

FOOD SAFETY LAW

I. GENERAL PROVISIONS

Subject-matter of the Law

Article 1

This Law shall regulate the basis and principles for assuring the high level of protection of human life and health and consumers' interest, and requirements for production and circulation of safe food and feed.

This Law shall be based upon the common principles of reliable, scientifically based and efficient implementation of procedures related to selection and implementation of measures in the matters of food and feed safety, compatible with the requirements for protection of human life and health, animal health and welfare, plant health, and protection of environment.

Application of the Law

Article 2

This Law shall apply to all stages of production and circulation of food or feed.

This Law shall not apply to:

- primary production of food or feed for private domestic use,
- preparation, handling or storage of food for private domestic use or feed for animals used for production of food for private domestic use;
- direct supply of consumers with small quantities of primary products;
- feed for animals which are not used for production of food.

Principle of Free Trade

Article 3

This Law shall be applied in accordance with the principles of free trade, providing the high level of protection of human life and health.

Definition of food

Article 4

For the purposes of this Law, food shall mean any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

The food referred to in paragraph 1 of this Article shall also include water, notably:

- water used for public water supply as a drinking water;

- water used or incorporated into food during its production, preparation or processing;
- bottled water or otherwise packaged water, table water, spring water or mineral water.

The food referred to in paragraph 1 of this Article shall also include drink and any substance incorporated into the food during its production, preparation or processing, chewing gum, as well as supplements and food of mineral origin.

For the purpose of this Law, food shall not include the following:

- feed;
- live animals, unless they are intended for placing in the circulation for human consumption;
- plants prior to harvesting, picking or collection of fruits;
- medicines and medicinal products;
- cosmetic products;
- tobacco and tobacco products;
- narcotics or psychotropic substances;
- residues and contaminants.

Classification of Food **Article 5**

Based on the origin, food shall be classified as:

- food of animal origin;
- food of plant origin;
- composite food that contains products of plant origin and processed products of animal origin (hereinafter referred to as: composite food) and
- other food.

Definitions **Article 6**

The terms used in this Law shall have the following meaning:

1. **food or feed business** shall mean any activity, whether carried for profit or not, and whether public or private, carried out at any stage of production, processing, working, treatment, packaging, repackaging, wrapping, storage, transportation or distribution of food or feed;
2. **food or feed business operator** shall mean any company, other legal person, entrepreneur or natural person responsible for implementation and carrying out of prescribed requirements for ensuring safety of food and feed within their businesses.
3. **feed** shall mean any substance or product of plant or animal origin, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
4. **retail sale** shall mean:

- the handling and/or processing of food, preparation, storage and serving of food at the point of sale or delivery to the final consumer in catering facilities, or in facilities for collective and public nutrition, and catering;
 - sale to a final consumer in shops, supermarkets, mega markets and other sale facilities for individually labeled packaged food;
5. **wholesale** shall mean handling of food or feed, comprising collection, sorting, keeping, storage, transportation and distribution of food or feed for further sale or processing;
 6. **risk** shall mean the probability and severity of an adverse effect on health and life of humans and animals;
 7. **risk analysis** shall mean a process consisting of three interconnected components: risk assessment, risk management and risk communication;
 8. **risk assessment** shall mean a scientifically based process comprising hazard identification, hazard characterization, exposure assessment and risk characterization, which includes assessment of adverse effects on health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food;
 9. **risk management** shall mean a process, independent from risk assessment, of considering possible risk-related activities, in consultation with interested parties, by taking into account risk assessment and other relevant factors, as well as, selection of appropriate prevention and control measures;
 10. **risk communication** shall mean the interactive exchange of information and opinions through the risk analysis process as regards hazards and risks, risk-related factors and risk identification, among risk assessment authorities, responsible authorities, risk management authorities, consumers, food and feed business operators and other interested parties, including the professional interpretation of risk assessment results and the basis of risk management decisions;
 11. **hazard** shall mean a biological, chemical or physical agent in, or condition of food or feed with a potential to cause an adverse effect on life and health of humans and animals;
 12. **supplement** shall mean a food additive representing concentrated source of micronutrient that has physiological and nutritive effect;
 13. **traceability** shall mean the ability to trace a food, feed, food-producing animal, raw material or substance intended to be incorporated into food or feed, through all stages of production and circulation;
 14. **production of food** shall mean a process comprising all stages from the receipt of components, preparing, working, treatment, processing and packaging, as well as storage of food with the producer;
 15. **circulation** shall mean a process of handling of food after completion of the production process, which comprises storage, transportation, distribution, sale, displaying for the purpose of sale, exchange and conferring of food and feed, exports, imports, except for scientific-research purposes;

16. **primary production** shall mean the production, growing and/or rearing of agricultural products in plant production, animal husbandry and fishery, including harvesting and picking of fruits, milking, animal raising prior to slaughter, hunting, fishing and collection of indigenous fruit and plants from nature, including also, handling, transportation and storage of primary products at the place of production, resulting in a product which has not been technologically treated after harvesting, collection of fruits or quarry, excluding simple physical treatment;
17. **primary product** shall mean a product obtained through primary production;
18. **processing** shall mean a process of modification of primary product through the application of certain physical and chemical procedures;
19. **packaged food** shall mean a food in packaging;
20. **consumer** shall mean a person consuming food;
21. **facility** shall mean a business unit of a food or feed business operator which has been approved for performing activity or part of the activity;
22. **food or feed hygiene** shall mean a group of prescribed measures and requirements, whose fulfillment is necessary for control of hazards and ensuring that food or feed are fit for human or animal consumption, in accordance with their intended use;
23. **certification** shall mean a process comprising verification of conformity of food and feed with prescribed requirements and issuing of a certificate of conformity in a written form;
24. **monitoring of food and feed safety** shall mean a systematic implementation of prescribed and planned activities, which are undertaken for the purpose of obtaining general information on food and feed safety;
25. **food of animal origin** shall mean a food produced from animals, or originating from animals in a processed or unprocessed state (in specific cases, it may also include live animals, such as lobster or live shells);
26. **food of plant origin** shall mean a food originating from plants in a processed or unprocessed state;
27. **composite food** shall mean a food containing products of plant origin and processed products of animal origin;
28. **other food** shall mean a food of mineral origin, water, drinks, chewing gum, etc.;
29. **genetically modified organism** shall mean an organism, except human, whose genetic base has been altered using the recombinant DNA technology - genetic engineering (hereinafter referred to as: GMO)

Application of Other Laws

Article 7

Provisions of the law that govern general administrative procedure shall apply to all procedures administered pursuant to the provisions of this Law, unless otherwise provided by this Law.

II. RESPONSIBILITIES FOR ENFORCEMENT OF THE LAW

Responsible Authorities

Article 8

State administration activities in the food and feed safety area shall be performed by:

- ministry responsible for agricultural matters (hereinafter referred to as: the Ministry of Agriculture);
- ministry responsible for health matters (hereinafter referred to as: the Ministry of Health);
- state administrative authority responsible for veterinary matters;
- state administrative authority responsible for phytosanitary matters.

Performing of certain activities of public interest within the responsibilities of state administrative authorities referred to in paragraph 1 of this Article may be entrusted to authorized legal persons, in accordance with the law.

Responsibilities

Article 9

The Ministry of Agriculture shall, when performing activities referred to in Article 8, paragraph 1, item 1 of this Law, adopt annual control plan, monitoring plan, plan for managing emergency situations in the area of safety of food of plant origin at the primary production level, food of animal origin, composite food and feed, decide upon the appeals lodged against decisions issued in the first-instance procedure, and shall cooperate with international organizations and responsible authorities of other states in the food safety area, and perform other activities in accordance with this Law.

The Ministry of Health shall, when performing activities referred to in Article 8, paragraph 1, item 2 of this Law, adopt annual control plan, monitoring plan, plan for managing emergency situations in the area of safety of food of plant origin after the primary production, composite food and other food, cooperate with international organizations and responsible authorities of other states in the food safety area, determine fulfillment of prescribed requirements, issue and withdraw approvals and/or consents to perform activities to business operators dealing with food of plant origin after primary production, composite food and other food, and shall perform control, inspectoral supervision and other activities in accordance with this Law.

State administrative authority responsible for veterinary matters referred to in Article 8, paragraph 1, item 3 of this Law shall, for the purpose of enforcing this Law, prepare professional bases for annual control plan, monitoring plan, plan for managing emergency situations in the area of safety of food of animal origin, composite food and feed, adoption of regulations within its responsibilities, as well as determine fulfillment of prescribed requirements, issue and withdraw approvals to perform activities to business operators dealing with food of animal origin, composite food and feed after primary production, and shall perform control, inspectoral supervision and other activities in accordance with this Law.

State administrative authority responsible for phytosanitary matters referred to in Article 8, paragraph 1, item 4 of this Law shall, for the purpose of enforcing this Law, prepare professional bases for annual control plan, monitoring plan, plan for managing emergency situations in the area of safety of food of plant origin at the primary production level, adoption of regulations within its responsibilities, as well as determine fulfillment of prescribed requirements, perform control, inspectoral supervision and other activities in accordance with this Law.

