

LAW ON FOOD SAFETY

I. GENERAL PROVISIONS

Subject matter

Article 1

This Law shall govern the conditions for the food and feed safety, duties and responsibilities of food and feed business operators, including the traditional products, as well as other issues of relevance for food and feed safety, in order to ensure the protection of human life and health, environment, consumers and efficient market functioning.

Application of the Law

Article 2

- (1) This Law shall apply to all stages of production and distribution of food and feed.
- (2) 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 used for feeding food-producing animals for private domestic consumption.

Definition of food

Article 3

- (1) Food means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
- (2) Food also includes drink, chewing gums and any substance, including water, intentionally used respectively incorporated into the food during its manufacture, preparation or treatment that meets on control points the requirements prescribed for water accordance with specific legislation for quality of water for human consumption.
- (3) Food shall not include:
 - 1) feed;
 - 2) live animals unless they are prepared for placing on the market for human consumption;
 - 3) plants prior to harvesting; picking or collection of fruits;
 - 4) medicinal products in accordance with specific legislation for medicinal products;
 - 5) cosmetic products in accordance with specific legislation;
 - 6) tobacco and tobacco products;
 - 7) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs from 1961, and the United Nations Convention on Psychotropic Substances from 1971;
 - 8) residues and contaminants.

Food types

Article 4

- (1) According to the origin, the food shall be classified as:
 - 1) food of animal origin;
 - 2) food of non-animal origin.

Definitions

Article 5

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

- 1) **food business** means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;

- 2) **food business operator** means the natural or legal person or entrepreneur responsible for ensuring that the requirements of food law are met within the food business under their control;
- 3) **feed** (or *feedingstuff*) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
- 4) **feed business** means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any production, processing or storage of feed on one's own holding;
- 5) **feed business operator** means the natural or legal person or entrepreneur responsible for ensuring that the requirements of food law are met within the feed business under their control;
- 6) **retail** means the handling and/or processing, preparation and storage of food at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, restaurants and other food service operations, shops, supermarket distribution centres and wholesale outlets;
- 7) **wholesale market** means handling of food in one or more separate units that have common equipment and premises where food is sold to the operators of food;
- 8) **placing on the market** means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
- 9) **risk** means the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
- 10) **risk assessment** means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
- 11) **risk management** means the process of weighing the policy and measures, separated from the risk assessment, used to compare alternatives in relation to risk, in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need, selecting appropriate prevention and control measures;
- 12) **risk communication** means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses operators, the academic communities and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
- 13) **hazard** means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
- 14) **traceability** means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;
- 15) **stages of production, processing and distribution** means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer or supply and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;
- 16) **primary production** means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter, as well as hunting and fishing and the harvesting of products (wild fruits and plants) from nature;
- 17) **primary product** means a product obtained from primary production, including products obtained from the soil, livestock breeding, hunting and fishing;
- 18) **final consumer** means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity;

- 19) **food hygiene** means a set of prescribed measures and conditions necessary to control the hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use;
- 20) **official control** means any form of control that the competent authority performs for the verification of compliance with food and feed law, animals and plants health and animal welfare;
- 21) **verification** means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled;
- 22) **audit** means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives;
- 23) **inspection** means the examination of any aspect of food, feed, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of food and feed law and animal health and animal welfare;
- 24) **monitoring** means systematic conducting of a planned sequence of activities and measurements undertaken with a view to obtaining an overview of the situation, implementation of regulations concerning food and feed, animal health and animal welfare;
- 25) **surveillance** means systemic observation and control of one or more food or feed businesses, food or feed business operators or their activities;
- 26) **non-compliance** means non-compliance of prescribed requirements for food or feed, animal health and welfare;
- 27) **sampling for laboratory analysis** means taking feed or food or any other substance including those from the environment, relevant to the production, processing and distribution of food or feed or to the health of animals, in order to verify through laboratory analysis the compliance with the requirements for food and feed and animal health as laid down by legislation;
- 28) **official certification** means issuing, in a written or electronic form of a certificate for food or feed at imports, by which the inspector certifies the compliance of the requirements set;
- 29) **official detention** means the procedure by which the border inspector ensures that food or feed is not moved or tampered with pending a decision on its purpose and includes also storage of food or feed by food and feed business operators in accordance with instructions from the border inspector;
- 30) **equivalence** means the capability of different systems or measures to meet the same objectives;
- 31) **import** means release for free circulation of food or feed or the intention to release food or feed for free circulation in accordance with customs regulation;
- 32) **introduction** means imports under the customs supervision in accordance with the law governing customs procedures, as well as introduction into a free zone or free warehouse;
- 33) **documentary check** means the examination of commercial documents and, where necessary, of other prescribed documents accompanying the consignment;
- 34) **identity check** means a visual inspection to ensure that certificates or other documents accompanying the consignment match the labelling and the content of the consignment;
- 35) **physical check** means a check on the food or feed itself which may include checks on the means of transport, on the packaging, labelling and temperature, the sampling for analysis and laboratory testing and any other checks necessary to verify compliance with food law;
- 36) **control plan** means a plan on the structure and organisation of official controls;
- 37) **feed materials** means products of plant or animal origin, serving to meet animals' nutrition needs in their natural state, fresh or preserved, and of products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing feed additives, which are intended for use in oral animal feeding either directly as such, or after processing, or in the preparation of compound feed or as carrier of premixtures.

