

15 Annex - Energy

67. FOOD SAFETY LAW

Pursuant to Article 95 item 3 of the Constitution of Montenegro, I hereby issue the

Decree on Promulgating the Food Safety Law

I hereby promulgate the Food Safety Law passed by the Parliament of Montenegro at the second sitting of the second ordinary session in 2007 on 29 November 2007.

No: 01-1424/2

Podgorica, 14 December 2007

The President of Montenegro

Filip Vujanovic, manu propria

FOOD SAFETY LAW

(Official Gazette of Montenegro 14/07 of 21 December 2007)

I. GENERAL PROVISIONS

Subject-matter of the Law

Article 1

This Law shall regulate the basis and the principles for ensuring the high level of protection of human life and health, the protection of consumers' interests and the requirements for production and placing on the market of safe food or feed.

This Law shall be based on the principle of a reliable, scientifically based and efficient implementation of procedures as regards selection and implementation of measures in the matters of food or feed safety, appropriate to the requirements for protection of human life and health, animal health and welfare, plant health, and environmental protection.

Application of the Law

Article 2

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

This Law shall not apply to:

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

Free Trade Principle

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 used for human consumption.

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

- used for public water supply as a drinking water;
- used or incorporated into food during its production, preparation or processing;
- bottled water or otherwise packaged water, table water, spring or mineral water.

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

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

- a) feed;
- b) live animals, unless they are intended for placing on the market for human consumption;
- c) plants prior to harvesting, picking or collecting of fruits;
- d) medicinal products;
- e) cosmetic products;
- f) tobacco and tobacco products;
- g) narcotics or psychotropic substances;
- h) residues and contaminants.

Classification of Food

Article 5

According to the origin, the 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** means a profitable or non-profitable undertaking, public or private, carried out at all stages of production, processing, treatment, finalization, packaging, repackaging, wrapping, storage, transport or distribution of food or feed;
- 2) **food or feed business operator** means a company, other legal person, entrepreneur or natural person responsible for implementation and carrying out of prescribed requirements for ensuring safety of food or feed within their businesses.
- 3) **feed** means a substance or a product of plant or animal origin, including additives, that are processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
- 4) **retail sale** means:
 - the handling or processing of food, as appropriate, 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, in individual, labelled packages, to a final consumer in shops, supermarkets, mega markets and other sale facilities;
- 5) **wholesale** means the procedure of handling of food or feed comprising collection, sorting, keeping, storage, transport and distribution of food or feed for further sale or processing;
- 6) **risk** means the probability of occurrence of an adverse effect on health and life of humans and animals and the severity of the effect resulting from a hazard;
- 7) **risk analysis** means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
- 8) **risk assessment** means a scientifically based process consisting of hazard identification, hazard characterization, exposure assessment and risk characterization, which includes the assessment of adverse effects on human health arising from the presence of additives, contaminants, harmful substances or organisms causing food-borne diseases;
- 9) **risk management** means a process, distinct from risk assessment, of weighing different possible risk-related activities, in co-operation 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** means 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, competent authorities, risk management authorities, consumers, food or feed business operators and other interested parties, including the professional interpretation of risk assessment results, as the basis for decision-making in risk management;
- 11) **hazard** means a biological, chemical or physical agent in, or condition of food or feed with the potential to cause an adverse effect on life and health of humans and animals;
- 12) **supplement** means a food additive representing a concentrated source of a micronutrient that has physiological and nutritive effect;
- 13) **traceability** means 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 distribution;
- 14) **production of food** means a process comprising all stages from the receipt of the components, preparation, treatment, finalization, processing, packaging as well as storing food with the producer;

- 15) **placing on the market** means the process of handling of food after completion of the production process, which comprises storage, transport, distribution, sale, displaying for the purpose of sale, exchange and conferring of food and feed, export and import, except for scientific-research purposes;
- 16) **primary production** means the production and growing or rearing of agricultural products in plant production, livestock production and fishery, including harvesting and picking of fruits, milking and animal rearing prior to slaughter, hunting and fishing and collecting wild fruit and plants from nature, including also, handling, transport and storage of primary products at the place of production, resulting exclusively in a product which has not been subjected to technological procedures after harvesting, collecting of fruits or catch, except to a simple physical treatment;
- 17) **primary product** means a product obtained from primary production;
- 18) **processing** means a process of modifying a primary product through the application of certain physical and chemical procedures;
- 19) **packaged food** means a food in packaging;
- 20) **consumer** means a person consuming food;
- 21) **facility** means a business unit of a food or feed business operator approved for performing the undertaking or a part of the undertaking;
- 22) **food or feed hygiene** means a set of prescribed measures and requirements that need to be met in order to control the hazards and to ensure that food or feed are fit for human or animal consumption, in accordance with their intended use;
- 23) **certification** means 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** means a systematic implementation of a series of prescribed and planned activities undertaken for the purpose of having a general information on the situation in food and feed safety;
- 25) **food of animal origin** means a food produced from animals, or originating from animals, processed or unprocessed (in certain cases, it may also include live animals, such as lobsters or live shellfish);
- 26) **food of plant origin** means a food originating from plants, processed or unprocessed;
- 27) **composite food** means a food containing products of plant origin and processed products of animal origin;
- 28) **other food** means a food of mineral origin, water, drinks, chewing gum, etc.;
- 29) **genetically modified organism** means 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

Competent Authorities

Article 8

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

- ministry in charge of agriculture (hereinafter referred to as: the Ministry of Agriculture);
- ministry in charge of health (hereinafter referred to as: the Ministry of Health);
- administration authority in charge of veterinary matters;
- administration authority in charge of phytosanitary matters.

The administration authorities referred to in paragraph 1 of this Article may entrust carrying out of certain activities of public interest to authorized legal persons, in accordance with the law.

Responsibilities

Article 9

The Ministry of Agriculture shall, while performing the activities referred to in Article 8, paragraph 1, indent 1 of this Law, adopt annual control plan, monitoring plan, crisis management plans in the field 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 co-operate with international organizations and competent 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 the activities referred to in Article 8, paragraph 1, indent 2 of this Law, adopt annual control plan, monitoring plan, crisis management plan in the field of safety of food of plant origin after the primary production, composite food and other food, co-operate with international organizations and competent authorities of other states in the food safety area, establish the conformity with the requirements prescribed, 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, inspection and other activities in accordance with this Law.

The administration authority responsible for veterinary matters referred to in Article 8, paragraph 1, indent 3 of this Law shall, for the purpose of enforcing this Law, prepare technical bases for annual control plan, monitoring plan, crisis management plan in the area of safety of food of animal origin, composite food and feed, adoption of regulations within its scope of authority, establish the conformity with the requirements prescribed, issue and withdraw approvals to perform activities to business operators dealing with food of animal origin, composite food and feed after primary production, and performs control, inspection and other activities in accordance with this Law.