Division of Responsibilities

Article 10

Ministry of Health shall perform activities referred to in Article 8, paragraph 1, item 2 and Article 9, paragraph 2 of this Law in the area of safety of food of plant origin after primary production, composite food and other food in production, international trade, wholesale, retail sale, as well as of individually labeled packaged food of animal origin and composite food in retail sale.

State administrative authority responsible for veterinary matters shall perform activities referred to in Article 8, paragraph 1, item 3 and Article 9, paragraph 3 of this Law in the area of safety of food of animal origin, composite food and feed in production, international trade, wholesale, retail sale of meat, fish and other aquaculture products.

State administrative authority responsible for phytosanitary matters shall perform activities referred to in Article 8, paragraph 1, item 4 and Article 9, paragraph 4 of this Law in the area of safety of food of plant origin at the primary production level.

The Government of Montenegro (hereinafter referred to as: the Government) shall determine types and classification of composite food in a separate regulation, based on a proposal of the Ministry of Agriculture and the Ministry of Health.

Regulations of the Ministry of Agriculture

Article 11

The Ministry of Agriculture shall, for the purpose of enforcing this Law and following obtaining of an opinion from the Ministry of Health, adopt regulations governing:

- manner of processing and removal of food of plant origin at the primary production level, food of animal origin, composite food and feed which does not fulfill prescribed safety requirements;
- monitoring of safety of food of animal origin, composite food and feed, in order to determine presence of microbiological, chemical and biologic contaminants, additives and other ingredients and substances and assess the risk to life and health of humans and animals;
- hygiene requirements for food of plant origin at the primary production level and for food of animal origin, composite food and feed during all stages of production and circulation.

In addition to the regulations referred to in paragraph 1 of this Article, Ministry of Agriculture shall also adopt regulations governing:

- manner of performing examination of food of animal origin, composite food or feed in production and circulation;
- manner of performing examination of food of plant origin at the primary production level;
- microbiological criteria on allowed types and quantities of microorganisms, parasites, bacterial toxins and histamine dangerous for health in feed; and
- other regulations based on this Law.

Regulations of the Ministry of Health

Article 12

The Ministry of Health shall, for the purpose of enforcing this Law and following obtaining of an opinion from the Ministry of Agriculture, adopt regulations governing:

- microbiological criteria on allowed types and quantities of microorganisms, parasites, bacterial toxins and histamine dangerous for health in food;
- microbiological criteria for hygiene, methods for determining and evaluation;
- allowed quantities of heavy metals, metalloids, residues of pesticides, veterinary medicines, micro-toxins and other substances harmful to human health in food;
- allowed levels of radionuclide concentration in food;
- manner of processing and removal of food of plant origin after primary production, composite food and other food which does not fulfill prescribed safety requirements;
- monitoring of safety of food of plant origin after primary production, composite food and other food, in order to determine presence of microbiological, chemical and biologic contaminants, additives and other ingredients and substances and assess the risk to human life and health;

- manner of sampling and methods of performing water analysis;
- hygiene requirements for food of plant origin after primary production, composite food and other food during in any stage of production and circulation;
- safety requirements for food treated with ionizing radiation;
- safety requirements for food supplements.

In addition to the regulations referred to in paragraph 1 of this Article, Ministry of Health shall also adopt regulation governing manner of performing examination of food of plant origin after primary production, composite food and other food, as well as, other regulations pursuant to this Law.

National Council for the Assessment of Food Safety

Article 13

The National Council for the Assessment of Food Safety (hereinafter referred to as: the Food Council) shall be established for the purpose of continuous monitoring and assessment of food and feed safety with the aim of improving level of protection of human and animal life and health, developing proposals for decision making regarding professional matters, providing scientific and professional assistance in decision making, as well as, preparing regulations in the food and feed safety area.

The Food Council shall:

- analyze status and achievements in the food or feed safety area based on the available information;
- provide professional advice, expert and scientific support in order to enhance food or feed safety;
- propose undertaking of measures in order to eliminate food or feed related risks;
- provide opinions on draft and proposal laws, other regulations and general acts in the food or feed safety area;
- provide scientific and professional opinions during risk analysis, development and adoption of measures for elimination of risk and other measures in the food or feed safety area;
- cooperate with responsible state administrative bodies and authorities, and international institutions in the area of scientific and professional information exchange;
- provide proposals for informing, participation of public and education on significance of food and feed safety;
- undertake other tasks laid down in the act on establishment of the Food Council in accordance with this Law.

When performing tasks referred to in paragraphs 1 and 2 of this Article, the Food Council shall cooperate with ministries, responsible state administrative bodies and authorities.

Membership and Manner of Work of the Food Council
Article 14

Food Council shall be established by the Government of Montenegro.

Food Council shall have a president and 10 members, with a four year mandate, appointed by the Government based on a proposal from responsible authorities referred to in Article 8 of this Law.

Eminent public, scientific and professional individuals in the areas related to food or feed safety shall be primarily appointed as members of the Food Council.

Work of the Food Council shall be public.

Manner of work and organization of the Food Council shall be prescribed in detail in the internal rulebook of the Food Council.

The Food Council shall submit to the Government a report on its work at least once a year.

Professional and administrative-technical tasks for the Food Council shall be performed by the Ministry of Agriculture and the Ministry of Health based on a parity principle.

III. GENERAL PRINCIPES

1. PRINCIPLE OF RISK ANALYSIS

Risk Assessment
Article 15

In order to achieve the general goal of providing a high level of protection of human life and health, the measures implemented in accordance with this Law shall be based on the risk assessment, unless this is not possible due to the circumstances or the nature of measure as such.

Risk assessment shall be based on available and accessible scientific evidence and insights and shall be carried out in an independent, objective and transparent manner.

Risk assessment shall be carried out by the Food Council.

Risk Management
Article 16

Risk management shall be performed in such a manner as to ensure that preventive measures, surveillance and controls undertaken to reduce, eliminate or prevent the risk to human health in consumption of food are based on the results of risk assessment and other factors of relevance for elimination of risk, and to be efficient, impartial and appropriate.

Risk management shall be carried out by responsible authorities referred to in Article 8 of this Law, through surveillance, control and implementation of preventive measures.

Risk Communication
Article 17

Risk communication shall comprise an interactive exchange of information and opinions through the risk assessment process between the Food Council and the authorities responsible for the risk management referred to in Article 8 of this Law, other organizations and interested parties, consumers and food and feed business operators.

2. PRECAUTIONARY PRINCIPLE

Article 18

In specific circumstances where, following an assessment of available information, the possibility of harmful effects of food and feed on health of humans and animals is identified, and there is also a scientific uncertainty with respect to ensuring high level of protection of health, responsible authorities referred to in Article 8 of this Law shall undertake temporary risk management measures, until scientifically based opinions necessary for clarification of scientific uncertainty and implementation of comprehensive risk assessment are obtained.

Measures referred to in paragraph 1 of this Article shall correspond to the risk and shall not restrict trade in food or feed more than necessary to achieve the efficient protection of human life and health.

Undertaken measures shall be reviewed within an appropriate period of time corresponding to the identified risk.

3. PRINCIPLE OF TRANSPARENCY

Article 19

Where there is a reasonable doubt that food or feed may present a risk to human or animal health, responsible authorities referred to in Article 8 of this Law shall inform the public of the type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate such risk

4. PRINCIPLE OF PARTICIPATION OF THE PUBLIC

Public Discussion

Article 20

During the preparation, evaluation of effects and amendments of regulations or implementation of measures under this Law, the authority responsible for adoption of the regulation or the state administrative authority responsible for implementation of measures shall organize and carry out public discussions.

5. PRINCIPLE OF PROTECTION OF CONSUMERS' INTERESTS

Article 21

The consumers shall be informed of the content, characteristics, safe use and the manner of utilization of food through adequate labeling and marking of food, instructions and other documents accompanying food, in order to prevent fraudulent or deceptive practices with respect to the content, changes in the content, other characteristics and procedures with respect to food, which may mislead the consumer.

The manner of informing of consumers referred to in paragraph 1 of this Article, documentation and content of the accompanying documentation for food of plant origin at the primary production level, food of animal origin, composite food and feed shall be prescribed in the regulation issued by the Ministry of Agriculture, or in the case of food of plant origin after primary production, composite food and other food in the regulation of the Ministry of Health.

IV. FOOD SAFETY

1. FOOD SAFETY REQUIREMENTS

Safe Food Article 22

It shall be prohibited to produce and place on the market food that is not safe.

Food shall be deemed to be safe if it is not considered to be harmful to human health, and if it is fit for human consumption, if properly used.

Detailed Requirements for Determining Food Safety Article 23

When determining food safety, the following shall be considered:

- fulfillment of prescribed requirements in each stage of production and circulation, and requirements for handling, keeping and displaying of food prior to sale to the consumer, as well as the requirements for preparation and consumption of food in accordance with its intended use;
- information provided to the consumer, including information on the label and conformity thereof with the producer's specification, or other information generally available to the consumer concerning the prevention of harmful effects on human health from a particular category of food.