II. COMPETENT AUTHORITIES FOR FOOD SAFETY

Competent Authorities

Article 6

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

- State administrative authority in charge of food safety, agriculture and veterinary issues (hereinafter referred to as: the Ministry), and
- Administrative authority in charge of food safety (hereinafter referred to as: the Administrative Authority).

Scope of authority of the Ministry

Article 7

- (1) The Ministry:
 - 1) Proposes food and feed safety policy;
 - 2) Adopts regulations for the enforcement of this Law;
 - 3) Adopts annual monitoring programs (residues in food of animal origin and feed, pesticide residues in food, zoonoses, microbiological criteria in food, contaminants in food and feed and other programmes in accordance with this Law);
 - 4) Organizes conducting of official controls in accordance with this Law;
 - 5) Adopts a multi-annual official controls plan for food and feed in accordance with this Law;
 - 6) Submits annual reports on food and feed safety to the Government of Montenegro (hereinafter: the Government) and the European Commission in accordance with this Law;
 - 7) Cooperates with international organizations and competent authorities of other states in the field of food and feed safety;
 - 8) Performs other activities in accordance with this Law.
- (2) The Ministry shall be the central authority for food and feed safety and the contact point with the European Commission in the field of food safety.

Scope of authority of the Administrative authority

Article 8

The Administration Authority:

- 1) Establishes the compliance with the requirements and issues approvals for carrying out business operations in establishments for production, processing and distribution of food and feed;
- 2) Registers food and feed establishments;
- 3) Sets up and keeps the Central Register of Approved Establishments carrying out food and feed business operations;
- 4) Prepares and implements the multi-annual official controls plan for food and feed in accordance with this Law;
- 5) Prepares annual reports on implementation of the multi-annual official controls;
- 6) Prepares technical basis for:
 - adoption of legislation for the enforcement of this Law;
 - monitoring programmes in accordance with this Law;
 - contingency plan in the field of food and feed safety;
- 7) Cooperates with the European Commission, and
- 8) Performs other technical and administrative tasks in accordance with the Law.

The regulations for the prevention of the consequences that may be caused with food or feed
Article 9

In order to provide a high level of human health protection and the efficient undertaking measures to prevent the consequences that may be caused by food or feed Government shall issue further regulations on:

- pathogens, microorganisms that are not pathogens and parasites to which the risk assessment determined the risk to human health which is contained in food or feed and other special microbiological criteria;
- measures to prevent poisoning people with food;
- measures to prevent the harmful effects of food on human and animal when a risk assessment found that certain foods or animal feed presents a risk;
- cumulative toxic effects originating from food or feed;
- foods intended for certain categories of consumer with special health care and sensitivity that causes effects on the health of consumers;
- foreign substances present in food and feed or suspected to be present in the series and in the rest of the series of food or feed;
- method of preventing the placing on the market of food and feed which are not suitable for human consumption and animals due to the content of certain contaminants;
- measures taken to remedy deficiencies with aim to establish food safety system and the specific requirements for hygiene of food and feed in primary production and after primary production;
- preventing, eliminating or reducing risks directly or indirectly via the environment to an acceptable level, where they are exposed to people and animals;
- pathogens that can cause serious illness in humans by eating contaminated food or feed;
- measures to prevent *Trichinella* in humans from consuming the meat of domestic swine, wild boar, horses and other animals that are infected by trichinellosis and method of sampling carcasses and methods for the detection of *Trichinella* and determining the status of the farms and the requirements for the importation of meat and other animal diseases which are food transmitted to humans;
- establishing traceability for particular food or feed and measures to prevent and manage the risk in accordance with the precautionary principle;
- requirements for products of plant origin (germ), the traceability of germs, seeds intended for the production of germs and other foods;
- traceability requirements for genetically modified food;
- the initiation of proceedings and the withdrawal of food and feed from the market in order to prevent unforeseen adverse effects on human health, animal health or the environment, including ecosystems;
- the requirements for absence or reduction of the presence of gluten in the food;
- the requirements for use in or on foods, food ingredients with flavoring properties;
- measures for the prevention and reduction of patulin contamination in apple juice and apple juice, which is an ingredient of other drinks;
- the method of monitoring the level of hidden (background levels) for dioxins, dioxin-like polychlorinated biphenyls (hereinafter: PCBs) and other PCBs in food;
- determining the maximum levels of coccidiostats or histomonostats in food resulting from the transfer of these substances in non-target feed;
- elimination of the potential risks to human health which may be due to food and feed.