Administration authority responsible for phytosanitary matters referred to in Article 8, paragraph 1, indent 4 of this Law shall, for the purpose of enforcing this Law, prepare technical bases for annual control plan, monitoring plan, crisis management plan in the area of safety of food of plant origin at the primary production level, adoption of regulations within its scope of authority, establish the conformity with the requirements prescribed, perform control, inspection and other activities in accordance with this Law.

Division of Responsibilities

Article 10

The Ministry of Health shall perform the activities referred to in Article 8, paragraph 1, indent 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 labelled packaged food of animal origin and composite food in retail sale.

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

Administration authority responsible for phytosanitary matters shall perform the activities referred to in Article 8, paragraph 1, indent 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 the 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:

- method of treatment and disposal of food of plant origin at the primary production level, food of animal origin, composite food or feed which fails to satisfy the safety requirements prescribed;
- monitoring of safety of food of animal origin, composite food or feed, in order to determine presence of microbiological, chemical and biologic contaminants, additives and other ingredients and substances for the purpose of assessing the risk to human and animal life and health;
- hygiene requirements for food of plant origin at the primary production level and for food of animal origin, composite food or feed during all stages of production and distribution to the market.

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

- methods for examination the food of animal origin, composite food or feed in production and on the market;
- methods for examination of food of plant origin at the primary production level;
- microbiological criteria on allowed species and quantities of microorganisms, parasites, bacterial toxins and histamine in feed that are dangerous to health;
- 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 species and quantities of microorganisms, parasites, bacterial toxins and histamine in food that are dangerous to health;
- microbiological criteria for hygiene, determination methods and evaluation;
- allowed quantities of heavy metals, metalloids, pesticides residues, veterinary medicinal products, mycotoxins and other substances in food harmful to human health;
- allowed levels of radionuclide concentration in food;
- method of treatment and disposal of food of plant origin after primary production, composite food and other food which fails to satisfy the safety requirements prescribed;
- monitoring of safety of food of plant origin after primary production, composite food and other food, in order to determine the presence of microbiological, chemical and biological contaminants, additives and other ingredients and substances in order to assess the risk to human life and health;
- sampling methods and methods used for water analysis;
- hygiene requirements for food of plant origin after primary production, composite food and other food in any stage of production and distribution on the market;
- safety requirements for food subjected to ionizing radiation;
- safety requirements for food supplements.

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

National Council for Food Safety Assessment

Article 13

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

The Food Council shall:

- analyze the status and achievements in the food or feed safety area based on the data available;
- provide expert 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 laws and proposals of laws, other regulations and general acts in the food or feed safety area;
- provide scientific and expert opinions during risk analysis, development and adoption of measures for elimination of risks and other measures in the food or feed safety area;
- co-operate with competent state administration authorities, administration authorities, and international institutions in the area of scientific and technical information exchange;

- provide proposals for providing information to, participation of the public and education on significance of food or feed safety;
- undertake other tasks as laid down by the act on establishing 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 the ministries, competent state administration authorities and administration authorities.

Composition and Method of Work of the Food Council

Article 14

The Food Council shall be established by the Government of Montenegro.

The Food Council shall have a president and 10 members appointed by the Government, based on a proposal from the competent authorities referred to in Article 8 of this Law, for the period of four years.

Members of the Food Council shall be appointed primarily from eminent public, scientific and professional individuals in the areas related to food or feed safety.

The work of the Food Council shall be public.

The method of work and organization of the Food Council shall be laid down in more detail by the Food Council rules of procedure.

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

The expert 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 PRINCIPLES

1. RISK ANALYSIS PRINCIPLE

Risk Assessment

Article 15

In order to achieve the general objective of 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, except where this is not appropriate to the circumstances or to the nature of the measure.

Risk assessment shall be based on the accessible and available scientific evidence and information 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 so as to ensure that preventive measures, surveillance and control undertaken to reduce, eliminate or avoid the risk to human health by 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 the competent 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 throughout the risk assessment process between the Food Council and the authorities in charge of the risk management referred to in Article 8 of this Law, other organizations and interested parties, consumers and food or 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, but there is also a scientific uncertainty with respect to ensuring high level of protection of health, the competent 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.

The measures referred to in paragraph 1 of this Article shall be proportionate to the risk and shall not restrict trade in food and feed more than is required to achieve the efficient protection of human life and health.

The measures undertaken shall be reviewed within a period of time corresponding to the risk identified.

3. TRANSPARENCY PRINCIPLE

Article 19

Where there is a hazard that food or feed may present a risk to human or animal health, the competent authority referred to in Article 8 of this Law shall immediately inform the public, through the media outlets with a national-wide coverage, of the type of food or feed, the risk that it presents, 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 revision of regulations or implementation of measures under this Law, the authority adopting the regulation or the administration authority in charge of implementation of the measure shall organize and carry out public discussions.

5. PRINCIPLE OF PROTECTION OF CONSUMERS' INTERESTS

Article 21

The consumers shall be informed of the composition, characteristics and safe use and the method of use of food by labelling and marking, provision of instructions and other documents accompanying food, in order to prevent fraudulent or deceptive practices with respect to the composition, change of composition, other characteristics and procedures which may mislead the consumer.

The method for providing information to the 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 or feed shall be prescribed in a regulation of the Ministry of Agriculture, and for food of plant origin after primary production, composite food and other food in the regulation of the Ministry of Health.

IV. FOOD SAFETY

FOOD SAFETY REQUIREMENTS

Safe Food

Article 22

It shall be prohibited to produce and place on the market food that is unsafe.

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:

- compliance with the prescribed requirements in all stages of production and distribution to the market, 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 occurrence harmful effects on human health from a particular category of food.

In 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 on the health of consumers, and possible effects on 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 from the exterior 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 levels above those prescribed;
- 2) it contains natural toxins or other natural toxic substances in levels above those prescribed;

- 3) it contains heavy metals, metalloids, pesticides residues, veterinary medicinal products, mycotoxins and other substances in levels above those prescribed;
- 4) it contains additives which must not be used in a certain type of food, or if the content of allowed additives in the food is higher than prescribed;
- 5) it contains radionuclides above the prescribed level, or if the food is irradiated above the level permitted;
- 6) the packaging, materials, and items in contact with food fail to satisfy the prescribed requirements;
- 7) it originates from animals that were not examined before and after slaughter, and when meat was not marked in accordance with the regulations;
- 8) it originates from diseased or dead animals, or animals for which slaughter and further slaughterhouse treatment are not allowed for any reason;
- 9) sensorial characteristics of food (taste, smell, colour, appearance, structure, etc.) are changed due to physical, chemical, microbiological or other processes;
- 10) it contains substances which are not toxicologically evaluated, checked and safe for human consumption;
- 11) it contains mechanical impurities;
- 12) packaging is damaged in such a way that microbiological and chemical changes may occur;
- 13) it was not produced, treated, packed, stored or distributed in a prescribed manner;
- 14) it is not labelled and marked in a prescribed manner;
- 15) it fails to satisfy the nutritional composition requirements prescribed.

