among them as well as separation of unclean from clean part of the establishment's area.

The clean part of the establishment's area referred to in the paragraph 2 of this Article consists of the following:

- 1) buildings,
- 2) offices,
- 3) premises for production and trade in food of animal origin,
- 4) premises for storage of additives, spices and packaging materials,
- 5) premises or area for washing and disinfection of conveyances used for transport of food of animal origin.

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The unclean part of the establishment's area referred to in the paragraph 2 of this Article consists of the buildings or areas for the following:

- 1) reception and keeping of animals for slaughter,
- 2) washing and disinfection of conveyances used for transport of animals for slaughter,
- 3) collecting and storage of waste of animal origin,
- 4) primary treatment of wastewaters,
- 5) boiler room,
- 6) workshop for technical maintenance of equipment,
- 7) conveyances repair workshop.

The area of the establishment referred to in the paragraph 1 of this Article shall be surrounded by a fence at least 2 meters high, which prevents uncontrolled entry of persons and animals.

The area's entry and exit points shall be under control.

Cats, dogs and other animal species must not be introduced or kept in the establishment's area.

Access roads

Article 11

The access roads and paths within the establishment's area shall be wide enough to provide unhindered communication of conveyances and constructed from solid material, suitable for washing and cleaning, which includes construction of hydrants and drains for washing and cleaning of access roads and paths within the establishment area, in line with the type and capacity of the establishment's operations.

In the establishment area, clean roads and paths shall be separated from the unclean ones and they must not cross each other.

Clean paths referred to in the paragraph 2 of this Article are paths used for receipt and dispatch of finished products.

Unclean paths referred to in the paragraph 2 of this Article are paths used for delivery of waste of animal origin and other materials stored in the unclean part of the establishment's area.

All areas of the establishment that are not covered by concrete or asphalt shall be covered with greenery.

Layout

Article 12

The layout, design, construction, siting and size of food premises should provide the following:

- 1) adequate maintenance, cleaning and disinfection, prevention or reduction of air-borne contamination, and provide adequate working space to allow for the hygienic performance of all the operations;
- 2) prevent the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
- 3) efficient implementation of good food hygiene practices, including protection against contamination and pest control;
- 4) provide conditions for temperature-controlled handling and storage of sufficient capacity for keeping the products of animal origin at appropriate temperatures and designed to allow monitoring and recording of those temperatures.

Offices may be located outside the establishment area.

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The area for washing and disinfection of conveyances, the workshop for technical maintenance of equipment, the conveyances repair workshop and the boiler room may be located between the clean and unclean area of the establishment.

The area or place for washing of conveyances for transport of food of animal origin need not be provided in the establishment in case the business operator contracted a natural or legal person or an entrepreneur registered for washing of conveyances.

Technological course in the establishment

Article 13

The establishment for production and trade in food of animal origin referred to in the Article 4 of this Rulebook and premises in the establishment shall be designed and constructed so as to provide implementation of hygiene procedures according to which production course is directed from reception of raw material to release of a finished product.

The movement paths of staff, raw material and products as well as placement of equipment should prevent contamination of products of animal origin by physical or time separation of the operations.

The premises where products of animal origin are treated, processed or packaged must not be in direct communication with the outdoor area or areas that may jeopardize the safety of products of animal origin.

Maintenance of premises

Article 14

Premises in establishments for production and trade in food of animal origin shall be kept clean and in functional condition.

Lighting requirements

Article 15

Premises for production and trade in food of animal origin shall be equipped with adequate natural or artificial lighting. In order to provide natural lighting, un-tinted glass or other un-tinted materials shall be used in windows. The artificial lighting shall provide diffuse light that does not change the colour of the object lighted. Light sources should be distributed so as to scatter the light in the premises as equally as possible. The artificial light source shall be protected by a closed, transparent shield which must not be made of enamel or glass.

Light intensity is controlled by lux-meter.