III. FOOD SAFETY PRINCIPLES

General principle

Article 10

Food and feed safety should be based on provision of a high level of protection of human life and health, protection of consumers' interests, the protection of animal health and welfare, plant health and environmental protection and free movement of food and feed produced and placed on the market.

Risk analysis principle

Article 11

- (1) Risk analysis is a process that consists of risk assessment, risk management and risk notification, carried out in order to achieve a high level of protection of human health and life, except where this is not appropriate to the circumstances or the nature of the measure.
- (2) The risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
- (3) The risk assessment referred to in paragraph 2 of this Article may be carried out by scientific-research institutions in food safety, complying with the requirements in terms of qualified staff and authorised by the Ministry.
- (4) In case there are no scientific-research institutions meeting the requirements referred to in paragraph 3 of this Article exist in Montenegro, the Ministry may authorise a specialised institution of an European Union Member State for assessment of food and feed risks.
- (5) The institutions referred to in paragraph 3 of this Article:
 - 1) Collect and analyse data in order to provide characterisation and monitoring of risks with either direct or indirect effect on food or feed safety;
 - 2) Provide expert advice and scientific support to improvement of food or feed safety;
 - 3) Propose undertaking of measures for elimination of food or feed risks;
 - 4) Co-operate with competent state authorities and administrative authorities in the information exchange area;
 - 5) Give proposals for notification, public participation and education on importance of food or feed safety;
 - 6) Provide scientific opinions and scientific and technical support to bodies referred to in Article 6 of this Law in the field of food or feed safety, human nutrition, placing on the market of novel food, nutrient enriched food, food for special dietary needs, feed for special dietary needs and genetically modified food and feed, animal health and protection and plant protection;
 - 7) Initiate revision of the legislation on safety of food and feed;
 - 8) Provide information to bodies referred to in Article 6 of this Law on results of risk assessments made.
- (6) More detailed requirements in terms of qualified staff referred to in paragraph 3 of this Article shall be laid down by a regulation of the Ministry.

Risk management

Article 12

- (1) Risk management is carried out so as to ensure that the preventative measures, supervision and official controls undertaken in order to reduce, eliminate or avoid the risk to human and animal health by ingestion of food, are based on risk assessment results and other factors of relevance or risk elimination, and that they are unbiased, efficient and appropriate.
- (2) Risk management is carried out by the administrative body through surveillance, official controls and preventive measures.
- (3) In the course of risk management, results of risk assessment and/or scientific opinions by the institution referred to in Article 11 paragraph 3 of this Law, the European Food

Safety Authority – EFSA) (hereinafter referred to as: EFSA) and other factors of relevance for safety shall be taken into account.

Cooperation with other institutions

Article 13

(1) With a view to conducting an adequate risk assessment, the institutions referred to in Article 11 paragraph 3 of this Law may establish co-operation with other scientific institutions, other administrative bodies, laboratories and other legal entities involved in the food and feed safety system in the country and abroad.

(2) The cooperation referred to in paragraph 1 of this Article shall be exercised at the scientific level through coordination of activities, exchange of data, development and implementation of joint projects, exchange of know-how and best practices in the area of additives and nutrition sources added to food, additives and products or substances used in feed, plant protection products and residues thereof, genetically modified organisms, food for special dietary needs, food and allergies, biological hazards, contaminants in the food chain, animal health and welfare, plant health protection, materials coming into contact with food, enzymes, dyes and auxiliary materials and provision of scientific and technical assistance and other expert opinions.

Precaution

Article 14

(1) Food and feed safety should be based on the principle of reliable, scientifically justified and effective implementation of procedures and taking measures in the field of food and feed safety, appropriate to the requirements of protecting human life and health, animal health and welfare, plant health and environmental protection.

(2) Where, based on the information available potential harmful effects of food and feed to human and animal health is identified, and there are also scientific dilemmas, temporary risk management measures necessary to ensure a high level of health protection shall be undertaken pending the availability of more reliable scientific information necessary for a comprehensive risk assessment.

(3) 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 to an extent beyond that necessary to ensure efficient protection of human and animal health, taking care of technical and economic feasibility and justified reasons, and they shall be reviewed within a reasonable period of time depending on the type of the risk identified and the type of scientific data necessary for clarification of scientific dilemmas and implementation of a comprehensive risk assessment.