When determining whether food is harmful to human health, the following shall be taken into account:

- possible direct or indirect, short-term or long-term, adverse effects of food on the health of consumers, and possible effects upon future generations,
- possible cumulative toxic effect,
- particular health sensitivity of a specific category of consumers, where the food is intended for that category of consumers.

Unfitness of food for human consumption shall be determined based on the intended use of food, for reasons of possible contamination, whether by extraneous matter or otherwise (putrefaction, deterioration or decay, etc.).

When food determined to be unsafe is a part of a batch, lot, or consignment of food of the same category and description, all food in such batch, lot, or consignment shall be considered to be unsafe, unless proven otherwise.

Unsafe Food Article 24

Food shall be considered unsafe for human consumption if:

- 1) it contains microorganisms, parasites, bacterial toxins or histamine in larger quantities than prescribed;
- 2) it contains natural toxins or other natural toxic substances in larger quantities than prescribed;
- 3) it contains heavy metals, metalloids, residues of pesticides, veterinary medicines, micro-toxins and other substances in larger quantities than prescribed;
- 4) it contains additives which may not be used in a certain type of food, or if content of allowed additives in the food is higher than prescribed;
- 5) it contains radionuclide above the prescribed limit, or if it is polluted by radiation over the permitted limit;
- 6) the packaging, materials, and articles coming in contact with food do not fulfill prescribed requirements;
- 7) it derives from animals that were not examined before and after slaughter, and when meat was not marked in accordance with the regulations;
- 8) it derives from diseased or dead animals, or animals for which slaughter and further slaughterhouse treatment are not allowed regardless of the reason;
- 9) due to physical, chemical, microbiological or other processes, sensory characteristics of food (taste, smell, color, appearance, structure, etc.) are changed;
- 10) it contains substances which are not toxicologically evaluated, verified, and safe for human consumption;
- 11) it contains mechanical impurities;
- 12) packaging is damaged in such a way that microbiological and chemical changes of food may occur;
- 13) it was not produced, processed, packed, stored or distributed in a prescribed manner;
- 14) it is not labeled and marked in a prescribed manner;
- 15) it does not fulfill prescribed nutrition content requirements.

2. FEED SAFETY REQUIREMENTS

Safe Feed Article 25

It shall be prohibited to produce and place on the market feed which is not safe and to feed food-producing animals with such feed.

Feed shall be deemed to be safe if it fulfills prescribed requirements.

Detailed requirements that must be fulfilled for the feed to be deemed safe shall be prescribed in a regulation issued by the Ministry of Agriculture.

Unsafe Feed Article 26

Feed shall be deemed to be unsafe if:

- it has an adverse effect on animal or human health;
- the products derived from food-producing animals are unsafe for human consumption.

When feed determined to be unsafe is part of a batch, lot or consignment of feed of the same category and description, it shall be presumed that all feed in such batch, lot, or consignment is unsafe, unless proven otherwise.

Detailed Requirements for Determining of the Unsafe Feed Article 27

Feed shall be considered unsafe if:

- 1) it contains microorganisms, parasites, bacterial toxins or histamine in larger quantities than prescribed;
- 2) it contains natural toxins or other natural toxic substances in larger quantities than prescribed;
- 3) it contains heavy metals, metalloids, residues of pesticides, veterinary medicines, micro-toxins and other substances harmful to human and animal health in larger quantities than prescribed;
- 4) it contains additives which may not be used in a certain type of feed, or if content of allowed additives in the feed is higher than prescribed;
- 5) it contains radionuclide above the prescribed limit, or if it is polluted by radiation over the permitted limit;
- 6) the packaging, materials, and articles coming in contact with feed do not fulfill prescribed requirements;
- 7) due to physical, chemical, microbiological or other processes, sensory characteristics of feed (taste, smell, color, appearance, structure, etc.) are changed;
- 8) it contains substances which are not toxicologically evaluated, verified, and safe for animal feeding;
- 9) it contains mechanical impurities;
- 10) packaging is damaged in such a way that microbiological and chemical changes of feed may occur;
- 11) it was not produced, processed, packed, stored or distributed in a prescribed manner;
- 12) it is not labeled and marked in a prescribed manner;
- 13) it does not fulfill prescribed nutrition content requirements.

3. PROHIBITION OF CIRCULATION

Article 28

When food or feed may represent an immediate threat to life and health of humans and animals, or when food or feed do not fulfill prescribed requirements, and there are reasons to suspect the safety of food or feed, responsible state administrative authorities referred to in Article 8 of this Law may order restriction or prohibition of circulation of food or feed, or withdrawal of food or feed from the circulation until threat or suspicion in the safety of food are removed.

Measure for restriction and prohibition of circulation referred to in paragraph 1 of this Article shall be prescribed in the order issued by the Ministry of Agriculture or the Ministry of Health.

State administrative authorities referred to in paragraph 2 of this Article may, depending on the nature of risk referred to in paragraph 1 of this Article, issue the instruction for implementation of urgent measures in order to avoid the immediate threat to human health and life.

4. LABELING, MARKING, PRESENTATION AND ADVERTISING

Labeling and Marking

Article 29

Food or feed must be labeled and marked in production and circulation. Data contained in the declaration and marks must correspond to the data specified in the producers' specification and requirements prescribed in this Law and regulations issued based on this Law.

Declaration or mark must contain the data which enable traceability of food or feed, raw materials, material and substances which are being incorporated in food or feed, food-producing animals and final products, in all stages of production and circulation.

Declaration shall not contain the data assigning medical characteristics to food or feed.

Declaration or data presented in the declaration for food or feed being placed in the circulation must be written in the language officially used in Montenegro.

Detail requirements for content, type of the data and manner of their presentation in the declaration, as well as manner of labeling of food of plant origin at the primary production level, food of animal origin, composite food and feed shall be prescribed in the regulation issued by the Ministry of Agriculture, or in the case of food of plant origin after primary production, composite food and other food in the regulation issued by the Ministry of Health.

Presentation and Advertising

Article 30

Advertising and presentation of food or feed, manner of designing, displaying of food or feed, as well as information on food or feed available through print-media and other media must not mislead the consumer or animal keeper.

It shall be prohibited to assign medical characteristics to food or feed during advertising or presentation.

Detailed requirements for advertising and presentation of food of plant origin at the primary production level, food of animal origin, composite food and feed shall be prescribed in the regulation issued by the Ministry of Agriculture, or in the case of food of plant origin after primary production, composite food and other food in the regulation issued by the Ministry of Health.

5. MATERIALS, PACKAGING AND ITEMS COMING INTO CONTACT WITH FOOD OR FEED

Article 31

Materials, packaging and items coming into contact with food or feed shall comprise the products that are in the direct contact with food or feed or those coming into contact with food or feed.

Materials, packaging and items referred to in paragraph 1 of this Article shall be produced in accordance with the good manufacture and hygiene practice, in such a manner as to prevent migration of their ingredients into food or feed in quantities which may harm human or animal health, and change the content or sensory characteristics of food or feed, under common and prescribed conditions for use.

Detailed requirements for materials, packaging and items referred to in paragraphs 1 and 2 of this Article shall be prescribed in a regulation issued by the Ministry of Health, subject to the prior opinion from the Ministry of Agriculture.

6. FOOD OR FEED ADDITIVES

Article 32

Additive shall mean a substance which is not used as a food, but represents a distinctive ingredient of food or feed which is added to food or feed due to the technological reasons during production, processing, preparation, treatment, packaging, transport or storage, and either directly or indirectly through its intermediate products becomes or may become food or feed ingredient.

Detailed requirements regarding safety, use and maximum allowed quantities of additives shall be prescribed in a regulation issued by the Ministry of Health, subject to the prior opinion from the Ministry of Agriculture.

7. QUICK FROZEN FOOD

Article 33

Quick frozen food shall mean a food subjected to the appropriate quick-freezing process achieving maximum cross-crystallization within the minimal time period depending on the type of food.

Temperature within the quick frozen food, following warmth stabilization, shall be constantly maintained at -18°C or below.

Detail requirements for quick frozen food referred to in paragraphs 1 and 2 of this Article shall be prescribed in a regulation issued by the Ministry of Agriculture for food of animal origin and composite food, or in the case of food of plant origin after primary production, composite food and other food in the regulation issued by the Ministry of Health.

8. DIET FOOD

Article 34

Diet food shall mean a food produced or prepared for the purpose of fulfilling specific nutritive needs which are the result of special physical, physiological or pathological state and disorder in humans, including also food used for nutrition of children and nurslings.

Food intended for nutrition of persons requiring achievement of specific effects through controlled use of food and food supplements shall also be considered as diet food.

Detailed requirements regarding safety and nutritive content of diet food referred to in paragraphs 1 and 2 of this Article shall be prescribed in the regulation issued by the Ministry of Health.

9. NOVEL FOOD

Article 35

Novel food shall mean a food and food ingredients, which, to a great extent, have not been used for human consumption and are not a result of genetic modification.