Light intensity in specific workplaces and production premises should be as follows:

- 1) in stables and pens for accommodation of animals for slaughter – 100lx; in sites where animals are examined before slaughter 550lx at 90 cm from the floor surface;
- 2) in pens for animals suspected of having a disease 200lx above the whole area at 90 cm from the floor surface and at the examination site by the animal restraining box 550lx;
- 3) in places where hide is removed from the bovine head and where heads are removed from carcasses 200lx at the height where the operations concerned are performed;
- 4) at the place where bovine heads are washed 550lx;
- 5) at the place where bovine heads are examined 550lx;
- 6) at the place where offal is examined 550lx,
- 7) at the place where bovine carcasses or halves are examined 550lx at the height level of shoulder-joint and front legs;

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- 8) at the place where bovine carcasses or halves are washed 550lx at the height level of shoulder-joint and front legs;
- 9) at the place where bovine thoracal organs and liver are treated 550lx on the working surface of the table;
- 10) at the place where bovine carcasses, halves and organs retained are kept 550lx;
- 11) at the place where swine halves are examined 550lx, at the height level of mandibular lymph nodes,
- 12) at the place where swine thoracal and abdominal organs are examined 550lx at the height level of movable containers of the table for examination of offal;
- 13) at the place where swine tongue, thoracal organs and liver are examined 550lx at the working surface of the table;
- 14) at any place for veterinary examination of animals for slaughter and products of animal origin 550lx;
- 15) at the place where stab wounds on swine halves are treated 550lx at the height level where the stab wound is cut out;
- 16) at the place where swine carcasses or halves or organs retained are examined 550 lx at the height level of mandibular lymph nodes and containers for offal;
- 17) at any place where unclean parts are divided from clean parts, i.e. where more intensive light is necessary for hygienic product treatment (eg. Primary treatment of swine tongues, final treatment of swine halves or bovine quarters, etc.) 550 lx at the height level of front legs;
- 18) at rooms for cooling bovine and swine halves 110lx at the height level of front legs;
- 19) at rooms for cooling offal 220 lx at the lowest level of products stored;
- 20) in all production premises at least 220lx at the height level of working surfaces.

Ventilation requirements

Article 16

The premises for production and trade in food of animal origin shall have an appropriate system of natural or mechanical ventilation, water steam and unpleasant odour outlet. Inlets for fresh air supply shall be placed so as to prevent contamination of air by dust, unpleasant odour or other contaminated area agents. The inlets shall have filters and protective nets to prevent entry of insects and pests. The ventilation system shall be constructed so as to enable easy access to filters and other parts for cleaning or replacement.

Dressing room requirements

Article 17

The establishment for production and trade in food of animal origin, depending on the type and capacity of its operations, shall have a room or area where staff changes its clothes (dressing room), connected with the production premises by a closed corridor.

The dressing room shall have sanitary facilities for personal hygiene of staff (bathrooms and toilets), supplied with natural or artificial ventilation.

Dressing rooms and sanitary facilities in the clean part of the establishment's area shall be separated from the dressing rooms and sanitary facilities in the unclean part of the establishment's area.

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Every member of staff shall have his/her own closet/locker for civilian footwear and clothes and a separate closet or shelf for working footwear and clothes and seats fixed to the closet or fitted between the lines of lockers, made of materials that are easily washed and disinfected.

The closet/locker referred to in the paragraph 2 of this Article shall:

- 1) be made of material that is easily washed and disinfected,
- 2) be placed on a stand, with a top slanted forward under an angle,
- 3) have ventilation outlets.

The dressing room shall have premises or areas for collection of dirty and supply of clean protective clothes.

If necessary, the dressing rooms may have a special area or room for washing and drying of working footwear and protective aprons (hangers) with natural or artificial ventilation.

Sanitary facilities requirements

Article 18

Per every ten workers employed in a shift one lavatory meeting the requirements set by the Article 27 of this Rulebook shall be provided for washing hands in the bathroom, and one shower stall.