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 satisfies the prescribed requirements.

More detailed requirements that the safe feed should satisfy 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.

Where feed, established as 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.

More Detailed Requirements for Determining Unsafe Feed

Article 27

Feed shall be considered unsafe if:

- 1) it contains microorganisms, parasites, bacterial toxins or histamine in levels above those prescribed;
- 2) it contains natural toxins or other natural toxic substances in levels above those prescribed;
- 3) it contains heavy metals, metalloids, residues of pesticides, veterinary medicinal products, mycotoxins and other substances harmful to human and animal health, in levels above those prescribed;
- 4) it contains additives which must not be used in a certain type of feed, or if the content of allowed additives in the feed is higher than prescribed;
- 5) it contains radionuclides above the prescribed limit, or if it is irradiated above the permitted limit;
- 6) the packaging, materials, and items coming in contact with feed fail to satisfy the prescribed requirements;
- 7) sensorial characteristics of feed (taste, smell, colour, appearance, structure, etc.) are changed due to physical, chemical, microbiological or other processes;
- 8) it contains substances which are not toxicologically evaluated, verified, and safe for animal feeding;
- 9) it contains mechanical impurities;
- 10) packaging is damaged so that microbiological and chemical changes may occur;
- 11) it was not produced, treated, packed, stored or distributed in a prescribed manner;
- 12) it is not labelled and marked in a prescribed manner;
- 13) it fails to satisfy the nutritional composition requirements prescribed.

3. PROHIBITION OF PLACING ON THE MARKET

Article 28

When food or feed represents a direct hazard to human or animal life and health, or when food or feed fail to satisfy the requirements prescribed, and there are reasons to suspect the safety of food or feed, the competent public administration authorities referred to in Article 8 of this Law may order restriction or prohibition of placing on the market of food or feed, or withdrawal of food or feed from the market until the hazard, or suspicion, as regards its safety are removed.

The measures of restriction and prohibition of placing on the market referred to in paragraph 1 of this Article shall be prescribed by a decree issued by the Ministry of Agriculture or the Ministry of Health. The competent administration authorities referred to in paragraph 1 of this Article shall immediately inform the public, through the media outlets with national-wide coverage, of the measures of restriction or placing on the market referred to in the paragraph 1 of this Article.

The public administration 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 hazards to human or animal health.

4. LABELLING, MARKING, PRESENTATION AND ADVERTISING

Labelling and Marking

Article 29

The food or feed in production and at the market shall be labelled and marked. The data from the label and mark must correspond to the data specified in the producers' specification and requirements prescribed in this Law and regulations adopted based on this Law.

The label, or the mark, shall contain the data enabling the traceability of food or feed, raw materials, material and substances incorporated into the food or feed, food-producing animals and final products, in all stages of production and placing on the market.

The label must not contain the data ascribing medicinal characteristics to food or feed.

The label, or data presented in the label for food or feed placed on the market shall be written in Montenegrin language.

The detailed requirements for the content, the type of the data and method of their presentation in the label, as well as the method of marking the food of plant origin at the primary production level, food of animal origin, composite food and feed shall be prescribed in a regulation of the Ministry of Agriculture, or in the case of food of plant origin after primary production, composite food and other food, in a regulation of the Ministry of Health.

Presentation and Advertising

Article 30

Advertising and presentation of food or feed, design, environment where the it is displayed, as well as information on food or feed available through print and other media must not mislead the consumer or animal keeper.

It shall be prohibited to ascribe medicinal characteristics to food or feed during advertising or presentation.

More 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 of the Ministry of Agriculture, or in the case of food of plant origin after primary production, composite food and other food in a regulation of 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 mean the products in the direct contact with food or feed or those coming into contact with food or feed.

The materials, packaging and items referred to in paragraph 1 of this Article shall be produced in accordance with the good manufacturing and hygiene practice, so as to prevent migration of their ingredients into food or feed in quantities which might harm human or animal health, and change the composition of food or feed or sensorial characteristics thereof, under common and prescribed conditions for use.

More detailed requirements to be satisfied by materials, packaging and items referred to in paragraphs 1 and 2 of this Article shall be laid down in a regulation of the Ministry of Health, subject to the prior opinion from the Ministry of Agriculture.

6. FOOD OR FEED ADDITIVES

Article 32

Additive means a substance which is not used as a food, but represents a distinctive ingredient of food and 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 a food or feed ingredient.

More detailed requirements to be satisfied by additives in terms of safety, use and maximum permitted quantities shall be laid down in a regulation of the Ministry of Health, subject to the prior opinion from the Ministry of Agriculture.

7. QUICK FROZEN FOOD

Article 33

Quick frozen food means food subjected to an appropriate quick-freezing process whereby the zone of maximum crystallization is crossed as rapidly as possible, depending on the type of food.

The temperature in the centre of quick frozen food after thermal stabilization shall be continuously maintained at a level of -18 C or lower.

More detailed requirements for quick frozen food referred to in paragraphs 1 and 2 of this Article shall be laid down 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 a regulation of the Ministry of Health.

8. DIETETIC FOOD

Article 34

Dietetic food means food produced or prepared for the purpose of fulfilling specific nutritive needs resulting from certain physical, physiological or pathological conditions and disorders in humans, including also food used for nutrition of children and infants.

The food intended for nutrition of persons requiring achievement of certain effects through a controlled use of food and food supplements is also considered dietetic food.

More detailed requirements that need to be satisfied by food referred to in paragraphs 1 and 2 of this Article in terms of safety and nutritive composition shall be laid down in a regulation of the Ministry of Health.

9. NOVEL FOOD

Article 35

Novel food means food and food ingredients which have not been used for human consumption to a significant degree and are not a result of genetic modification.

Novel food comprises the following categories of food and food ingredients:

- with new or intentionally modified primary molecular structure;
- consisting of, or isolated from, micro-organisms, fungi, or algae;
- consisting of, or isolated from, plants or animals, excluding the food and food ingredients obtained by traditional methods of plant reproduction and animal breeding known to be safe for consumption;
- obtained through a technological process that has not been used in the past, resulting in a significant change in 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;
- differ from food or food ingredients which, according to the intended use, it 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.

More detailed requirements to be satisfied by novel food referred to in paragraphs 1 and 2 of this Article shall be laid down in a regulation of the Ministry of Health subject to the prior opinion from the Ministry of Agriculture.

10. GENETICALLY MODIFIED FOOD OR FEED

Article 36

Genetically modified food or feed means food consisting of, or produced from GMOs.

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

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

More detailed requirements to be satisfied by genetically modified food or feed referred to in paragraph 1 of this Article in terms of safety shall be laid down in a regulation of the Ministry of Agriculture subject to the prior opinion from the Ministry of Health.

11. REQUIREMENTS FOR WATER

Article 37

Pure water means 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 means water intended for human consumption:

- 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 trade in food or feed.

For the purpose of this Law, table water means bottled water, underground drinking water treated for the purpose of improving the quality, whereas quality obtained after treatment must comply with the regulations on drinking water.