Novel food shall comprise the following categories of food and food ingredients:

- food or food ingredients with new or intentionally modified primary molecular structure;
- food or food ingredients consisting of, or isolated from, micro-organisms, fungi, or algae;
- food or food ingredients consisting of, or isolated from, plants or animals, excluding the food and food ingredients obtained by traditional ways of plant and animal breeding or cultivation for, which there is an evidence that they are safe for consumption;
- food or food ingredients obtained through a technological process that hasn't been used in the past, where such process significantly changes composition or structure of food or food ingredients and therefore affects their nutritional value, human metabolism, or level of substances acceptable for human consumption.

Categories of novel food referred to in paragraph 1 of this Article must not:

- be harmful to health of consumers;
- mislead the final consumer;
- defer from food or food ingredients, which, according to the intended use, categories of novel food should substitute, to an extent that would alter its nutritive value and safety.

Novel food shall not include additives approved for use in food or feed.

Detailed requirements for novel food referred to in paragraphs 1 and 2 of this Article shall be prescribed in the regulation issued by the Ministry of Health subject to the prior opinion from the Ministry of Agriculture.

10. GENETICALLY MODIFIED FOOD AND FEED

Article 36

Genetically modified food or feed shall mean food consisting of, or produced from GMO.

Categories of food referred to in paragraph 1 of this Article must not:

- be harmful to human and animal health;
- mislead the final consumer;
- defer from food or feed, or food or feed ingredients, which, according to the intended use, categories of genetically modified food should substitute, to an extent that would alter its nutritive value and safety.

Detail requirements regarding safety of genetically modified food or feed referred to in paragraph 1 of this Article shall be prescribed in the regulation issued by the Ministry of Agriculture subject to the prior opinion from the Ministry of Health.

11. REQUIREMENTS FOR WATER

Article 37

Pure water shall mean natural water, water from artificial accumulations, or purified seawater, fresh or salt water, which does not contain micro-organisms, harmful substances, or in the case of seawater toxic sea planktons, in quantities that might affect safety of food, either directly or indirectly.

For the purpose of this Law, drinking water shall mean water intended for human consumption, notably:

- water from public water-supply system or spring water whether in original packaging or after processing, bottled or otherwise packaged water intended for drinking, cooking, preparation of food or other household purposes, as well as water supplied through the distribution network, reservoirs, bottled or otherwise packaged water;
- water used in production and circulation of food or feed.

For the purpose of this Law, table water shall mean bottled water, subterranean drinking water, which is processed for the purpose of improving the quality, whereas quality obtained after processing must comply with the regulations on drinking water.

For the purpose of this Law, natural mineral water shall mean water of certain mineral composition, with traces of elements or their compounds.

Detailed requirements regarding safety of water referred to in paragraphs 1, 2, 3 and 4 of this Article shall be prescribed in the regulation issued by the Ministry of Health subject to the prior opinion from the Ministry of Agriculture.

V. RESPONSIBILITIES OF FOOD AND FEED BUSINESS OPERATORS AND HYGIENE REQUIREMENTS

1. GENERAL RESPONSIBILITIES

Obligations

Article 38

Food or feed business operator must ensure fulfillment of requirements prescribed in this Law and regulations issued based on this Law at all stages of production and circulation within the performed business activity.

Food or feed business operator shall notify the responsible authority referred to in Article 8 of this Law of any change in the production process, in particular, any change in production assortment and production specification, within 15 days prior to introduction of change, at the latest.

Food or feed business operator must to employ at least one person with a university or specialization degree in an area corresponding to the performed business activity.

Detailed requirements regarding professional competences of employees, according to the types of business activities, production capacities and manner of engaging of persons referred to in paragraph 3 of this Article shall be prescribed in a regulation issued by the Ministry of Agriculture for food of animal origin, composite food and feed, or in the case of food of plant origin after primary production, composite food and other food in a regulation issued by the Ministry of Health.

Responsibilities

Article 39

Food or feed business operator shall be responsible for safety of food or feed at all stages of production and circulation.

Liability for Damages

Article 40

Food or feed business operator shall be liable for any damage caused by food or feed, in accordance with general regulations.

Food or feed business operator shall also be liable for any damage caused to the consumer, if information specified on the label and mark do not correspond to the characteristics of food and feed to which they apply in accordance with general regulations.

Traceability

Article 41

Food or feed business operator must ensure traceability of food and feed, raw materials, matter and substances which are incorporated into food or feed, as well as traceability of food-producing animals, at all stages of production and circulation.

Operators referred to in paragraph 1 of this Article must establish a system and procedures that enable identification of any food or feed business operator from whom they have been supplied or to whom they supply with raw materials, matter and substances which are incorporated into food or feed, food-producing animals and finished products at all stages of production and circulation.

Detailed requirements regarding content, volume, type and manner of keeping of records referred to in paragraph 2 of this Article shall be prescribed in a regulation issued by the Ministry of Agriculture, subject to the prior opinion from the Ministry of Health.

Withdrawal of Unsafe Food or Feed from Circulation Article 42

If a food or feed business operator finds or suspects that a food or feed which it has imported, produced or placed into circulation does not fulfill prescribed food or feed safety requirements, it shall immediately initiate a procedure to withdraw the food or feed from the circulation in cases when such food or feed is no longer under the direct control of the food or feed business operator in question, and inform the responsible authorities referred to in Article 8 of this Law.

Where the food has reached the consumer, the operator referred to in paragraph 1 of this Article shall effectively and accurately inform the consumers of the reason for withdrawal of food or feed, and if necessary, recall food or feed already supplied, where other measures are not sufficient.

Food or feed retail business operator that could not directly affect the food or feed safety shall cooperate and provide available information related to traceability of food or feed.

2. GENERAL HYGIENE REQUIREMENTS FOR FOOD OR FEED REQUIREMENTS IN PRIMARY PRODUCTION

Article 43

Food or feed business operator shall be obliged to comply with general hygiene requirements when performing activities of:

- a) primary production;
- b) transportation, storage and handling of primary products at the place of production, in such a manner that the nature of the product is not significantly changed;
- c) transportation of live animals used in food production;
- d) transportation of primary products of plant origin, fish and hunting game, whose nature has not been significantly changed from the place of production to the destination facility.

Detailed conditions and the manner of complying with requirements referred to in paragraph 1 of this Article shall be prescribed in a regulation issued by the Ministry of Agriculture.

Production and Circulation Requirements

Article 44

Food or feed business operator performing activities of production and circulation of food or feed after primary production shall comply with general hygiene requirements with respect to: facilities, premises, equipment, water and energy supply, removal of waste material, transport conditions, personal hygiene and training of persons handling or coming into contact with food or feed, during all stages of production or circulation of food or feed.

Detailed conditions and the manner of complying with requirements referred to in paragraph 1 of this Article according to the type of performed activity shall be prescribed in a regulation issued by the Ministry of Agriculture or the Ministry of Health.

3. SPECIFIC HYGIENE REQUIREMENTS FOR FOOD AND FEED

Article 45

In addition to the general hygiene requirements referred to in Article 44 of this Law, food or feed business operator shall comply with specific hygiene requirements at all stages of production and circulation of food or feed, with respect to:

- 1) physical, chemical and microbiological criteria;
- 2) compliance of temperature regimes with requirements for specific phases of production and circulation;
- 3) maintenance of cooling chain;
- 4) sampling and examination; and
- 5) compliance with producer's specification.

Detailed conditions and the manner of complying with requirements referred to in paragraph 1 of this Article shall be prescribed in the regulation issued by the Ministry of Agriculture for food of animal origin, composite food and feed, or in the regulation issued by the Ministry of Health for food of plant origin after primary production, composite food and other food.

4. HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

Article 46

Food or feed business operator performing activities of production and circulation of food or feed shall establish, maintain and continuously apply procedures based on HACCP principles.

When a product, processing method or a production process is changed, food or feed business operator shall harmonize established procedures with the introduced changes.

Food or feed business operator in primary production and related activities referred to in Article 43, paragraph 1 of this Law, shall establish a procedure for implementation of good hygiene, manufacturing and raising practices.

Food business operator applying traditional methods during production process in facilities of smaller production capacity located in areas with specific geographic limitations may perform production in facilities which fulfill prescribed requirements.

Traditional methods of production, general and specific hygiene requirements, capacities of production facilities referred to in paragraph 4 of this Article, and the documentation to be submitted along with the request for approval of facility shall be prescribed in the regulation issued by the Ministry of Agriculture for food of plant origin at the primary production level, food of animal origin and composite food, or in the regulation issued by the Ministry of Health for food of plant origin after primary production, composite food and other food.

Detail rules for establishment, maintenance and implementation of system based on HACCP principles shall be prescribed in the in the regulation issued by the Ministry of Agriculture for food of plant origin at the primary production level, food of animal origin and composite food, or in the regulation issued by the Ministry of Health for food of plant origin after primary production, composite food and other food

Manuals, Instructions and Guides **Article 47**

Manuals, instructions and guides for implementation of good hygiene practice, good manufacturing practice, good raising practice and procedures based on HACCP principles may be developed by associations of food or feed producers in consultations with the Food Council, based on a request from and at the expense of food or feed business operators, according to the type of activity in the area of production and circulation of food or feed.