The shower cubicle shall meet the following requirements:

- 1) shower stall walls shall be covered by waterproof material of white or light colour and if they are prefabricated, they shall be made of corrosion-resistant materials of smooth and even surface;
- 2) a shower stall shall have cold and hot water, soap dish and soap;
- 3) a towel hanger and a clothes hanger shall be fitted at the entry into the shower stall,
- 4) the floor of the shower stall shall be slanted towards the drain at an appropriate angle and covered by a rubber or plastic mat.

Flush toilets (WC), separate for men and women, shall be constructed separately from the dressing rooms and bathrooms.

In establishments where dressing rooms are far from production premises, flush toilets shall be placed in the near vicinity of these premises, separated by a corridor and a buffer room.

The door between the anteroom of the flush toilets (buffer-room) and the room with stalls as well as the doors on the flush toilet stall partitions should open both ways (swing doors). The doors on flush toilet stall partitions shall be fitted 30 centimetres above the floor surface.

An appropriate number of lavatories, meeting the requirements set by the Article 27 of this Rulebook, shall be placed in the anteroom of the flush toilet for hand washing. The door at the entry into the anteroom should have an automatic door closer.

The following shall be provided in flush toilets:

No. of workers of the same gender	Number of toilet bowls
1 to 15	1
16 to 35	2
36 to 55	3
56 to 80	4
For every 30 workers above 80	1

Flushing of toilet bowls should be done by foot pedals. Up to one-third of all toilet bowls in men's flush toilets may be replaced with pissoirs, which should be fitted in a separate part of the flush toilet.

Requirements for staff dining room

Article 19

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An adequately equipped room (dining room) shall be provided for staff in establishments referred to in the Article 4 of this Rulebook.

The staff must not bring food into the production premises or dressing rooms.

Appropriately located rooms for smoking and rest of workers during the working hours shall be provided, with natural or artificial ventilation, hand washing facilities and benches or chairs.

Equipment sanitation premises requirements

Article 20

In establishments for production and trade in food of animal origin, appropriate area or premises shall be provided for cleaning, washing, disinfection and storage of equipment, depending on the capacity of the operations in the establishment concerned.

The floor, walls and ceilings of the area or premises referred to in the paragraph 1 of this Article shall be waterproof, of smooth surface, fitted with drainage in the floor, ventilation device and buffers mounted on walls.

The premises or area for washing and sanitation of equipment should be fitted with cold and hot water of minimum 83°C, a circle thermometer fitted onto the outlet of the hot water pipe, a source of light of a prescribed intensity and mats for equipment.

In case tankless water heater is used for washing and sanitation of containers, it shall be fitted into a room close to production premises, with appropriate ventilation. The tankless device shall have its own water steam outlet, circle thermometer and an opening made in order to control the pipes for hot water supply and wastewater discharge directly into the sewer, through a siphon.

There shall be a separate room or area with adequate equipment for storage of sanitation equipment and substances (tools, agents for cleaning, washing and disinfection, etc.)

Food washing premises requirements

Article 21

In establishments for production and trade in food of animal origin, appropriate area or premises shall be provided for food washing, depending on the capacity of the operations in the establishment concerned.

The equipment used for food washing should have cold or hot water supply.

Requirements for inspectors' room

Article 22

Where the competent authority finds it necessary, the business operator producing food of animal origin shall provide and equip a separate room for the veterinary inspectors.

V HYGIENE REQUIREMENTS FOR CONSTRUCTION AND DESIGN OF PREMISES FOR PRODUCTION AND TRADE IN FOOD OF ANIMAL ORIGIN

Indoor layout

Article 23

The layout and design of premises for production and trade in food of animal origin should make possible good hygiene practices, including protection against contamination in the course of all production or trade phases.