Protection of Consumers' Interests

Article 15

Food information on the basis of which the consumer decides on the consumption of food shall be complete and accurate for the purpose of consumers' protection and prevention of the following:

- fraudulent or deceptive practices;
- the adulteration in food, and
- any other practices which may mislead the consumer.

Transparency

Article 16

In the course of preparation of legislation, evaluation of their effects or revision of food or feed legislation, or undertaking of measures in accordance with this Law, public consultations shall be organized in accordance with the law, except where the urgency of the matter does not allow it.

Public information

Article 17

In case of a threat where some food or feed may pose a risk to human or animal health, the Ministry shall, without delay, through print or electronic media, inform the general public about the type of food and feed, the risk it may pose, as well as the measures undertaken or are to be undertaken to prevent, reduce or eliminate that risk.

IV. IMPORT AND EXPORT

Import of food and feed

Article 18

- (1) Food and feed imported for the purpose of placing on the market on the territory of Montenegro shall meet the requirements as laid down by this Law or requirements that are at least equivalent to the requirements laid down by this Law unless otherwise provided for under a special agreement with the exporting country.
- (2) Equivalent requirements referred to in paragraph 1 of this Article shall be considered as requirements for which the competent authority of the exporting country objectively demonstrates that they meet the same or higher level of human health protection in relation to the level required by this Law.
- (3) The assessment of equivalency of the requirements referred to in paragraph 2 of this Article, shall be done by the Administrative Authority at request of an interested party.

Export of food and feed

Article 19

- (1) Food or feed exported or re-exported shall meet the requirements as laid down by this Law, as well as the requirements of the importing country or the requirements as laid down by a special agreement with the importing country.
- (2) Notwithstanding the paragraph 1 of this Article, except in the case where food or feed is harmful to health or unsafe, it may be exported or re-exported from the territory of Montenegro on the basis of the agreement from the competent authorities of the importing country and provided they are informed of the reasons and circumstances for which the food or feed concerned could not be placed on the market on the territory of Montenegro.

VII. GENERAL FOOD SAFETY REQUIREMENTS

Prohibition of placing food on the market

Article 20

- (1) It shall be forbidden to place unsafe food on the market.
- (2) The food shall be deemed to be unsafe if:
 - 1) It is harmful to human health; and/or
 - 2) It is unfit for human consumption.

Determining food safety

Article 21

- (1) In determining the safety of food, the following shall be taken into account:
 - 1) normal conditions of consumption of food and conditions at each stage of production, processing and distribution;
 - 2) information available to the consumer, including information on labels and other information concerning the prevention of adverse effects of food on health.
- (2) In determining the food harmfulness, the following shall be taken into consideration:
 - 1) Probable immediate and/or short-term and/or long-term effects of that food to the health of a person consuming it and the impact on subsequent generations;
 - 2) Probable cumulative toxic effects;

- 3) The particular health sensitivity of specific categories of consumers where the food is intended for that category of consumers.
- (3) In determining that the food is unfit for human consumption, regard shall be taken of whether the food is unfit for its intended use for reasons of possible contamination by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
- (4) Where food found unsafe is a part of a batch, lot or consignment of food of the same food type according to description and category, it shall be considered that all food in that batch, lot or consignment is unsafe, unless, based on a detailed assessment, it is established that the rest of the batch, lot or consignment is safe.
- (5) Where food meets the requirements as laid down by a specific regulation on food safety related to that food, but there are reasons to suspect its safety, the Administrative Authority shall take appropriate measures to impose restriction on its placing on the market or withdrawal from the market, regardless of its compliance.
- (6) The measures referred to in paragraph 5 of this Article shall be laid down by a regulation of the Ministry.

Prohibition on placing feed on the market

Article 22

- (1) It shall be forbidden to place feed on the market or feed food-producing animals with it if it is unsafe.
- (2) Feed shall be deemed to be unsafe if:
- It has an adverse effect on human or animal health;
 - It is derived from food-producing animals unsafe for human consumption.

Determining feed safety

Article 23

Where feed non-compliant with the requirements set for feed safety is a part of a batch, lot or consignment of feed of the same feed type according to description and category, it shall be considered that all feed in that batch, lot or consignment is unsafe, unless, based on a detailed assessment, it is established that the rest of the batch, lot or consignment is safe.

Presentation of food and feed

Article 24

When placing it on the market, food or feed shall not mislead the consumer or buyer with signs, advertising and/or presenting, shape, appearance or packaging, packaging materials, the manner in which it is arranged and the setting in which it is displayed and the food information made available through the media.