VI. APPROVING OF FACILITIES AND ENTRY IN THE REGISTER OF APPROVED FACILITIES

Article 48

Companies, other legal persons, entrepreneurs and natural persons may perform production and circulation of food or feed only in facilities entered in the register of approved facilities that fulfill requirements prescribed by this Law and regulations issued based on this Law.

Companies, other legal persons, entrepreneurs and natural persons may not begin their activities prior to obtaining the decision of the responsible authorities referred to in Article 50 of this Law.

Request for Approval of Facilities

Article 49

Request for approval of facilities for production and circulation of food of plant origin after primary production, composite food and other food, along with the prescribed documentation shall be submitted to the Ministry of Health.

Request for approval of facilities for production and circulation of food of animal origin and feed, along with the prescribed documentation shall be submitted to the state administrative authority responsible for veterinary matters.

Content of the request and the documentation to be submitted along with the request referred to in paragraph 1 of this Article shall be prescribed in the regulation issued by the Ministry of Health.

Content of the request and the documentation to be submitted along with the request referred to in paragraph 2 of this Article shall be prescribed in the regulation issued by the Ministry of Agriculture.

Determining Fulfillment of Requirements

Article 50

Fulfillment of requirements prescribed in this Law for facilities referred to in Article 49, paragraph 1 of this Law, based on the direct examination, shall be determined by the decision issued by the Ministry of Health.

Fulfillment of requirements prescribed in this Law for facilities referred to in Article 49, paragraph 2 of this Law, based on the direct examination and shall be determined by the decision issued by the state administrative authority responsible for veterinary matters.

Notwithstanding paragraphs 1 and 2 of this Article, temporary decision may be issued for the period of 180 days from the day of examination for production facilities that fulfill general hygiene requirements with respect to facilities, premises, water and energy supply and removal of waste, until specific hygiene requirements are fulfilled.

The applicant shall bear the expenses of examination of facilities performed by the responsible authorities referred to in paragraphs 1 and 2 of this Article.

Registers of Approved Facilities

Article 51

Register of the Approved Facilities referred to in Article 49, paragraph 1 of this Law shall be kept by the Ministry of Health.

Register of the Approved Facilities referred to in Article 49, paragraph 2 of this Law shall be kept by the state administrative authority responsible for veterinary matters.

Entry in the Register

Article 52

The facility for which it was determined that it fulfills prescribed requirements shall be entered in the Register of Approved Facilities pursuant to the decision on fulfillment of prescribed requirements of responsible authority referred to in Article 50 of this Law.

The decision on entry in the Register of Approved Facilities shall be issued to the food or feed business operator.

The decision referred to in paragraph 2 of this Article shall contain, in particular:

- name and the address of the corporate headquarters of the food or feed business operator, and location of the approved facility;
- name, surname and the address of the food or feed business operator, natural person, and location of the approved facility;
- type of activity for which the facility has been approved;
- capacity of the facility and production assortment of facility;
- control number of facility.

Shape, content and manner of keeping of registers and the procedure for entry in registers referred to in Article 51 of this Law, shall be prescribed in the regulation issued by the Ministry of Health for facilities referred to in Article 49, paragraph 1 of this Law, or in the regulation issued by the Ministry of Agriculture for facilities referred to in Article 49, paragraph 2 of this Law.

Removal from the Register

Article 53

The facility shall be removed from the register of approved facilities referred to in Article 52 of this Law pursuant to the decision of the responsible authority referred to in Article 50 of this Law:

- upon a request from the food or feed business operator;
- when, during the control procedure, it is determined that the facility has ceased to fulfill prescribed requirements and deficiencies have not been corrected within the specified period;
- when the food or feed business operator discontinues to perform its activity, or when the ownership of the facility is transferred to another person;
- when the measure of permanent prohibition of performing activity is issued.

VII. GENERAL OBLIGATIONS IN THE FOOD AND FEED TRADE

Food and Feed Safety Measures in International Trade

Article 54

Food or feed safety measures in international trade may be introduced:

- 1) only to the extent necessary to protect human life and health, and provided they are based on scientific principles and available scientific evidence, international standards, guidelines, and recommendation;
- 2) in such a manner as to avoid arbitrary or unjustified discrimination between countries where identical or similar conditions prevail, including discrimination between the territory of Montenegro and other countries;
- 3) based on the assessment of risk to human life and health conducted in accordance with the risk assessment techniques of international organizations;
- 4) in a manner that would not constitute a disguised restriction on international trade.

Article 55

Assessment of risks to human life and health in the food or feed safety area shall be based on scientific evidence and shall take into account processes and production methods, inspection, sampling and testing methods and relevant ecological conditions.

Notwithstanding paragraph 1 of this Article, in cases where relevant scientific evidence is insufficient for objective assessment of risk or in urgent circumstances, responsible state administrative authority referred to in Article 8 of this Law may introduce provisional measure on the basis of available information, including that from the international organizations, as well as on the basis of food or feed safety measures applied by other countries.

Food or feed safety measures that result in a higher level of protection of human life and health than would be achieved by measures based on the international standards, guidelines or recommendations may be introduced if there is a scientific justification or if it is determined that such level of protection is appropriate.

Food or feed safety measures, including the provisional measures referred to in paragraph 2 of this Article and measures introduced in urgent circumstances, shall be reviewed by the responsible authority referred to in Article 8 of this Law when new scientific data becomes available.

Regulation on introduction of a food or feed safety measures shall be published in the “Official Gazette of Montenegro”.

Article 56

If an international standard, guideline or recommendation does not exist or the content of the food or feed safety measure is not substantially the same as the content of an international standard, guideline or recommendation, and if the measure may have a significant effect on international trade, the responsible state administrative authority referred to in Article 8 of this Law shall:

- 1) publish a notice on intention to introduce a measure at an early stage of its development;
- 2) notify interested WTO members, in accordance with rules of international agreements, of the products to be covered by the measure, together with a brief rationale of the proposed measure;
- 3) provide, upon request of the responsible authorities of other countries and in accordance with international agreements, copies of the proposed regulation for introduction of a measure and, identify the parts which deviate from international standards, guidelines or recommendations; and
- 4) allow reasonable time for submission of comments, and discuss these comments upon request from interested parties.

Notification referred to in paragraph 1, item 2 of this Article shall be submitted at least 75 days before commencement of the procedure for introduction of the proposed food or feed safety measure.

Article 57

Where, due to the urgent problems of protection of human health and life, it is necessary to impose food or feed safety measures without any delay, Ministry of Health and Ministry of Agriculture shall introduce such measure in an urgent proceedings within the scope the their responsibilities referred to in Article 8 of this Law.

Provisions of Article 56 of this Law shall not apply to food or feed safety measures introduced in urgent circumstances, referred to in paragraph 1 of this Article.

The responsible state administrative authority referred to in Article 8 of this Law shall notify interested WTO members of the food or feed safety measure introduced in urgent circumstances if the content of such food or feed safety measure is not substantially the same as the content of an international standard, guideline or recommendation and if the measure may have a significant effect on international trade, and, shall notify the type and origin of food or feed covered by the measure, with a brief rationale of the measure, nature of urgent problems, and invite interested parties to provide comments with respect to the measure introduced in urgent circumstances.

Food or feed safety measures introduced in urgent proceedings of responsible state administrative authorities referred to in Article 8 of this Law shall be reviewed within six months after their publication in the “Official Gazette of Montenegro” to determine the further necessity of such measure.

Article 58

The responsible state administrative authority referred to in Article 8 of this Law shall provide information, documentation and answers in accordance with obligations arising from international agreements, regarding the following:

- 1) proposed or introduced food or feed safety measures;
- 2) control, inspection procedure, approval and production procedures;
- 3) risk assessment procedures and manner of determining the appropriate level of protection of human life and health in the Republic of Montenegro (hereinafter referred to as Montenegro);
- 4) membership and participation in international and regional organizations and systems for protection of human health, existence and content of bilateral and multilateral agreements and arrangements.

For the provided information and documentation referred to in paragraph 1 of this Article, a fee may be charged in the amount equal to actual costs of the service rendered.

Fee referred to in paragraph 2 of this Article shall represent the revenue of the budget of the Montenegro.

The amount of the costs referred to in paragraph 2 of this Article shall be prescribed by the Government.

Article 59

Food or feed safety measures applied in another country shall be accepted as equivalent to the measures in Montenegro, if the responsible authority of such country demonstrates in an objective manner that its measures achieve the same or higher level of human health protection than the level required in Montenegro.

The responsible state administrative authority referred to in Article 8 of this Law, at the request of interested party, shall conduct necessary consultations and assess the equivalence of measures referred to in paragraph 1 of this Article, and decide on recognition or rejection of equivalence of a foreign measure.

Recognition of the equivalence of food or feed safety measures shall be published in the "Official Gazette of Montenegro".