The premises shall meet the following requirements:

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- 1) materials used for the design of premises for production and trade in food of animal origin shall be resistant to wear and corrosion, easy to clean, wash and disinfect.
- 2) Floors should:
 - a. be made of solid, waterproof, non-toxic material, resistant to cleaning and disinfection agents, easy to clean, wash and disinfect and non-slippery;
 - b. have adequate slant towards drainage channels or drains;
 - c. be maintained so as to keep them undamaged;
- 3) areas and corners where floors and walls or two walls meet shall be rounded;
- 4) wall surfaces in premises for production and trade in food of animal origin should be maintained so as to keep them undamaged, made or covered up to the ceiling by a solid, waterproof and non-toxic material of even and smooth surface of light colour;
- 5) in premises and corridors where transport is done over the floors shall be fitted with buffers made from corrosion-resistant material or with appropriate parapets made of concrete or other material in order to prevent product contamination;
- 6) wall corners and pillars shall be protected with buffers made of corrosion-resistant materials or other appropriate materials of even and smooth surfaces, which shall be made at the same line as the wall surface;
- 7) ceilings and interior roof construction shall have even surfaces of light colour, except in premises where technological procedures require derogation;
- 8) ceilings and interior roof constructions should be maintained so as to keep them undamaged, constructed and designed so as to prevent contamination of raw material or products from the panelling material or condensation;
- 9) windows shall have the frame made from corrosion-resistant material and the bottom edge of the window's wall frame or the parapet of the bottom edge shall be slanted towards the floor at an angle of at least 25 degrees in order to prevent the accumulation of dirt.
- 10) windows that can be opened shall be fitted with protective nets that prevent entry of insects and pests, designed so as to provide easy maintenance;
- 11) windows shall be closed where open windows may let in the dust, unpleasant odour or smoke during the production;
- 12) doors shall be made from corrosion-resistant and non-absorbent material or other material that is easy to wash, and disinfect where necessary, and shall be kept in good repair;
- 13) door frames shall be covered by a corrosion-resistant material and designed so that the area of connection with the wall is at the same level with the wall surface;
- 14) outer door, or entry into the establishment shall close automatically and designed so as to prevent entry of rodents and other pests into the establishment and, where necessary, be fitted with an air-curtain;
- 15) the air curtain shall be designed so as to turn on automatically at opening;
- 16) surfaces (including the equipment surfaces) in premises and areas for production and trade in food of animal origin and in particular those in contact with the products, shall be maintained in good repair, be made of corrosion-resistant materials, easy to clean, wash and disinfect, where necessary.

VI HYGIENE REQUIREMENTS FOR MOVABLE AND TEMPORARY PREMISES

Premises layout

Article 24

Movable and temporary premises (tents, market stalls, conveyances for sale and vending machines) shall be sited, designed and constructed so as to make possible good hygiene practice, including the protection against contamination and pests during all phases of production or trade, as appropriate.

The movable and temporary premises referred to in the paragraph 1 of this Article, depending on the type of operation, shall meet the following requirements, where necessary:

- 1) have available appropriate area for maintaining adequate personal hygiene of staff (including the sanitary facilities, hand washing facilities and changing facilities);
- 2) surfaces (including the equipment surfaces) and in particular those in contact with food of animal origin shall be maintained in good repair and made of material that is corrosion-resistant, easy to wash and clean and disinfect, where necessary,
- 3) have available adequate conditions for hygienic handling and cleaning of food of animal origin;
- 4) have adequate supply of hot and cold water meeting the potable water requirements prescribed;
- 5) have available adequate premises or containers for hygienic storage and disposal of non-edible products and waste;
- 6) have available adequate equipment for maintaining and monitoring of temperature conditions for food of animal origin;
- 7) placed so as to avoid the risk of contamination in all handling phases.

VII TRANSPORT REQUIREMENTS

Article 25

Conveyances, containers and other facilities and equipment used for transport of food of animal origin shall be regularly washed, cleaned and maintained in good repair and condition in order to protect the food of animal origin against contamination, and shall be made so as to ensure easy cleaning washing and disinfection.

Receptacles in conveyances may be used only for transport of food of animal origin.

Where conveyances, containers, other facilities and equipment are also used for transport of other commodities in addition to food of animal origin or for transport of different types of food of animal origin at the same time, they shall be thoroughly cleaned between two different loading or unloading operations in order to eliminate the contamination risk.