Food and feed safety suspicions

Article 25

Where food or feed meets the requirements as laid down by this Law, but its safety is suspected, the Ministry may restrict its placing on the market or withdraw food or feed from the market.

Responsibility of the food and feed business operators

Article 26

Food and feed business operators, at all stages of production, processing and distribution within their businesses, shall ensure that the food or feed meets the requirements laid down by the law and shall control the compliance of the requirements laid down by the law.

Traceability

Article 27

- (1) Food and feed business operators shall put in place traceability at all stages of production, processing and distribution of food, feed, food-producing animals and substances added or expected to be added to food or feed.
- (2) Food and feed business operators shall put in place the traceability system and the procedures to identify the following persons:
 - who supply food, feed, food-producing animals and substances that are added or expected to be added to food or feed;
 - to whom the products are supplied;
- (3) Food and feed which is placed on the market or likely to be placed on the market shall be adequately labelled or identified to enable traceability through relevant documentation or information.
- (4) More detailed requirements for traceability of food of animal origin shall be laid down by a regulation of the Ministry.

Obligations of the food business operator

Article 28

- (1) If a food business operator suspects or establishes that food which it has imported, produced, processed or distributed is non-compliant it shall, without delay, initiate the procedure to withdraw the food in question from the market where the food has left its immediate control and inform the Administrative Authority thereof.
- (2) Where the product has reached the consumer, the food business operator shall immediately inform the consumers of the reasons for the withdrawal of food and, if necessary, recall from consumer the food that has already been delivered when the high level of health protection cannot be achieved by other measures.
- (3) Food business operator, carrying out retail or distribution activities which do not involve the packaging and labelling of food, shall immediately initiate the procedures to withdraw the non-compliant food from the market, collaborate with the producer and the Administrative Authority and other competent authorities in undertaking of measures and provide the necessary information regarding the traceability of food.
- (4) Where food business operator suspects or establishes that the food placed on the market may be harmful to human health, it shall, without delay, undertake measures to prevent risks and inform the Administrative authority thereof.

Obligations of the feed business operator

Article 29

- (1) If a feed business operator suspects or establishes that food which it has imported, produced, treated, processed or distributed is non-compliant it shall, without delay, initiate the procedure to withdraw the feed in question from the market and inform the Administrative Authority thereof.
- (2) In case referred to in paragraph 1 of this Article and Article 25 of this Law, feed shall be destroyed unless the Administrative Body orders undertaking of measures to ensure elimination of deficiencies identified.
- (3) The feed business operator shall immediately inform the animal owners or keepers of the reasons for withdrawal of feed and, if necessary, request recall of the feed already delivered.
- (4) The feed business operator, carrying out retail or distribution activities which do not involve the packaging and labelling, shall immediately initiate the procedures to withdraw the non-compliant feed from the market, collaborate with the producer and the Administrative Authority in undertaking of measures and provide the necessary information regarding the traceability of feed.
- (5) Where the feed business operator suspects or establishes that the feed placed on the market may be harmful to animal health or indirectly to human health, it shall, without

delay, undertake measures to prevent risks and inform the Administrative authority thereof.

Liability for damage
Article 30

- 1) Food or feed business operator shall be liable for damage caused by food and/or feed, in accordance with the general legislation on liability for the damage caused.
- 2) Food and/or feed business operator shall be liable also for damage, in accordance with the general legislation on liability for the damage caused, if the information and data on food or feed, made available to the consumer or buyer, do not correspond to the properties of food or feed.

VI. RAPID ALERT AND NOTIFICATION SYSTEM

Rapid Alert and Notification System
Article 31

- (1) The Rapid Alert System for the notification of a direct or indirect risk to human health deriving from food or feed shall be established as an information network.
- (2) The system referred to in paragraph 1 of this Article shall be established and maintained by the Ministry as the contact point for the exchange of information with the European Commission – the *Rapid Alert System for Food and Feed (hereinafter referred to as: the RASFF)*.
- (3) The manner of establishing the system referred to in paragraph 1 of this Article, the competent authorities and organizations in charge of the exchange of information, the procedure of exchange and content of information shall be governed by a regulation of the Ministry.

Emergency measures
Article 32

- (1) Where it is established that food or feed may pose a serious risk to human or animal health or the environment and that the risk could not be prevented with the implementation of appropriate measures, the Ministry shall order the implementation of one or more of the following measures, depending on the risk nature or level:
 - 1) In the case of food or feed of domestic origin:
 - temporary ban on the placing on the market or use of food or feed;
 - specific requirements for the handling of food or feed, or
 - other appropriate measures;
 - 2) in the case of imported food or feed:
 - temporary ban on imports of food and feed from the exporting country or part of the exporting country or the country of transit;
 - specific measures for the handling of food or feed, or
 - other appropriate measures.