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

More detailed requirements to be satisfied by water referred to in paragraphs 1, 2, 3 and 4 of this Article in terms of safety shall be laid down in a regulation of the Ministry of Health subject to the prior opinion from the Ministry of Agriculture.

V. OBLIGATIONS OF FOOD OR FEED BUSINESS OPERATORS AND HYGIENE REQUIREMENTS

1. GENERAL OBLIGATIONS

Obligations

Article 38

Food or feed business operator shall ensure that, at all stages of production and placing on the market within their respective business activity, the requirements prescribed in this Law and regulations issued based on this Law, are complied with.

Food or feed business operator shall notify the competent authority referred to in Article 8 of this Law of any change in the production process, in particular, any change in product range and product specification, no later than 15 days prior to introduction of the change.

Food or feed business operator shall employ in its production at least one person with a university or specialization degree in a field appropriate to the performed business activity.

More detailed requirements regarding professional competences of employees, by types of business activities, production capacities and the method of employing the persons referred to in paragraph 3 of this Article shall, for food of animal origin, composite food or feed be laid down in a regulation of the Ministry of Agriculture, or in the case of food of plant origin after primary production, composite food and other food in a regulation of 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 distribution.

Liability for Damage

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 they refer to in accordance with the general regulations.

Traceability

Article 41

Food or feed business operator shall ensure traceability of food and feed, raw materials, material and substances incorporated into food and feed, as well as of food-producing animals, at all stages of production and distribution.

The operator referred to in paragraph 1 of this Article shall have in place a system and procedures ensuring the identification of food or feed business operators supplying it with or whom they supply with raw materials, materials and substances incorporated into food or feed, food-producing animals and finished products at all stages of production and distribution.

More detailed requirements regarding content, scope, type and method of keeping of records referred to in paragraph 2 of this Article shall be laid down in a regulation of the Ministry of Agriculture, subject to the prior opinion from the Ministry of Health.

Obligation of Withdrawal of Unsafe Food or Feed from the Market

Article 42

If a food or feed business operator finds or suspects that a food or feed it has imported, produced or placed on the market fails to satisfy the prescribed food or feed safety requirements, it shall immediately initiate a procedure for its withdrawal from the market in cases where such food or feed is no longer under its direct control, and it shall notify the competent authority 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 consumer of the reasons for withdrawal of food and 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 the traceability of food or feed.

2. GENERAL HYGIENE REQUIREMENTS FOR FOOD OR FEED

Requirements in Primary Production

Article 43

General hygiene requirements shall be satisfied by a food or feed business operator engaged in:

- a) primary production;
- b) transport, storage and handling of primary products at the place of production that do not substantially alter their nature;
- c) transport of live animals used in food production;
- d) transport of primary products of plant origin, fish and hunting game, whose nature has not been substantially altered from the place of production to the destination facility.

More detailed conditions and the method of satisfying the requirements referred to in paragraph 1 of this Article shall be laid down in a regulation of the Ministry of Agriculture.

Requirements for Production and Placing on the Market

Article 44

Food or feed business operator engaged in production and circulation of food or feed after primary production shall comply with the general hygiene requirements with respect to: facilities, premises, equipment, water and energy supply, disposal 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 placing on the market of food or feed.

More detailed conditions and the method of complying with the requirements referred to in paragraph 1 of this Article according to the type of business shall be laid down in a regulation of the Ministry of Agriculture or the Ministry of Health, as appropriate.

3. SPECIFIC HYGIENE REQUIREMENTS FOR FOOD OR 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 the specific hygiene requirements at all stages of production and circulation of food or feed, with respect to:

- a) physical, chemical and microbiological criteria;
- b) compliance of temperature regimes with the requirements for specific phases of production and distribution;
- c) keeping the cold chain;
- d) sampling and examination;
- e) compliance with the producer specification.

More detailed conditions and the method of complying with the requirements referred to in paragraph 1 of this Article shall be laid down in a regulation of the Ministry of Agriculture for food of animal origin, composite food or feed, or in a regulation of 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 engaged in production and placing on the market of food or feed shall establish, maintain and continuously apply the procedures based on HACCP principles.

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

Food or feed business operator in primary production and accompanying activities referred to in Article 43, paragraph 1 of this Law, shall establish a procedure for implementation of good hygiene practice, good manufacturing practice and Good Farming Practice.

Food business operator applying traditional methods during production process in establishments of smaller production capacity located in areas with specific geographic limitations may engage in production in establishments satisfying the requirements prescribed.

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

More detailed rules for setting up, maintenance and implementation of a HACCP-based system shall be prescribed in a of the Ministry of Agriculture for food of plant origin at the primary

production level, food of animal origin and composite food, or in a regulation of the Ministry of Health for food of plant origin after primary production, composite food and other food

Instructions, Manuals and Guides

Article 47

Instructions, manuals, and guides for implementation of good hygiene practice, good manufacturing practice, Good Farming Practice and HACCP-based procedures may be developed by associations of food or feed producers in consultations with the Food Council, at 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 distribution of food or feed.

VI. APPROVAL OF ESTABLISHMENTS AND ENTRY IN THE REGISTER OF APPROVED ESTABLISHMENTS

Article 48

Companies, other legal persons, entrepreneurs and natural persons may engage in production and placing on the market of food or feed only in establishments registered in the register of approved establishments satisfying the requirements laid down by this Law and regulations issued based on this Law.

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

Request for Approval of Establishments

Article 49

Request for approval of establishments for production and placing on the market of food of plant origin after primary production, composite food and other food, and the prescribed documentation shall be submitted to the Ministry of Health.

Request for approval of establishments for production and placing on the market of food of animal origin and feed, and the prescribed documentation shall be submitted to the administration authority responsible for veterinary matters.

The content of the request and the documentation to be submitted along with the request referred to in paragraph 1 of this Article shall be laid down in a regulation of the Ministry of Health.

The content of the request and the documentation to be submitted along with the request referred to in paragraph 2 of this Article shall be laid down in a regulation of the Ministry of Agriculture.

Establishing the Conformity with the Requirements

Article 50

The conformity with the requirements laid down by this Law for the establishments referred to in Article 49, paragraph 1 of this Law, based on a direct examination, shall be established by a decision of the Ministry of Health.

The conformity with the requirements laid down by this Law for the establishments referred to in Article 49, paragraph 2 of this Law, based on a direct examination, shall be established by a decision of the administration authority in charge of veterinary matters.

Notwithstanding paragraphs 1 and 2 of this Article, a temporary decision may be issued for the period of 180 days from the day of examination for production establishments conforming with the

general hygiene requirements with respect to the establishment, premises, water and energy supply and waste disposal, pending the conformity with the specific hygiene requirements.

The expenses of the examination of establishments done by the competent authorities referred to in paragraphs 1 and 2 of this Article shall be borne by the applicant.