Food of animal origin in bulk, liquid, granulate or powder form shall be transported in receptacles, containers or equipment reserved for the transport of food of animal origin. Such receptacles, containers or equipment shall be marked in a clearly visible and indelible manner, with "transport of food of animal origin" or with "for food of animal origin only".

Food of animal origin in conveyances, containers or equipment shall be placed and protected so as to minimise the risk of contamination.

Where transport of food of animal origin requiring a temperature regime in the course of transport, the conveyances, containers or equipment used for transport of food of animal origin shall be equipped with appropriate thermo devices, allowing reading and monitoring of temperatures during the transport.

VIII EQUIPMENT REQUIREMENTS

Article 26

The equipment that the food of animal origin comes into contact with:

- 1) should be kept in good repair and order, be effectively cleaned and, where necessary, disinfected;
- 2) cleaning and disinfection are to take place at a frequency sufficient to eliminate any risk of contamination;
- 3) should be installed so as to enable efficient cleaning of the equipment and the surrounding area;
- 4) should be kept in good repair and order, be made of smooth and solid material, corrosion-resistant, non-toxic, non-absorbing, odour-free, which is easily washed and disinfected, with the exception of disposable containers and packaging, in compliance with the relevant regulations;
- 5) its surfaces in contact with food of animal origin should be without any indentations, cracks, open joints, uneven edges and hidden corners or any damage, while all welded parts should be even, smooth and in the same level as surrounding area.

The food of animal origin as well as waste of animal origin may be transported by movable containers, channels with gravitation fall, pneumatically or by other adequate equipment that should be designed so as to prevent contamination and allow easy maintenance.

The equipment used for transport of food of animal origin must not be used for other purposes.

The equipment for keeping, storing and transport of food of animal origin must not be used for transport and conveyance of non-edible products.

Stands shall be provided for movable containers so as to prevent contamination of clean containers and raw materials or products of animal origin.

Movable containers for edible products, non-edible products and waste of animal origin shall be marked in a clearly visible way.

Movable containers used for reception and transport of waste of animal origin shall be designed so as to allow closing and, if necessary, locking.

Immovable containers shall have their own system for discharge of wastewaters after washing.

The equipment referred to in the paragraph 1 of this Article should be equipped with all appropriate control devices, in line with the technological requirements of the operations carried out in the premises.

Where chemical additives are used in order to prevent the corrosion of equipment and containers, these shall be applied in accordance with the good practice.

The devices for sanitation of knives, saws and other hand utensils shall be distributed evenly and installed in an appropriate number and shall be of appropriate form.

The sanitation device (sterilizer) shall have the flow of water of the lowest temperature of 83°C.

A thermometer shall be installed by the pipe for supply of hot water, overflow pipe and discharge pipe and water drain for discharge linked to the sewer through a terminated drain.

Hand washing facilities requirements

Article 27

In premises for production or trade in food of animal origin, hand washing facilities shall be made available and distributed regularly.

The hand washing facilities consist of the following:

48. RULEBOOK ON HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL OR PLANT ORIGIN

- 1) a basin made of stainless steel, driven by a pedal or some other appropriate means (photo-cells, sensors, etc.) with hot and cold water supply. The basin's water drain shall be connected to the sewer by a siphon.
- 2) a container for soap,
- 3) paper towels mounted above or beside the basin,
- 4) containers for disposal of used towels, placed immediately by the basin.

In production premises with static workplaces, hand washing facilities should be placed in the immediate vicinity of the workplace concerned.

In production premises with dynamic workplaces, an adequate number of regularly distributed hand washing facilities shall be provided.

IX WATER SUPPLY REQUIREMENTS

Water supply

Article 28

The establishment for production and trade in food of animal origin shall be supplied with water that meets the requirements set for potable water (from the municipal waterworks or personal water well) of adequate volume and with an appropriate pressure.

For steam production (boiler room), refrigeration, fire control and similar needs (technical water) water that does not meet the requirements set for potable water may be used, but its pipeline shall be completely separated from the pipeline with potable water and shall be visibly and clearly marked.

The technical water shall not come into contact and shall not mix with the potable water.