Crisis management
Article 33

- (1) In the case that food or feed poses either a direct or indirect risk to human health, animal health or the environment that cannot be prevented, eliminated or reduced to an acceptable level by implementation of measures as laid down by this Law (hereinafter referred to as: the crisis), the measures laid down by the general contingency plan shall be implemented.
- (2) The plan referred to in paragraph 1 of this Article shall include the following: types of crises with either direct or indirect risks to human health, the measures and manner of their implementation to eliminate the risk of food and feed, authorities and organizations responsible for the implementation of the measures, means and equipment needed to implement the plan, the manner of control of implementation of measures and the manner of public information.

- (3) The general contingency plan shall be adopted by the Government.
- (4) The plan referred to in paragraph 1 of this Article shall be prepared by the Ministry, and it shall organize simulation exercises for implementation of the contingency plan.

Operational contingency plan

Article 34

- (1) The general contingency plan shall be implemented on the basis of the operational contingency plan (hereinafter referred to as: the operational plan) laying down the measures to be implemented urgently once it is established that food or feed poses a risk to human or animal health, either directly or through the environment.
- (2) The operational plan shall lay down in particular the following:
 - The authority and organizations for implementation of measures;
 - Financial and other resources necessary;
 - The manner and procedure for the exchange of information among competent authorities and organizations, and persons either directly or indirectly involved in implementation of measures.
- (3) The operational plans shall be adopted by the Ministry and it shall organize simulation exercises for implementation.
- (4) Revisions of the general contingency plan and the operational plan shall be done on the basis of the experiences gained during implementation and in the case of change of competent authorities and organizations.
- (5) More detailed contents of the operational plan shall be laid down by a regulation of the Ministry.
- (6)

VII. CONDITIONS FOR PLACING FOOD AND FEED ON THE MARKET

Obligations of business operators for food hygiene

Article 35

- (1) The food business operator shall:
 - Be primarily responsible for food safety;
 - Be responsible for food safety at all stages of production, processing, treatment and distribution;
 - maintain the cold chain (ensure the maintenance of prescribed constant temperature for this type of food at all stages of production processing and distribution) for food that could not be safely stored at room temperature, especially for frozen food;
 - apply the procedures based on the principles of Hazard Analysis and Critical Control Points (hereinafter referred to as: HACCP), together with the implementation of good hygiene practices;
 - follow the instructions for good practices at all stages of the food chain, in order to comply with the food hygiene regulations and for the implementation of HACCP principles;
 - establish microbiological criteria and temperature control requirements that are based on scientific risk assessment;
 - ensure that imported food meets the same hygiene requirements or equivalent requirements as food produced on the territory of Montenegro.

General obligations

Article 36

Food business operator, at all stages of production, processing and distribution of food under its control shall ensure for such food the compliance with the food hygiene requirements as laid down by this Law.

Food hygiene requirements

Article 37

- (1) Food business operator shall, depending on his business operations, establish and implement the appropriate general and specific food hygiene requirements referred to paragraphs 6 and 7 of this Article.
- (2) Business operator with food of animal origin carrying out the primary production with accompanying activities, or activity after primary production shall, in addition to the requirements referred to in paragraph 1 of this Article, establish and carry out also the special requirements for products of animal origin referred to Article 44 paragraph 6 of this Law.
- (3) The food business operator shall, depending on the food type, implement also the special food hygiene measures in order to ensure the following:
 - compliance with microbiological criteria for food;
 - compliance with the requirements for control of the temperature regime for food;
 - maintenance of the cold chain;
 - sampling and laboratory testing, and
 - meeting the other requirements as laid down by this Law.
- (4) Where the food business operator takes samples and performs laboratory tests on its own, it may apply methods that produce results equivalent to the results obtained applying the reference methods, if these are scientifically validated in accordance with the internationally recognized rules or protocols, unless sampling methods and analyses are defined by specific regulations.
- (5) The food business operator referred to in paragraph 1 of this Article shall use the good practices instructions, guidelines and instructions referred to in Article 53 of this Law, in order to meet the requirements as laid down by this Law.
- (6) The requirements for food hygiene referred to in paragraph 1 of this Article shall be laid down by a regulation of the Government.
- (7) The regulation referred to in paragraph 6 of this Law shall lay down also the requirements in terms of facilities, premises, equipment, water and power supply, waste disposal, heat treatment, packaging, personal hygiene, training of staff and transport at all stages of production, processing and distribution of food, including the primary production of food with accompanying activities.