Registers of Approved Establishments

Article 51

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

The Register of Approved Establishments referred to in Article 49, paragraph 2 of this Law shall be kept by the administration authority in charge of veterinary matters.

Entry in the Register

Article 52

The establishment for which it was established that it conforms with the prescribed requirements shall be entered in the Register of Approved Establishments pursuant to the decision on conformity with the prescribed requirements of the competent authority referred to in Article 50 of this Law.

The decision on entry in the Register of Approved Establishments 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 head office of the food or feed business operator, the company and the location of the approved establishment;
- name, surname and the address of the food or feed business operator, natural person, and the location of the approved establishment;
- type of activity for which the establishment has been approved;
- capacity of the establishment and product range of the establishment of facility;
- control number of the establishment.

The form, content and method of keeping of registers and the procedure for entry in the registers referred to in Article 51 of this Law, shall be laid down in a regulation of the Ministry of Health for establishments referred to in Article 49, paragraph 1 of this Law, or in a regulation of the Ministry of Agriculture for establishments referred to in Article 49, paragraph 2 of this Law.

Removal from the Register

Article 53

The establishment shall be removed from the register of approved establishments referred to in Article 52 of this Law pursuant to the decision of the competent authority referred to in Article 50 of this Law:

- at a request from the food or feed business operator;
- when, during the control procedure, it is established that the establishment no longer complies with the prescribed requirements, or where deficiencies have not been corrected within the specified period of time;
- when the food or feed business operator ceases its activity, or where the establishment has been alienated;

- where the measure of permanent prohibition of work is issued.

VII. GENERAL OBLIGATIONS IN THE FOOD OR FEED TRADE

Food or 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 based on scientific principles and available scientific evidence, international standards, guidelines and recommendations;
- 2) so as to avoid arbitrary or unjustified discrimination between countries where identical or similar conditions prevail, including discrimination between its own territory and that of other countries;
- 3) based on the assessment of risk to human life and health conducted in accordance with the methodology of international organizations;
- 4) so that it does not constitute a disguised restriction on foreign trade.

Article 55

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

Notwithstanding the paragraph 1 of this Article, in absence of sufficient scientific evidence for an objective risk assessment or in emergencies, the competent public administration authority referred to in Article 8 of this Law may introduce temporary measures on the basis of information available, including those from the international organizations, or those on food or feed safety measures applied by other countries.

Food or feed safety measures may be applied in order to ensure a higher level of protection of human life and health than the level achieved by measures based on the international standards, guidelines or recommendations where that is scientifically justified or where it is assessed that such protection level is appropriate.

Food or feed safety measures, including the temporary measures referred to in paragraph 2 of this Article and measures introduced in emergencies, shall be reviewed by the competent public administration authority referred to in Article 8 of this Law when new scientific data become available.

The act on introduction of food or feed safety measures shall be published in the "Official Gazette of Montenegro".

Article 56

In absence of international standards, guidelines or recommendations or where food or feed safety measures are not in accordance with the international standards, guidelines or recommendations, and where the measure may have a significant impact on foreign trade, the competent public administration authority referred to in Article 8 of this Law shall:

- 1) publish a notification of intention to introduce a measure at an early stage of its development;
- 2) notify the interested WTO members, in accordance with rules of international agreements, of the products the measure applies to, together with a justification of the measure proposed;

- 3) provide, at request of the competent authorities of other countries and in accordance with international agreements, copies of the proposed act introducing the measure proposed, indicating the derogations from international standards, guidelines, recommendations;
- 4) set the deadline for submitting comments, and, at request of interested parties, organize consultations.

The 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, in order to protect the human health and life, it is necessary to undertake a food or feed safety measure without delay, the Ministry of Health, or the Ministry of Agriculture, as appropriate, shall introduce such measure by an urgent procedure within the scope the their respective authorities referred to in Article 8 of this Law.

The provisions of Article 56 of this Law shall not apply to food or feed safety measures introduced by urgent procedure referred to in paragraph 1 of this Article.

The competent public administration authority referred to in Article 8 of this Law shall notify the interested WTO members of the food or feed safety measure introduced by urgent procedure, where the measure is not in accordance with the international standards, guidelines or recommendations and if the measure may have a significant effect on international trade, and shall indicate the type and the origin of food or feed the measure applies to, together with the justification of the measure, nature of the emergency, and invite the interested parties to provide comments on the measure introduced by urgent procedure.

Food or feed safety measures introduced by urgent procedure of competent public administration authorities referred to in Article 8 of this Law shall be reviewed within six months from the day of their publication in the Official Gazette of Montenegro in order to establish the need for its extension.

Article 58

The competent public administration authority referred to in Article 8 of this Law shall provide information, documentation and notifications arising from international agreements, regarding the following:

- 1) proposed and introduced food or feed safety measures;
- 2) control, surveillance, approval and production procedures;
- 3) risk assessment procedures and method of establishing the appropriate level of protection of human life and health in 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.

The fee referred to in paragraph 2 of this Article shall be the revenue of the budget of the Montenegro.

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

Article 59

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

The competent public administration authority referred to in Article 8 of this Law, in accordance with the authority referred to in Article 9 of this Law, shall, at the request of an interested party, conduct the necessary consultations and assess the equivalence of measures referred to in paragraph 1 of this Article, and shall decide on acceptance or rejection of equivalence of the foreign measure.

The recognition of the equivalence of a foreign food or feed safety measure shall be published in the Official Gazette of Montenegro.

Article 60

Procedure for verification of compliance with the requirements prescribed by food or feed safety measures shall be carried out:

- 1) urgently, without 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 before the competent authority, including the control of use of additives and the control of the tolerance level for contaminants in food or feed;
- 3) so as to ensure protection of confidential information;
- 4) taking samples solely in the quantity that is necessary for the control and approval procedures;
- 5) if specification of food or feed has been changed after the control, the procedure for changes shall be conducted insofar as it is necessary to determine that the food or feed, regardless of the change, comply with the relevant regulations.

GENERAL REQUIREMENTS FOR IMPORT

Import of Food or Feed

Article 61

Food or feed imported to Montenegro for the purpose of production and distribution shall meet requirements pursuant to this Law and the regulations adopted on the basis of this Law.

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

Special Import Conditions

Article 62

The competent public administration 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, taking into account international recommendations and guidelines, prescribe special conditions for import and transit of consignments of food or feed, in accordance with the law governing foreign trade.

Food or feed may be imported only through designated border crossings, where customs and appropriate inspection are in place, in accordance with the law.

The border crossings referred to in paragraph 2 of this Article shall meet the prescribed technical conditions for inspections.

More detailed technical requirements that the border crossings referred to in paragraphs 2 and 3 of this Article should comply with, shall be laid down by a regulation of the Ministry of Agriculture.

Export of Food or Feed

Article 63

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

Notwithstanding the paragraph 1 of this Article, except where the food or feed are unsafe, export or re-export is allowed if the competent authorities of the country of the final destination explicitly agree with that.