Water used for production of ice which becomes a part of or comes into contact with the food of animal origin shall meet the requirements set for potable water, or where it is used to chill whole fish, those set for clean water. The ice shall be made, stored and handled under conditions that shall protect it from contamination.

Steam used directly in contact with food must not contain any substance that may contaminate food and pose a hazard to human health.

Water used for cooling following the heat treatment in hermetically sealed containers must not be a source of contamination. Clean water may be used for washing whole fishery products, for external washing live bivalve molluscs, echinoderms, tunicates and marine gastropods.

Clean seawater may be used for live bivalve molluscs, echinoderms, tunicates and marine gastropods.

Where water referred to in paragraphs 7 and 8 of this Article is used, adequate facilities shall be made available for its supply.

Water taps

Article 29

An adequate number of hot and cold water taps for washing of equipment and premises shall be available in the establishment, in line with the type and the capacity of the establishment concerned.

The temperature of hot water for sanitation of equipment and premises shall be minimum 83°C at the tap.

Rubber hoses for washing, where not in use, shall be placed on holders mounted in suitable parts of walls, in immediate vicinity of water taps.

The pipelines for cold and hot water, steam, refrigeration and sewer shall be laid so as to prevent contamination of products by impurities and condensation and shall be insulated or covered by protection.

Water supply network protection

Article 30

In order to protect the water supply network against contamination that may arise from occurrence of negative pressure in the water supply system, negative pressure valves shall be installed where:

- 1) taps, to which rubber or plastic hoses for washing are attached, have thread screw or some other fixture,
- 2) hose ends are immersed in water, or, if its outlet is below the water level in the container.

Negative pressure valves shall be functional, placed immediately before the water tap or other fixture, and accessible for control.

Wastewater drainage

Article 31

All wastewaters from the establishment for production and trade in food of animal origin, with the exception of rainfall wastewaters, shall be appropriately treated prior to their discharge into the recipient (municipal sewer or natural recipient) and shall meet the requirements set by relevant legislation.

As a part of the treatment system, there shall be at least a grate with openings of up to 6mm in order to retain and collect waste of animal origin or other, appropriate system with the same effect, at the end point before the water is discharged into the recipient. Prior chopping or maceration of waste of animal origin is not allowed.

Waste of animal origin shall be collected and categorized in line with the requirements set by relevant legislation.

In premises where water is used, water drainage shall be provided so that wastewaters do not flow over the floors. In premises where wastewater channels are fully or partially open, the drainage shall be designed so as to prevent flow of wastewaters from a contaminated area towards or into a clean area.

Wastewaters from equipment and from floors shall be drained into the sewer directly. For drainage of water in all the premises (except in those with the temperature regime below 0°C) appropriate number of water drains shall be placed.

Shafts shall be secured so as not to let unpleasant odour out.

Drains shall be supplied with an efficient system that prevents return of unpleasant odour from the sewer.

Equipment used for treating edible parts (tables for treatment of thoracal organs, device for heat treatment of stomachs, bladder, etc) and static equipment for sanitation of utensils (standing sterilizer) shall have a terminated drainage into the sewer.

X STAFF PERSONAL HYGIENE REQUIREMENTS

Article 32

Only persons who do not suffer from, or do not carry an infectious disease may work in production and trade in food of animal origin, which is proved by a certificate on mandatory health examination performed by an authorized health organization, in compliance with the regulations.

48. RULEBOOK ON HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL OR PLANT ORIGIN

Persons suffering from infectious diseases or diseases that may be transferred by food, suffering from purulent skin and mucous membrane diseases, diarrhoea, open wounds shall not be allowed to enter the zone where food of animal origin is handled in case direct or indirect contamination of food of animal origin is possible.

A handler of food of animal origin, employed in all phases of production and trade, shall, without delay, report a disease or disease symptoms to the business operator in writing, and if possible, state the cause of the disease in question.

Other person may enter the premises for production of food of animal origin only if health requirements referred to in the paragraph 1 of this Article are met, which is certified by signing of a statement.