Derogations

Article 38

- (1) The hygiene requirements referred to in Articles 37, 39 and 40 of this Law shall not apply to:
 - primary production of food for private domestic use;
 - preparation, handling or storage of food intended for private domestic consumption;
 - food business operators that directly supply small quantities of primary products to the final consumer or to local market retail facilities directly supplying the final consumer;
 - collection centres and tanneries that collect and treat skin and hide as raw material for the production of gelatine or collagen.
- (2) The hygiene requirements concerning the facility, premises and equipment, types of primary products referred to in paragraph 1 indent 3 of this Article, the criteria for the determination of small quantities of primary products and local markets shall be laid down by a regulation of the Government.

Personal hygiene of staff

Article 39

- (1) The food business operator shall, at all stages of production, processing and distribution, ensure that persons performing food-handling tasks shall maintain a high degree of personal hygiene and wear suitable, clean and, where necessary protective clothing and footwear referred to Article 37 paragraph 6 and 7 of this Law.
- (2) The food business operator shall, at all stages of production, processing and distribution, ensure that persons suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted with infected wounds or diarrhoea shall not handle food or enter any food-handling area if there is any likelihood of direct or indirect contamination.
- (3) Persons referred to in paragraph 2 of this Article shall immediately report the illness or symptoms or their causes, to the person responsible in the food business facility.

Staff training

Article 40

- (1) The food business operator shall, at all stages of production, processing and distribution, ensure that persons who:
 - come into direct contact with food are supervised, instructed and/or trained regarding the food hygiene rules commensurate with their work activity;
 - are responsible for the development and maintenance of procedures based on HACCP principles or for the application of appropriate guides, have received adequate training on the implementation of HACCP principles.
- (2) The training referred to in paragraph 1 of this Article may be delivered as in-service training, organization of training courses, information campaigns of the association of food business operators or competent authorities, guides or in other appropriate ways.

Hazard Analysis and Critical Control Points

Article 41

- (1) Food business operators shall put in place, implement and maintain permanent procedures based on the HACCP at all stages of production, procession and distribution of food after primary production and the accompanying activities.
- (2) The HACCP principles shall consist of the following:
 - identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
 - identifying the critical control points in stages referred to paragraph 1 of this Article at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
 - establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards to acceptable levels;
 - establishing and implementing effective monitoring procedures at critical control points;
 - establishing corrective actions to be undertaken when the monitoring system indicates that a critical control point is not under control;
 - establishing procedures, which shall be carried out regularly, to verify the efficient functioning of measures outlined in indents 1 to 5 of this paragraph;
 - establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures referred to in indents 1-6 of this paragraph.
- (3) Food business operator shall, when making changes to the product, process or production stage, make changes also to established procedures.
- (4) The food business operator shall:

- at the request of the Administrative Authority, demonstrate compliance of established procedures referred to in paragraph 1 of this Article, commensurate to the nature and scope of activity;
 - provide chronological and timely documentation of actions taken within the established procedures;
 - maintain documentation and records.
- (5) Notwithstanding the paragraph 1 of this Article the food business operator, who carries out the activity in which critical control points cannot be identified in the preparation, production and processing of food shall put in place the good hygiene practice.

Derogations **Article 42**

- (1) A food business operator with a small volume of production, treatment and processing of products or using traditional production methods or located in an area with specific geographical constraint may be granted derogations in terms of requirements concerning construction, development and equipping of the establishment in order to facilitate business operations.
- (2) The food business operator producing traditional products may be granted derogations for premises where such products are exposed to surroundings needed for development of specific traits of the traditional product concerned and materials that the equipment for production of such products is made of.
- (3) More detailed conditions for derogations referred to in paragraph 1 of this Article shall be laid down by a regulation of the Government.

Microbiological criteria for food **Article 43**

- (1) A food business operator may place on the market only food that meets the microbiological criteria as laid down by this Law.
- (2) The food business operator shall at every stage of production, processing and distribution, including the retail sale of food, take measures based on HACCP principles, with application of good hygiene practice, so that:
 - supply, handling and processing of raw materials and food is done under control, meeting the microbiological criteria for processes hygiene;
 - comply with the food safety criteria throughout the self-life of the product, under specified conditions of distribution, storage and use.
- (3) The food business operator producing and preparing food shall prepare a sampling plan for finished food and surface swabs for the purpose of validation and verification of its procedures.
- (4) For the purpose of establishing the compliance of food with microbiological criteria during the shelf-life, the food business operator producing food, may carry out study food testing in accordance with the regulation referred to in paragraph 5 of this Article, and in particular for the food ready for consumption.
- (5) The microbiological criteria for food, the food safety hygiene processes, the study food testing and sampling method shall be laid down by a regulation of the Government.