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 or feed exported shall comply to the provisions of that agreement, provided that it is not in contravention of food or feed safety requirements under this Law.

Article 64

Provisions of Articles 61, 62 and 63 of this Law shall also apply to customs free zones and bonded warehouses.

Documentation

Article 65

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

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

For imported consignments, a certificate referred to in paragraph 2 of this Article shall be written in Montenegrin language and in the language of the exporting country.

Exceptions

Article 66

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

More detailed requirements to be met by food or feed referred to in paragraph 1 of this Article, types and quantities for food of animal origin, composite food or feed shall be laid down by a

regulation of the Ministry of Agriculture, and for food of plant origin after primary production, composite food and other food by the regulation of the Ministry of Health.

VIII. SAMPLING AND EXAMINATION

Sampling

Article 67

When taking food or feed samples it shall be binding to take, under the same conditions and at the same time, no more than three samples in the quantities necessary for examination (for the first examination, second examination at the request of food or feed business operators and the super examination).

Notwithstanding paragraph 1 of this Article, sampling may be done, as regards the number, time or quantity in the way that is appropriate to the available material, perishability of the product or specific circumstances.

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

The more detailed method, sampling procedure, marking, handling of samples and quantities necessary for laboratory examinations of food of plant origin at primary production level, food of animal origin, composite food or feed shall be laid down by a regulation of the Ministry of Agriculture, while for food of plant origin after primary production, composite food and other food it shall be laid down by a regulation of the Ministry of Health.

Laboratory Examinations Methods

Article 68

Laboratory examination methods used in examination, as well as confirmation methods and reference methods used in the case of dispute, the output criteria, examination parameters, variability measurement results and procedures necessary for validation of methods, shall comply with the regulations.

More detailed requirements related to the methods referred to in paragraph 1 of this Article for food of plant origin at primary production level, food of animal origin, composite food or feed shall be laid down by a regulation of the Ministry of Agriculture, while for food of plant origin after primary production, composite food and other food it shall be laid down by a regulation of the Ministry of Health.

Authorized Laboratories

Article 69

Examination of samples of food or feed in accordance with 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 a laboratory with the capacity of a legal entity, which meets the requirements prescribed by a regulation adopted by the Ministry of Health, upon prior opinion of the Ministry of Agriculture.

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

Authorization for examination of samples taken in the procedure of implementation of monitoring and inspection of food at the level of primary production, the safety of food of animal origin, composite food and feed shall be issued by the Ministry of Agriculture.

Authorization for examination of samples taken in the procedure of implementation of monitoring and inspection of safety of food of plant origin after primary production, composite food and other food shall be issued by the Ministry of Agriculture.

The authorization to laboratories for examination referred to in paragraphs 3 and 4 of this Article may be issued for individual examinations and a group of examinations.

When a laboratory ceases to meet the requirements for accreditation, the authorization issued in accordance with this Law shall be withdrawn.

The procedure and the method of authorization of laboratories shall be laid down by a 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 carried out for the purpose of control of food or feed safety, the competent authorities 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 several examinations.

For individual tests and groups of tests performed for the purpose of control of food or feed safety, the competent authority may authorize a reference laboratory of another state for its reference laboratory.

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

- co-operate with reference laboratories of other states, notably with reference laboratories of the European Union within their respective scopes of authority;
- co-ordinate activities of authorized laboratories responsible for examination of samples in accordance with the prescribed requirements;
- organize, when possible, comparative examinations in several authorized laboratories – inter-laboratory tests;
- ensure supply of information obtained from other reference laboratories to the competent authority and authorized laboratories;
- ensure scientific and technical assistance to the competent authority for implementation of coordinated control plans adopted in accordance with Article 73 of this Law;
- perform other activities specified under this Law and regulations adopted based on this Law.

IX. PLAN FOR CRISIS MANAGEMENT, REPORTS AND MONITORING

Crisis Management Planning

Article 71

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

The plan referred to in paragraph 1 of this Article shall specify the type 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 the report on implementation of the food safety control plan and the monitoring plan no later than March 31, for the previous year.

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

Monitoring of Food and Feed Safety

Article 73

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

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

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

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

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

X. INSPECTION

Article 74

Inspection over the implementation of this Law and regulations adopted on the basis of this Law shall be carried out by the Ministry of Health through a sanitary inspector; the administration authority in charge of veterinary affairs through a veterinary inspector and the administration authority in charge of phytosanitary affairs through a phytosanitary inspector.

Powers of Inspectors

Article 75

The sanitary inspector shall carry out surveillance over the safety of food of plant origin after primary production, composite and other food in production, in international trade, wholesale and retail trade as well individually labelled packaged food of animal origin in retail trade.

The veterinary inspector shall carry out surveillance over the safety of food of animal origin, composite food and feed in production, in international trade, in wholesale and trade in meat, fish and other aquaculture products.

The phytosanitary inspector shall carry out surveillance over the safety of food of plant origin at primary production level.

Inspection shall be carried out using the control methods and techniques, such as the surveillance and taking of samples appropriate to the subject of control.

Powers of a Sanitary Inspector

Article 76

In addition to the powers of inspectors provided by the law governing the inspection, a sanitary inspector shall have, in particular, the powers to:

- 1) check control systems put in place by a food business operator and the results obtained;
- 2) inspect the establishment, surroundings, premises, equipment and means of transport;
- 3) inspect and, if necessary, sample raw materials, materials and substances used in food preparation and production;
- 4) inspect and, if necessary, take samples of semi-processed products;
- 5) inspect and, if necessary, take samples of processed products;
- 6) inspect and, if necessary, take samples of materials, packaging and items coming into contact with food;
- 6) control the process of cleaning, disinfection, pest and rodent control, the method of use and storage of substances used for cleaning and disinfection, pest and rodent control used in food businesses;
- 7) control the method of labelling, marking, presentation and advertising;
- 8) control the efficiency of procedures related to the Hazard Analysis and Critical Control Points (HACCP), Good Manufacturing Practice (GMP) and Good Hygiene Practices (GHP);
- 9) control method of keeping the records prescribed that may be of relevance for assessment of compliance with this Law and regulations adopted based on this Law;
- 10) take samples of water and ice from the establishment where food is produced and distributed;
- 11) take swabs from working surfaces, equipment and hands of persons handling and coming into contact with food;
- 12) read the values of results obtained by measuring instruments in the establishment for production and distribution of food and in the means of transport;
- 13) take measurements using the official equipment in order to confirm the results obtained by measurement carried out by the food operator;
- 14) check the compliance with other prescribed general and special hygiene requirements in the establishment for production and distribution of food;
- 15) carry out any other activity necessary in order to ensure accomplishing of the objectives of this Law.