Personal hygiene of staff

Article 33

When working in establishments referred to in the Article 4 of this Rulebook, the staff shall use working clothes and footwear, use and maintain the utensils entrusted and abide by the requirements set for handling of food of animal origin.

In production premises where staff comes into direct contact with products of animal origin, the staff may work only in clothes and footwear that consists of the following:

- 1) in production, trade, packaging, loading and unloading of food of animal origin and equipment washing: trousers and blouse or overcoat, cap or head scarf and rubber or plastic aprons of white colour, rubber or plastic boots, overshoes or leather shoes and rubber or plastic gloves if product protection is required;
- 2) in animal slaughter and preparation of fish for processing: a working overall or trousers and blouse, cap and rubber apron of white colour and boots;
- 3) in loading and unloading of meat: overcoat, cap or head scarf of white colour, apron, boots or overshoes made of rubber or plastic;
- 4) in storage of edible products of animal origin: overcoat or blouse, cap or head scarf of white colour and apron made of plastic or rubber;
- 5) in unloading of animals and preparation of animals for slaughter, unloading of non-edible products of animal origin and wastes and technical maintenance of premises, devices and equipment: coloured trousers and blouses, overcoat or overall, coloured cap or head scarf and waterproof footwear.

Staff working in premises with temperature below 0°C shall wear white working clothes over the protective clothes.

Working clothes are made of material that can be boiled and ironed.

Staff change their working clothes on daily basis or more often if the nature of the operations requires it.

Washing and drying shall be provided for hygienic maintenance of working clothes using the establishment's own laundry-room or services of other laundry shops.

Utensils shall be made of corrosion-resistant metal or plastic or other material prescribed.

Utensils shall be maintained in a proper hygienic condition during work. Depending on the nature of work and after each dirtying, the utensils shall be cleaned with water of minimum 83°C.

After work, utensils shall be cleaned and washed and placed in cassettes or closets provided for that purpose.

Staff working in direct production and trade in food of animal origin shall have trimmed hair, be shaven and have tidy hair. Fingernails on hands shall be always clean and tidily cut. Staff wearing longer tidy hair shall use hair nets or scarves during work.

48. RULEBOOK ON HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL OR PLANT ORIGIN

Wearing wrist watches and jewellery and use of cosmetics shall be prohibited during work in production premises.

Prior to entering the toilet, utensils and a part of protective clothes (apron and overcoat) have to be left at a specific place, and hands have to be washed after using the toilet.

Staff employed in production and trade in products of animal origin shall be healthy and must not be carriers of disease agents or contaminants of food of animal origin.

Injuries on hands shall be protected by rubber gloves or finger cover.

XI STAFF TRAINING REQUIREMENTS

Article 34

Food business operators shall, depending on the type of operation performed by a staff member when handling food of animal origin during production and trade, provide the following training:

- 1) on elementary hygiene requirements for feed of animal origin and personal hygiene;
- 2) on maintaining and implementation of procedures based on HACCP principles.

During production and trade, the handlers of food of animal origin shall have a certificate on completion of the training referred to in the paragraph 1 of this Article.

The training referred to in the paragraph 1 of this Article shall be organized at least once in three years, or at shorter intervals where the competent authority deems it necessary.

XII HEAT TREATMENT

Article 35

The food of animal origin produced and placed on the market in hermetically sealed containers shall be produced so that during processing of unprocessed product or during further processing of a processed product every part of the product treated is subjected to a given temperature for a given period of time so that contamination of product during the heat treatment process is prevented.

The business operator producing food referred to in the paragraph 1 of this Article shall regularly check the main parameters (temperature, pressure, sealing, microbiology criteria), depending on the technological process, including by the use of automatic reading of values during the heat treatment procedure.

The heat treatment process used shall be in compliance with the internationally recognized standards (pasteurisation, ultra high temperature or sterilisation).

XIII GENERAL REQUIREMENTS FOR FOOD OF ANIMAL ORIGIN

Article 36

A food business operator producing food of animal origin should not accept and use raw materials and ingredients, other than live animals, if they are known to be, or are presumed to be, contaminated with parasites, pathogenic microorganisms, toxic or other foreign substances to such an extent that, even after application of customary processing procedures, the final product would be unfit for human consumption.