Article 60

Procedure for verification of fulfillment of requirements prescribed in food or feed safety measures shall be carried out:

- 1) promptly, without any undue delay and discrimination of imported products in respect of similar domestic products;
- 2) based solely on the facts and information necessary to conduct the proceedings in front of the competent authority, including approvals for use of additives, or for determination of the tolerance level for contaminants in food and feed;

- 3) in such a manner as to ensure protection of confidentiality of information;
- 4) taking samples solely in the quantity that is necessary for the control and approval procedures;
- 5) if specification of food and feed changes after the control is performed, the procedure for changes shall be conducted insofar as it is necessary to determine that the food and feed, regardless of the change, comply with the relevant regulations.

GENERAL REQUIREMENTS FOR IMPORT

Import of Food and Feed

Article 61

Food and feed that are imported in Montenegro for the purpose of production and distribution shall meet requirements pursuant to this Law and the regulations based on this Law.

Notwithstanding paragraph 1 of this Article, if an international agreement is concluded between Montenegro and the exporting country, food and feed imported in Montenegro for the purpose of production and distribution shall comply to this agreement, provided that it is not in contravention of food and feed safety requirements.

Specific Conditions for Import

Article 62

The responsible authorities referred to in Article 8 of this Law, in accordance with their powers referred to in Article 9 of this Law, may, following the risk assessment and taking into account international recommendations and guidelines, prescribe specific conditions for import and transit of consignments of food and feed, in accordance with the law that regulates foreign trade.

Food and feed may be imported only through specified border crossings, where a customs office and the appropriate inspectorial supervision have been established in accordance with the law.

Border crossings referred to in paragraph 2 of this Article shall meet the prescribed technical conditions for carrying out inspections.

The detailed technical requirements, which must be fulfilled at the border crossings referred to in paragraphs 2 and 3 of this Article, shall be prescribed by regulation issued by the Ministry of Agriculture.

Export of Food and Feed

Article 63

Food and feed that are exported or re-exported from Montenegro shall meet requirements pursuant to this Law, unless otherwise requested by the authorities of the importing country, when food and feed which are exported or re-exported must meet requirements prescribed by the laws in force in the importing country, which are not in contravention with food and feed safety requirements under this Law.

Notwithstanding the paragraph 1 of this Article, except where the food or feed are unsafe, it shall be possible to export or import with the intention to re-export, if the competent authorities of country that is the end destination explicitly agree.

Notwithstanding paragraphs 1 and 2 of this Article, if the provisions of an international agreement concluded between Montenegro and an importing country are implemented, food and feed that are exported shall comply to this agreement, provided that it is not in contravention of food and feed safety requirements under this Law.

Article 64

Provisions of Articles 61, 62 and 63 of this Law shall be also applied to free trade zones and customs warehouses.

Documentation

Article 65

Consignments of food and feed that imported, exported, re-exported and transited, shall be accompanied by prescribed international approval (certificate) or other prescribed documentation, unless otherwise provided by an international agreement.

Certificate referred to in paragraph 1 of this Article shall be: original, designated by a serial number, filled and signed by the competent authority of the exporting country, on form established by the appropriate international organization.

For any consignments that are imported, a certificate referred to in paragraph 2 of this Article shall be written in the language that is in official use in Montenegro and in the language of the exporting country.

Exceptions

Article 66

Notwithstanding Article 65 of this Law, it shall be allowed to import or bring in the food for the purpose of providing crew and passengers in international means of transport; food used during travel in the means of transport; food and feed delivered by mail-order (by post, telephone or internet), as well as feed used for pets during the travel.

Detailed requirements that have to be met by food and feed referred to in paragraph 1 of this Article for food of animal origin, combined food and feed shall be prescribed by the regulation issued by the Ministry of Agriculture, and for food of plant origin after primary production, combined food and other food by the regulation issued by the Ministry of Health.

VIII. SAMPLING AND EXAMINATION

Taking Samples

Article 67

In taking of food and feed samples, under the same conditions and in the same time, there is an obligation to take three samples at the most, in the quantities necessary for examination (for the first examination, second examination upon the request of food or feed business operators and the super examination).

Notwithstanding paragraph 1 of this Article, sampling in respect of number, time or quantity may be performed in accordance with the available materials, perishability of the product or specific circumstances.

Handling of samples and their marking shall ensure legal as well analytic authenticity.

Detailed manner, sampling procedure, marking, handling of samples and needed quantity for laboratory examinations of food of plant origin at primary production level, food of animal origin, combined food and feed shall be prescribed by the Ministry of Agriculture, while for food of plant origin after primary production, combined food and other food shall be prescribed by the Ministry of Health.

Laboratory Examinations Methods

Article 68

Laboratory examinations methods that are used in examination, as well as methods of confirming and reference methods, which are used in the case of dispute, output criteria, parameters of examinations, changeability of results of measurement and needed procedures for methods validity, shall comply with regulations.

The detailed requirements related to methods referred to in paragraph 1 of this Article for food of plant origin at primary production level, food of animal origin, combined food and feed shall be prescribed by the Ministry of Agriculture, while for food of plant origin after primary production, combined food and other food shall be prescribed by the Ministry of Health.

Authorized Laboratories

Article 69

Examinations of samples of food and feed under this Law may be carried out by authorized laboratories.

Authorization for examinations referred to in paragraph 1 of this Article may be granted only to the laboratory that is a legal entity, which meets requirements prescribed by the regulation that shall be adopted by the Ministry of Health, upon prior consent of the Ministry of Agriculture.

The laboratories referred to in paragraph 1 of this Article must be accredited.

Authorization for sample examinations taken in the procedure of implementation of monitoring and inspectoral supervision, safety of food of plant origin at primary production level, safety of food of animal origin, combined food and feed shall be granted by the Ministry of Agriculture.

Authorization for sample examinations taken in procedure of implementation of monitoring and inspectoral supervision, safety of food of plant origin after primary production, combined food and other food shall be granted by the Ministry of Agriculture.

Laboratory authorization for examination referred to in paragraphs 3 and 4 of this Article shall be granted for individual examinations and group examinations.

When laboratory cease to meet the requirements for accreditation, the authorization granted under this Law shall be revoked.

Procedure and the manner of granting authorizations for laboratories shall be prescribed by the regulation referred to in paragraph 2 of this Article.

The list of authorized laboratories shall be published in the “Official Gazette of Montenegro”.

Reference Laboratories

Article 70

For each examination performed for the purpose of control of food and feed safety, the competent authority referred to in Article 8 of this Law shall authorize one laboratory as a reference laboratory for a particular examination. One laboratory may be a reference laboratory for more examinations.

For individual tests and groups of tests performed for the purpose of control of food and feed safety, the competent authority may authorize a laboratory that is referenced in other country, as referent laboratory.

The reference laboratories referred to in paragraphs 1 and 2 of this Article shall:

- co-operate with reference laboratories of other countries, notably with reference laboratories of the European Union within their powers;
- co-ordinate activities of authorized laboratories that are responsible for analyzing of samples in accordance with prescribed requirements;
- organize, when it is possible, comparative examinations in several authorized laboratories – inter-laboratory tests;
- provide information that are acquired from other reference laboratories to the competent authority and authorized laboratories;
- provide scientific and technical assistance to the competent authority for applying coordinated plans adopted in accordance with Article 73 of this Law;
- perform other activities specified under this Law and by-laws enacted based on this Law.

IX. PLAN FOR CRISIS MANAGEMENT, REPORTS AND MONITORING

Planning Crisis Management Article 71

When there are direct or indirect risks for human health, animal health or environment deriving from food and feed which are not likely to be anticipated, prevented, eliminated or reduced to an acceptable level by existing measures, the measures laid down by the plan for crisis management in the field of the safety of food and feed shall be applied.

The plan referred to in paragraph 1 of this Article shall contain types of situation, procedures necessary to manage a crisis, principle of transparency and a communication strategy.

Annual Reports Article 72

The administrative authorities referred to in Article 8 of this Law shall submit to the Government of Montenegro the report on implementation of the control plan and the monitoring plan of food safety, not later than March 31st, for the previous year.

The Government may make available reports referred to in Article 8 of this Law to the European Commission, on its request.

Monitoring of Food and Feed Safety

Article 73

Systematic control measures of microbiological, chemical and biological contaminants in food and feed (hereinafter referred to as: monitoring of food safety), conditions and method of implementation of monitoring, methods of control, conditions and method of sample taking and keeping, record keeping of samples and methods of laboratory analysis for certain microbiological, chemical and biological contaminants shall be prescribed by the Ministry of Agriculture for food of plant origin at primary production level, food of animal origin, combined food and feed, while for food of plant origin after primary production, combined and other food shall be prescribed by the Ministry of Health.

Program of monitoring of food safety shall be adopted by the Ministry of Agriculture for food of plant origin at primary production level, food of animal origin, combined food and feed, while for food of plant origin after primary production, combined and other food shall be adopted by the Ministry of Health.

Program of monitoring referred to in paragraph 2 of this Article shall contain, in particular, funds needed for financing of program, measures to be undertaken in the event of presence of microbiological, chemical and biological contaminants, structure of administrative authorities and organizations for implementation of the program and other parameters important for implementation of the program.