In addition to the powers referred to in paragraph 1 of this Article, a sanitary inspector that inspects bonded warehouses and customs free zones shall have the power to:

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

Powers of a Veterinary Inspector

Article 77

In addition to the powers of inspectors provided by the law governing the inspection, a veterinary inspector shall have, in particular, the powers to:

- 1) check control systems put in place by an food and feed business operator, records and the results obtained;
- 2) inspect the establishment, surroundings, premises, equipment and means of transport;
- 3) inspect and, if necessary, sample raw materials, materials and substances used in food and feed preparation and production;
- 4) inspect and, if necessary, take samples of semi-processed products;
- 5) inspect and, if necessary, take samples of processed products;
- 6) inspect and, if necessary, take samples of materials, packaging and items coming into contact with food;
- 6) control the process of cleaning, disinfection, pest and rodent control, the method of use and storage of substances used for cleaning and disinfection, pest and rodent control used in food and feed businesses;
- 7) control the method of labelling, marking, presentation and advertising;
- 8) control the efficiency of procedures related to the Hazard Analysis and Critical Control Points (HACCP), Good Manufacturing Practice (GMP) and Good Farming Practices (GFP);
- 9) control method of keeping the records prescribed that may be of relevance for assessment of compliance with this Law and regulations adopted based on this Law;
- 10) take samples of water and ice from the establishment where food and feed is produced and distributed;
- 11) take swabs from working surfaces, equipment and hands of persons handling and coming into contact with food;
- 12) read the values of results obtained by measuring instruments in the establishment for production and distribution of food and feed and in the means of transport;
- 13) take measurements using the official equipment in order to confirm the results obtained by measurement carried out by the food and feed operator;

- 14) check the compliance with other prescribed general and special hygiene requirements in the establishment for production and distribution of food and feed;
- 15) carry out any other activity necessary in order to ensure accomplishing of the objectives of this Law.

In addition to the powers referred to in paragraph 1 of this Article, a veterinary inspector at the border crossing or bonded warehouses shall have the power to:

- 1) following a veterinary inspection of the consignment of food and feed and the accompanying documentation, allow import, transit or storage of food and feed by a decision made for each individual consignment separately that, based on the prescribed requirements, there are no veterinary obstacles for their import, transit or storage;
- 2) inspect and control the consignments of animals, food or feed intended for export, if they are reloaded or stored at the border crossing in the registered warehouses under the prescribed conditions;
- 3) issue or stamp, as appropriate, a certificate for animals, food and feed;
- 4) take samples of food and feed and forward them to the authorized laboratories for laboratory examination or perform the necessary examinations in the laboratory at the border crossing;
- 5) check and control the compliance with technical requirements in warehouses, customs free zones and bonded warehouses;
- 6) keep records of consignments of animals, food and feed exported, imported and in transit, when they cross the state border;
- 7) monitor and control disinfection of means of transport, warehouses and equipment in border crossings and bonded warehouses in the customs free zones;
- 8) monitor occurrence and movement of infectious diseases in neighbouring countries and notify the administration authority in charge of veterinary affairs and other competent authorities of the information acquired, according to the risk established.

Powers of a Phytosanitary Inspector

Article 78

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

- 1) inspect the establishment, surroundings, premises, equipment and means of transport in primary production of food of plant origin;
- 2) inspect and, if necessary, take samples of raw materials, materials and substances used for preparation of food of plant origin at primary production level;
- 3) inspect and, if necessary, take samples of materials, packaging and items coming into contact with food of plant origin at primary production level;
- 4) control the process of cleaning, disinfection, pest and rodent control, the method of use and storage of substances used for cleaning and disinfection, pest and rodent control used in business with food of plant origin at primary production;
- 5) control the method of labelling, 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 inspection, a sanitary inspector, in accordance with Article 75 paragraph 1 of this Law, after establishing that this Law or other regulation has been violated, he/she shall have obligation and the powers to:

- 1) order the withdrawal of unsafe food from the market;
- 2) order the restriction or prohibit trade in food, or order the withdrawal of food from the market until the hazard, or suspicions with respect to food safety is no longer present;
- 3) order the destruction of unsafe food in the prescribed manner;
- 4) order treatment of food in the prescribed manner;
- 5) prohibit advertising and marking of food in the manner misleading the customer;
- 6) prohibit the use of materials, packaging and items coming into contact with the food that could endanger human health and cause the change of food composition or the change of its sensorial characteristics under the normal and intended conditions of use;
- 7) prohibit the use of the establishment, premises, equipment and means of transport when they fail to meet the prescribed requirements;
- 8) prohibit the work to persons handling the food and coming into contact with food who fail to meet the prescribed requirements with regard to 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 inspecting a bonded warehouse and customs free zones shall also undertake the following administrative measures and actions:

- 1) prohibit import of a consignment of food, if:
 - the consignment or the means of transport fail to comply with the prescribed requirements;
 - the consignment of food is unsafe;
 - the consignment is not accompanied with prescribed documentation based on which the identity of the consignment can be established;
- 2) temporarily prohibit import of a consignment of food where elimination of shortcomings in the consignment and the accompanying documents is necessary, or if he/she suspects the consignment safety, in accordance with the risk analysis;
- 3) prohibit the use of the establishments for food storage in bonded warehouses, if they fail to comply with the prescribed requirements;
- 4) prohibit the use of the means of transport for food consignments, if they fail to comply with the prescribed requirements.
- 5) order the destruction of a consignment food established as unsafe, or at importer's request, order the return of the consignment to the supplier from abroad.

The costs incurred by enforcement of the measure of destruction, or return of unsafe food consignment, as appropriate, shall be borne by the importer.

Article 80

In addition to the administrative measures and actions provided by the law governing the inspection, the veterinary inspector, in accordance with Article 75 paragraph 2 of this Law, after establishing that this Law or other regulation has been violated, he/she shall have obligation and the powers to:

- 1) order the withdrawal of unsafe food or feed from the market;
- 2) order the restriction or prohibit trade in food or feed, or order the withdrawal of food or feed from the market until the hazard, or suspicions with respect to food safety is no longer present;
- 3) order the destruction of unsafe food or feed in the prescribed manner;
- 4) order treatment of food or feed in the prescribed manner;
- 5) prohibit advertising and marking of food or feed in the manner misleading the customer;
- 6) prohibit the use of the establishment, premises, equipment and means of transport when they fail to meet the prescribed requirements;
- 7) prohibit the use of materials, packaging and items coming into contact with the food or feed that could endanger human and animal health and cause the change of food composition or the change of its sensorial characteristics under the normal and intended conditions of use;
- 8) prohibit the work to persons handling and coming into contact with food or feed who fail to meet the prescribed requirements with regard to 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 controlling a border crossing or a bonded warehouse shall also undertake the following administrative measures and actions:

- 1) prohibit import, export or transit of consignments of animals, food or feed, if:
 - the consignment or the means of transport fail to comply with the prescribed requirements;
 - the consignment of food is unsafe;
 - the consignment is not accompanied with the prescribed documentation based on which the identity of the consignment can be established;
- 2) temporarily prohibit import, export or transit of a consignment of animals, food or feed where elimination of shortcomings in the consignment and the accompanying documents is necessary, or if he/she suspects the consignment safety, in accordance with the risk analysis;
- 3) prohibit the use of the establishments for food or feed storage in border crossings and bonded warehouses, if they fail to comply with the prescribed requirements;
- 4) prohibit the use of the means of transport for consignments of animals, food or feed if they fail to comply with the prescribed requirements.
- 5) order the destruction of a consignment of food or feed established as unsafe, or at importer's request, order the return of the consignment to the supplier from abroad.