Raw materials and ingredients stored in establishments for production of food of animal origin shall be kept in appropriate conditions and in the manner that prevents contamination and harmful deterioration.

At all stages of production and trade the food of animal origin shall be protected against any contamination likely to render the food harmful for human health or unfit for human consumption.

48. RULEBOOK ON HYGIENE REQUIREMENTS FOR FOOD OF ANIMAL OR PLANT ORIGIN

The business operator shall implement adequate procedures for protection against pests and set up an efficient system preventing domestic animals from having access to places where food of animal origin is produced and traded.

Raw materials, ingredients, intermediate products and finished products of animal origin that may be favourable for the reproduction of pathogenic micro-organisms or the formation of toxins should be kept at temperatures that shall prevent occurrence of a risk to human health and the cold chain is not to be interrupted.

By derogation from paragraph 5 of this Article, handling food of animal origin during production and trade may, for brief and limited period of time, be outside the temperature control, provided that such handling does not pose a risk to human health.

Business operator producing and trading food of animal origin should provide adequate premises for separate storage of raw materials from processed products as well as adequate separate storage space for storing them in refrigeration devices or cold rooms.

Where food of animal origin should be kept at chilled temperature, it is to be cooled immediately after the heat treatment, or in case heat treatment is not used in the final treatment stage, to a temperature that shall prevent occurrence of a risk to human health.

Food of animal origin shall be thawed at suitable temperature so as to minimise the risk of growth of pathogenic microorganisms or the formation of toxins. Where liquid from thawing might pose a risk to human health, it shall be drained so as to prevent contamination. After thawing, the food of animal origin shall be handled so as to minimise the risk from growth of pathogenic microorganisms or the formation of toxins.

Hazardous and/or non-edible substances, including animal feed, shall be adequately labelled and stored in separate rooms or containers that may be locked.

XIV REQUIREMENTS FOR WRAPPING AND PACKAGING OF FOOD OF ANIMAL ORIGIN

Article 37

For wrapping and packaging food of animal origin, the business operator may use materials, packaging and items that meet the requirements set.

Materials, packaging and items referred to in paragraph 1 of this Article shall be stored so as to prevent occurrence of a risk of contamination.

Procedures for wrapping and packaging food of animal origin shall be carried out so as to prevent contamination of the products.

Reusable materials, packaging and items for wrapping and packaging the food of animal origin shall be designed so that they are easy to clean and, where necessary, to disinfect.

XV REQUIREMENTS FOR WASTE FROM FOOD OF ANIMAL ORIGIN

Article 38

Waste of food of animal origin, non-edible by-products and other refuse shall be removed without delay from rooms where food of animal origin is placed, in order to avoid their accumulation.

Waste of food of animal origin, non-edible products and other refuse shall be disposed in containers that may be closed. The containers shall be kept in good repair and order and be designed so as to enable efficient washing, cleaning and disinfection.

Separate rooms or space shall be provided for storage of waste of food of animal origin, non-edible products and other refuse, and shall be designed so as to enable efficient cleaning and protection against entry of animals and pests.

Waste of food of animal origin, non-edible products and other refuse shall be destroyed in accordance with the relevant legislation and must not be a direct or indirect contamination source.

XVI FINAL PROVISIONS

Article 39

The day this Rulebook enters into force the Rulebook on requirements to be met by slaughterhouses for slaughter of imported animals (Official Gazette of the Federal Republic of Yugoslavia 53/89) and the Rulebook on requirements to be met by establishments for animal slaughter, treatment, processing and storage of food of animal origin (Official Gazette of the Federal Republic of Yugoslavia 53/89) shall be repealed as well as provisions of the Rulebook on requirements to be met by slaughterhouses, meat processing establishments, fish processing establishments and dairies (Official Gazette of the Socialist Republic of Montenegro 34/83).

Article 40

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

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Ministry of Agriculture, Forestry and Water Management

Minister

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