Program of monitoring referred to in paragraph 2 of this Article shall be adopted by the end of the current year for the following year.

Funds for implementation of program shall be provided from the Budget of Montenegro.

X. INSPECTORIAL SUPERVISION

Article 74

Inspectorial supervision of the implementation of this Law and regulations issued on its basis shall be administered by the Ministry of Health through a sanitary inspector; the administrative authority in responsible for veterinary affairs through a veterinary inspector and the administrative authority responsible for phytosanitary affairs through a phytosanitary inspector.

Powers of Inspectors

Article 75

The sanitary inspector shall conduct supervision of safety of food of plant origin after primary production, combined and other food in production, in the international market, in retail trade and wholesale trade as well individually packed food of animal origin in retail trade.

The veterinary inspector shall conduct supervision of safety of food of animal origin, combined food and feed in production, in the international commerce, in wholesale trade and in retail trade of meat, fish and other aquaculture products.

The phytosanitary inspector shall conduct supervision of safety of food of plant origin at primary production level.

Inspectorial controls shall be conducted by the use of control methods and techniques, like the supervision and taking of samples appropriate to the subject of control.

Powers of Sanitary Inspectors **Article 76**

In addition to the powers of inspectors provided by the law that governs the inspectorial supervision, a sanitary inspector shall have particular powers to:

- 1) check control systems established by food operator and check the derived results;
- 2) carry out inspection of facility, surrounding, premises, equipment and means of transport;
- 3) carry out inspection and, if necessary, sampling of raw materials, materials and substances used for preparation and production of food;
- 4) carry out inspection and, if necessary, take samples of semi-processed products;
- 5) carry out inspection and, if necessary, take samples of processed products;
- 6) carry out inspection and, if necessary, take samples of materials, packages and objects coming into contact with food;
- 7) control method of declaring, marking, presentation and advertising;
- 8) control efficiency of procedures linked with Hazardous Analysis and Critical Control Point (HACCP), Good Manufacture Practices (GMP) and Good Hygienic Practices (GHP);
- 9) control method of record keeping that may be important for assessment of compliance with this Law and by-laws enacted based on this Law;
- 10) take samples of water and ice from the facility used for production and distribution of food;
- 11) take swabs of working surfaces, equipment and hands of persons who handle and come into contact with food;
- 12) readout values of results derived through measuring instruments in the facility for production and distribution of food and in the transport vehicle;
- 13) take measurements by the use official equipment in order to confirm results derived through measurements performed by food operator;
- 14) check the compliance with other prescribed general and special hygienic requirements in the facility used for production and distribution of food;
- 15) carry out any other activity necessary in order to ensure fulfilling of goals of this Law.

In addition to the powers referred to in paragraph 1 of this Article, a sanitary inspector conducting inspectorial supervision at customs warehouse and customs free zones shall have a power to:

- 1) upon inspection of consignments of food and the accompanying documentation, allow import or warehousing, by an individual decision determining for each individual consignment that, based on the prescribed requirements, there are no obstacles for their import or warehousing;
- 2) take samples of food and send them to the authorized laboratory for laboratory examination;
- 3) check and control the compliance with technical requirements at customs warehouses and customs free zones;
- 4) keep records of imported consignments of food;
- 5) monitor and control disinfection of means of transport, customs warehouses and warehouses in the customs free zones.

Powers of Veterinary Inspectors **Article 77**

In addition to the powers of inspectors provided by the law that governs the inspectorial supervision, a veterinary inspector shall have particular powers to:

- 1) check control systems established by food and feed operator, check records and derived results;
- 2) carry out inspection of the facility, surrounding, premises, equipment and means of transport;
- 3) carry out inspection and, if necessary, take samples of raw materials, materials and substances used for preparation and production of food and feed;
- 4) carry out inspection and, if necessary, take samples semi-processed products;
- 5) carry out inspection and, if necessary, take samples of processed products;
- 6) carry out inspection and, if necessary, take samples of materials, packages and objects coming into contact with food;
- 7) control method of declaration, marking, presentation and advertising;
- 8) control efficiency of procedures linked with Hazardous Analysis and Critical Control Point (HACCP), Good Manufacture Practices (GMP), Good Hygienic Practices (GHP) and Good Farming Practices (GFP);
- 9) control method of record keeping that may be important for assessment of compliance with this Law and by-laws enacted based on this Law;
- 10) take samples of water and ice from the facility used for production and distribution of food and feed;
- 11) take swabs of working surfaces, equipment and hands of persons who handle and come into contact with food;
- 12) control and readout values of results derived through measuring instruments in the facility for production and distribution of food and in the transport vehicle;
- 13) take measurements by the use official equipment in order to confirm results derived through measurements performed by food or feed operator;
- 14) check the compliance with other prescribed general and special hygienic requirements in the facility used for production and distribution of food;
- 15) carry out any other activity necessary in order to ensure fulfilling of goals of this Law.

In addition to the powers referred to in paragraph 1 of this Article, a sanitary inspector conducting inspectorial supervision at a border crossing and the customs warehouse shall have a power to:

- 1) upon prior veterinary inspection of the consignment of food and feed and the accompanying documentation, allow import, transit or warehousing of food and feed by an individual decision determining for each individual consignment that, based on the prescribed requirements, there are no veterinary obstacles to their import, transit or warehousing;
- 2) inspect and control the consignments of animals, food and feed intended for export, if they are reloaded or warehoused at the border crossing in the registered warehouses under the prescribed conditions;
- 3) issue or attest certificate for animals, food and feed;
- 4) take samples of food and feed and send them to the authorized institution for laboratory examination or conduct necessary examinations in the laboratory at the border crossing;
- 5) check and control the compliance with technical requirements at warehouses, customs free zones and customs warehouses;
- 6) keep records of exported, imported and transited consignments of animals, food and feed when they cross the state border;
- 7) monitor and control disinfection of means of transport, customs warehouses and warehouses in the customs free zones;
- 8) monitor occurrence and movement of infectious diseases in neighboring countries and notify the administrative authority in responsible for veterinary affairs and other responsible authorities about the information acquired, depending on the risk determined.

Powers of Phytosanitary Inspectors **Article 78**

In addition to the powers of inspectors provided by the law governing the inspectorial supervision and other laws, in accordance with Article 75 paragraph 3 of this Law, a phytosanitary inspector shall have particular powers to:

- 1) carry out inspection of the facility, surroundings, premises, equipment and means of transport in primary production of food of plant origin;
- 2) carry out inspection and, if necessary, take samples of raw materials, materials and substances used for preparation of food of plant origin at primary production level;
- 3) carry out inspection and, if necessary, take samples of materials, packages and objects coming into contact with food of plant origin at primary production level;
- 4) control process of cleaning, disinfection, deodorization and decontamination (DDD), method of use and keeping of cleaning agents and DDD process, used in operations with food of plant origin at primary production;
- 5) control method of declaring, marking, presentation and advertising of food of plant origin at primary production level.

Administrative Measures and Actions

Article 79

In addition to the administrative measures and actions provided for by the law governing the inspectorial supervision, a sanitary inspector, in accordance with Article 75 paragraph 1 of this Law, after determining that this Law or other regulation has been violated, shall have responsibilities and powers to:

- 1) order the withdrawal of unsafe food from the channels of commerce;
- 2) order the restriction or prohibit trading with food or order the withdrawal of food from the channels of commerce, until the risk or doubts with respect to food safety is no longer present;
- 3) order the destruction of unsafe food in the prescribed manner;
- 4) order processing of food in the prescribed manner;
- 5) prohibit advertising and marking of food in the manner that mislead customers;
- 6) prohibit the use of materials, packages and objects coming into contact with food that could endanger human health and cause the change of food structure or the change of its sensory characteristics under the ordinary and anticipative conditions of use;
- 7) prohibit the use of facilities, premises, equipment and means of transport when prescribed requirements are not met;
- 8) prohibit the work to persons who operate and are coming into contact with food, which do not meet prescribed requirements in regard of personal hygiene;
- 9) undertake other measures in accordance with the law.

In addition to administrative measures and actions referred to in paragraph 1 of this Article, the sanitary inspector conducting inspectorial supervision at customs warehouse and customs free zones must take the following administrative measures and actions:

- 1) prohibit import of consignment of food, if:
 - the consignment or the means of transportation do not comply with prescribed requirements;
 - the consignment of food is unsafe;
 - the consignment is not accompanied with prescribed documentation, necessary to determine the identity of consignment;
- 2) temporary prohibit import of consignment of food if it is necessary to remove errors in consignment and accompanying documents, or if consignment safety is suspected, in accordance with risk analysis;
- 3) prohibit the use of the facilities for storage of food at customs warehouse, if not complying with the prescribed requirements;
- 4) prohibit the use of the means of transport for consignment of food, if not complying with the prescribed requirements.
- 5) order the destruction of consignment food established as unsafe and order the return of consignment to foreign supplier upon importer's request.

The costs of destruction measures or return of unsafe food shall be borne by the importer.