The costs incurred by enforcement of the measure of destruction, or return of unsafe food or feed consignment, as appropriate, shall be borne by the importer.

Article 81

In addition to the administrative measures and actions provided by the law governing the inspection, the phytosanitary inspector, in accordance with Article 75 paragraph 3 of this Law, after establishing that this Law or other regulation has been violated, he/she shall have obligation and the powers to:

- 1) order the restriction or prohibit trade in food of plant origin at primary production level, until the hazard, or suspicions 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, packaging and items coming into contact with food of plant origin at primary production level which could endanger human health and cause the change of food composition or its sensorial characteristics under the normal and intended conditions of transport, handling and storing;
- 4) undertake other measures in accordance with the law.

XI. PENALTY PROVISIONS

Article 82

A fine ranging from one hundred to three hundred minimal wages in Montenegro shall be imposed on a company or other legal entity or entrepreneur if they:

- 1) produce and place on the market unsafe food (Articles 22, 23 and 24);
- 2) produce and place on the market unsafe feed and feeds food-producing animals with such feed (Articles 25, 26 and 27);
- 3) fail to label and mark food or feed in production and trade in the prescribed manner (Article 29);
- 4) advertise and present food or feed so as to mislead the consumers and ascribe medicinal characteristics to food or feed (Article 30);
- 5) use materials, packaging and items coming into contact with food or feed which might jeopardize human or animal health and result in the change of the composition of food or feed or their sensorial characteristics under the normal and intended conditions of use (Article 31);
- 6) in food or feed business operations, they fail to ensure compliance with the requirements prescribed by this Law and regulations issued based on this Law in all stages of production and distribution (Article 38, paragraph 1);
- 7) in food or feed business operations, fail to notify the competent authority referred to in Article 8 of this Law of any change in the production process, any change in product range and producer specification, no later than 15 days prior to the introduction of change (Article 38, paragraph 2);
- 8) in food or feed business operations in the production process, depending on the type of business, fail to employ at least one person with a university or specialization degree in an area corresponding to the type business activity performed in accordance with the regulation (Article 38, paragraph 3);
- 9) in food or feed business operations, fail to ensure traceability of food or feed, raw materials, materials 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) in food or feed business operations, fail to set up a system and procedures ensuring identification of a food or feed operator from whom they are supplied or whom they supplies with raw materials, materials and substances that are incorporated into food or feed, food-producing animals and finished products at all stages of production and distribution (Article 41, paragraph 2);
- 11) in food or feed business operations, fail to initiate without delay the procedure for withdrawal of food or feed from the market, following the information or suspicion that the food or feed that they imported, produced or placed on the market failed to comply with the requirements prescribed for food or feed safety, and fail to notify the competent authority thereof (Article 42, paragraph 1);

- 12) in food or feed business operations, fail to inform efficiently and accurately the consumer of the reasons for withdrawing food or feed (Article 42, paragraph 2);
- 13) in food or feed business operations in retail trade that could not have had a direct 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) fail to comply with general hygiene requirements in food or feed business operations (Article 43, paragraph 1);
- 15) in food or feed business operations of production and trade in food or feed after primary production, fail to ensure fulfilment of general hygiene requirements with respect to: establishments, premises, equipment, water and electricity supply, waste disposal, transport conditions, personal hygiene and training of persons handling or coming into contact with food or feed, during all stages of production and distribution (Article 44);
- 16) in food or feed business operations, fail to ensure compliance with the specific hygiene requirements at all stages of production and distribution of food or feed (Article 45, paragraph 1);
- 17) in food or feed business operations, fail to set up, maintain and continuously apply documented procedures based on HACCP principles (Article 46, paragraph 1);
- 18) in food or feed business operations, when a product, method of treatment or production process is changed, fail to harmonize the established procedures with the changes introduced (Article 46, paragraph 2);
- 19) commences the business operations prior to obtaining a license from the competent authorities (Article 52, paragraph 2);

A fine of ten to twenty minimal wages in Montenegro shall be imposed on the natural person and the responsible person in the company or other legal person for the misdemeanour referred to in paragraph 1 of this Article.

Article 83

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

Article 84

A food or feed operator using in production and trade the additives and other materials and substances that must not be used and are harmful to human life and health, as well as a food or feed operator changing the labels or label information, the protective measure of prohibition of work for the period of one year shall be imposed on such operator in addition to the fine.

XII. TRANSITIONAL AND FINAL PROVISIONS

Article 85

The existing authorized laboratories shall obtain accreditation within two years from the day this Law enters into force.

Article 86

67. FOOD SAFETY LAW

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

Article 87

Pending the organization of the administration authority in charge of phytosanitary control, the phytosanitary control in the field of safety of food of plant origin at primary production level shall be carried out by the Ministry of Agriculture.

Article 88

Companies, other legal persons, entrepreneurs and natural persons registered for production and distribution of food or feed shall harmonize their operations with this Law by 1 January 2011, at the latest.

Article 89

Food or feed operators engaged in production and distribution of food or feed shall set up and apply the system of hazard analysis and critical control points (HACCP) referred to in Article 46 of this Law and the traceability system referred to in Article 41 of this Law as of 1 January 2010.

Article 90

Regulations based on the authority from this law shall be adopted within one year from the day this Law enters into force.

Article 91

Pending the adoption of regulations based on the authority from this Law, the regulations adopted on the basis of the Law on Health Safety of Foodstuffs and General Use Items (Official Gazette of the Federal Republic of Yugoslavia 53/91) and the Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07) shall apply, unless they are in contravention of this Law.

Article 92

The day this Law enters into force, the foodstuff-related provisions of the Law on Health Safety of Foodstuffs and General Use Items (Official Gazette of the Federal Republic of Yugoslavia 53/91) and of the Law on Health Surveillance Over Foodstuffs and General Use Items (Official Gazette of the Republic of Montenegro 26/73) shall be repealed.

The day this Law enters into force, the provision of Article 4 paragraph 1 of the Law on Sanitary Inspectorate (Official Gazette of the Republic of Montenegro 56/92) in the part referring to the issuing of sanitary approval for establishments for production and distribution of foodstuffs shall be repealed.

The day this Law enters into force the provisions of the Veterinary Law (Official Gazette of the Republic of Montenegro 11/04 and 27/07) referring to food-producing animals, food of animal origin and feed shall be repealed.

Article 93

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

67. FOOD SAFETY LAW

SU-SK Bo 01-637/12

Podgorica, 29 November 2007

The Parliament of Montenegro

President

Ranko Krivokapic, manu propria