Article 80

In addition to the administrative measures and actions provided by the law governing the inspectorial supervision, in accordance with Article 75 paragraph 2 of this Law, a veterinary inspector, after determining that this Law or other regulation has been violated, shall have responsibilities and powers to:

- 1) order the withdrawal of unsafe food and feed from the channels of commerce;
- 2) order the restriction or prohibit trading with food and feed or order the their withdrawal from the channels of commerce until the risk or doubts with respect to food and feed safety is no longer present;
- 3) order the destruction of unsafe food and feed in the prescribed manner;
- 4) order processing of food and feed in the prescribed manner;
- 5) prohibit advertising and marking of food and feed in manner the manner that mislead customers;
- 6) prohibit the use of facilities, premises, equipment and means of transport when prescribed requirements are not met;
- 7) prohibit the use of materials, packages and objects coming into contact with food and feed which could endanger human and animal health and cause the change of food or feed structure or the change of their sensory characteristics under the ordinary and anticipative conditions of use;
- 8) prohibit the work to persons who operate and are coming into contact with food, which do not meet prescribed requirements in regard of personal hygiene;
- 9) undertake other measures in accordance with the law.

In addition to administrative measures and actions referred to in paragraph 1 of this Article, the veterinary inspector conducting inspectorial supervision at the border crossing or the customs warehouse must take the following administrative measures and actions:

- 1) prohibit import, export or transit of consignment of animals, food or feed, if:
 - the consignment or the means of transportation do not comply with the prescribed requirements;
 - the consignment of food is unsafe;
 - the consignment is not accompanied prescribed documentation and certificate necessary to determine the identity of consignment;
- 2) temporary prohibit import, export or transit of consignment of animals, food or feed if it is necessary to remove errors in consignment or in accompanying documentation, or if consignment safety is suspected, in accordance with risk analysis;
- 3) prohibit the use of the facilities for storage of food and feed at the border crossing and customs warehouse, if not complying with the prescribed requirements;

- 4) prohibit the use of the means of transport for consignment of animals, food and feed, if not complying with the prescribed requirements.
- 5) order the destruction of consignment food or feed established as unsafe and order the return of consignment to foreign supplier upon importer's request.

The costs of destruction measures or return of unsafe food or feed shall be borne by the importer

Article 81

In addition to the administrative measures and actions provided by the law governing the inspectorial supervision and other laws, in accordance with Article 75 paragraph 3 of this Law, a phytosanitary inspector, after determining that this Law or other regulation has been violated shall have responsibilities and powers to:

- 1) order the restriction or prohibit trading with food of plant origin at primary production level until the risk or doubts with respect to its safety is no longer present;
- 2) order the destruction of unsafe food of plant origin at primary production level;
- 3) prohibit the use of materials, packages and objects coming into contact with food of plant origin at primary production level which could endanger human health and cause the change of food structure or the change of its sensory characteristics under the ordinary and anticipative conditions of transport, handling and storing;
- 4) undertake other measures in accordance with the law.

XI. PENAL PROVISIONS

Article 82

Any company, other legal person and entrepreneur who:

- 1) produces and places into circulation food which is not safe (Articles 22, 23 and 24);
- 2) produces and places into circulation unsafe feed and feeds food-producing animals with such feed (Articles 25, 26 and 27);
- 3) fails to label and mark food or feed in production and circulation in the prescribed manner (Article 29);
- 4) advertises and presents food or feed in such a manner as to mislead the consumers and assigns medical characteristics to food or feed (Article 30);
- 5) uses materials, packaging and items coming into contact with food or feed which may harm human or animal health and change the content or sensory characteristics of food or feed under ordinary and anticipative conditions of use (Article 31);

- 6) does not, in performing food or feed related activities, ensure fulfillment of requirements prescribed by this Law and regulations issued based on this Law in all stages of production and circulation (Article 38, paragraph 1);
- 7) does not, in performing food or feed related activities, notify the responsible authority referred to in Article 8 of this Law of any change in the production process, any change in production assortment and production specification, within 15 days prior to the introduction of change (Article 38, paragraph 2);
- 8) does not, in performing food or feed business activities, in the production process, depending to the type of the performed activity, employ at least one person with a university or specialization degree in an area corresponding to the performed business activity, in accordance with the provisions in force (Article 38, paragraph 3);
- 9) does not, in performing food or feed related activities, ensure traceability of food and feed, raw materials, matters and substances that are incorporated into food or feed, as well as traceability of food-producing animals, at all stages of production and circulation (Article 41, paragraph 1);
- 10) has not, in performing food or feed related activities, established a system and procedures which enable identification of any food or feed operator from whom it is supplied or whom it supplies with raw materials, matters and substances that are incorporated into food or feed, food-producing animals and finished products at all stages of production and circulation (Article 41, paragraph 2);
- 11) does not, in performing food or feed related activities, immediately initiate a procedure to withdraw the food or feed from the circulation, following the acknowledgement or suspicion that the food or feed that were imported, produced or placed into circulation do not fulfill the safety requirements prescribed for food or feed, and does not notify accordingly the responsible authority (Article 42, paragraph 1);
- 12) does not, in performing food or feed related activities, inform the consumer in an efficient and precise manner of the reasons for withdrawing food or feed (Article 42, paragraph 2);
- 13) in performing food or feed related activities in retail trade, that could not have an immediate effect on food or feed safety, fails to cooperate and provide available information related to traceability of food or feed (Article 42, paragraph 3),
- 14) fails to comply with general hygiene requirements in performing food or feed business activities (Article 43, paragraph 1);
- 15) does not, in performing food or feed related activities of production and circulation of food or feed after primary production, ensure fulfillment of general hygiene requirements with respect to: facilities, premises, equipment, water and energy supply, removal of waste material, transport conditions, personal hygiene and training of persons handling or coming into contact with food or feed, during all stages of production or circulation of food or feed (Article 44);

- 16) does not, in performing food or feed related activities, ensure fulfillment of specific hygiene requirements at all stages of production and circulation of food or feed (Article 45, paragraph 1);
- 17) does not, in performing food or feed related activities, establish, maintain and continuously apply documented procedures based on HACCP principles (Article 46, paragraph 1);
- 18) does not, in performing food or feed related activities, when a product, processing method or production process is changed, harmonize established procedures with the introduced changes (Article 46, paragraph 2);
- 19) commences performing of the activity prior to obtaining a license from the responsible authority (Article 52, paragraph 2);

Shall be fined for the misdemeanor in the amount equal to one hundred to three hundred lowest wages in Montenegro.

The natural person and the responsible person in the company and other legal person concerned shall also be fined for the misdemeanor referred to in paragraph 1 of this Article in the amount from equal to ten to twenty lowest wages in Montenegro.

Article 83

In addition to the fine, in the case of repeated misdemeanor referred to in Article 82 of this Law, the measure of prohibition of performing activity for the period of 90 to 180 days may be imposed on the food or feed operator.

Article 84

In the case when food or feed operator uses additives and other matters and substances prohibited for use and harmful to the human life and health in production and circulation, or, in the case when food or feed operator changes the labeling or data in the labeling, such operator shall, in addition to the fine, be subject the measure of prohibition of performing activity for the period of one year.

XII. TRANSITIONAL AND FINAL PROVISIONS

Article 85

Existing authorized laboratories shall obtain accreditation within two years from the effective date of this Law.

Article 86

Program of monitoring referred to in Article 73 of this Law and plan for crisis management referred to in Article 71 of this Law shall be established by 1 January 2010.

Article 87

Until the organizing of administrative authority responsible for phytosanitary control, phytosanitary control in the field of safety of food of plant origin at primary production level shall be conducted by the Ministry of Agriculture.

Article 88

Companies, other legal persons, entrepreneurs and natural persons who are registered for production and distribution of food and feed shall ensure compliance of their activities with this Law by 1 January 2011.

Article 89

Food and feed operators who conduct production and distribution of food and feed shall establish and apply system of analysis and critical control points (HACCP) referred to in Article 46 of this Law and the system of traceability referred to in Article 41 of this Law from 1 January 2010.

Article 90

Implementing regulations for this Law shall be adopted within one year from the effective date of this Law.

Article 91

Until the implementing regulations based on this Law are passed, the regulations based on the Law on Health of Foodstuffs and Items of General Use (FRY OG No. 53/91) and the Veterinary Law (RM OG No. 11/04 and 27/07) shall apply, unless they are in contravention to this Law.

Article 92

On the effective date of this Law, the provisions of the Law on Health of Foodstuffs and Items of General Use (FRY OG No. 53/91) and the Law on Health Control Over Foodstuffs and Items of General Use (RM OG No. 26/73) concerning on foodstuffs shall cease to apply.

On the effective date of this Law, the provision of Article 4 paragraph 1 of the Law on Sanitary Inspection (RM OG No. 56/92) in part concerning on issuing of sanitary approval for production and distribution of foodstuffs shall cease to be effective.

On the effective date of this Law, the provisions of the Veterinary Law (RM OG No. 11/04 and 27/07) concerning animals for production of food, food of animal origin and feed shall cease to be effective.

Article 93

This Law shall come into force on the eighth day after its publication in the “Official Gazette of Montenegro”.