Obligations of business operators for food of animal origin **Article 44**

- (1) The business operator for food of animal origin shall, in addition to the requirements referred to in Articles 37, 39, 40, 41 and 43 of this Law, comply also with the specific hygiene requirements for unprocessed and processed products of animal origin referred to paragraph 6 of this Article.
- (2) The specific requirements referred to in paragraph 1 of this Article shall not apply to foods containing products of plant origin and processed products of animal origin, unless otherwise provided for by the Law.

- (3) The processed products of animal origin, used for preparation of food referred to in paragraph 2 of this Article, shall comply with the specific requirements for hygiene products of animal origin during production and handling.
- (4) The specific hygiene requirements referred to in paragraph 1 of this Article shall not apply to:
 - 1) primary production of products of animal origin intended for private domestic consumption;
 - 2) preparation, handling or storage of products of animal origin intended for private domestic consumption;
 - 3) food business operator that directly supplies small quantities of primary products to the final consumer or to local market retail facilities directly supplying the final consumer, as follows:
 - poultry meat and lagomorphs slaughtered on the holding;
 - wild game or wild game meat that hunters supply the final consumer with;
- (5) In addition to specific hygiene requirements for products of animal origin, the regulations governing human health, animal health, animal welfare, animal identification and traceability of products of animal origin shall apply.
- (6) The specific hygiene requirements for food of animal origin referred to in paragraph 1 of this Article, and specific requirements for food business operators referred to in paragraph 4 item 3 of this Article, the criteria for determining the small quantities of products and local markets shall be laid down by a regulation of the Government.
- (7) More detailed requirements for implementation of general and specific hygiene measures for certain products of animal origin, the requirements in terms of animal health and public health shall be laid down by a regulation of the Government.

Elimination of surface contamination

Article 45

- (1) From surface-contaminated products of animal origin the contaminants may be removed only with drinking water, clean water and substances that are permitted for use in reduction of surface contamination.
- (2) The types of substances referred to in paragraph 1 of this Article and the manner of their application for reduction of surface contamination shall be laid down by a regulation of the Government.

Health and identification marks

Article 46

- (1) Food business operator shall not place on the market the food of animal origin originating from the establishment that has not been approved in accordance with Article 50 paragraph 13 of this Law and which is not marked:
 - with health mark, and/or
 - identification mark.
- (2) Food business operators may place an identification mark on a product of animal origin only if the product was produced in approved establishments in accordance with Article 50 of this Law.
- (3) Health and identification marks referred to in paragraph 1 of this Article and the method of labelling of food of animal origin shall be laid down by a regulation of the Government.

Register of establishments

Article 47

- (1) Food or feed business operator may perform the activity at all stages of production, processing and/or distribution of food or feed only in registered or approved establishments.

- (2) The approved, or registered establishments shall be entered in the Central Register of registered or approved establishments (hereinafter referred to as: the Register) which shall be kept by the Administrative Authority.
- (3) The Register shall be published on the website of the Administrative Authority.
- (4) The manner of and keeping of the Register shall be laid down by a regulation of the Ministry.

Registration of establishments

Article 48

- (1) Prior to commencing business operations in an establishment where operations subject to registration are to be carried out, the food or feed business operator shall submit to the Administrative Authority the request for registration of the establishment.
- (2) The Administrative Authority, on the basis of the request referred to in paragraph 1 of this Article, shall issue a decision on the registration of the establishment and on the entry in the Register if is together with request submit documentation referred to paragraph 3 of this Article.
- (3) The types of establishments where operations subject to registration are carried out, the form for the request for registration and the documentation to be submitted along with the request shall be laid down by a regulation of the Ministry.

Removal from the Register

Article 49

The establishment referred to in Article 48 of this Law shall be deleted from the Register:

- at the request of the food or feed operator;
- based on the inspector's decision on prohibition imposed on carrying out of operations in the establishment due to non-compliance with the conditions prescribed for carrying out of operations for which the decision on entry in the Register was issued;
- based on the information by the food and feed operator or by inspector that the business operations in the establishment concerned have ceased for more than one year.

Approval of establishments

Article 50

- (1) Feed or food business operators shall not commence business operations in an establishment where business operation subject to approval is carried out without prior approval of the establishment for carrying out of business operations in the establishment concerned (hereinafter referred to as: the approval).
- (2) Food or feed business operator shall prior to the commencement of operations, submit the to the Administrative Authority the request for the approval of the establishment.
- (3) Along with the request, referred to in paragraph 2 of this Article, the following shall be submitted in particular:
 - a drawing of the establishment with the layout;
 - description of the technological procedure.
- (4) Proof of registration of feed or food business operators mentioned in paragraph 2 of this article in the Central Register of Business Entities obtain Administrative Authority ex officio.
- (5) Upon submitting a proper request referred to in paragraph 3 of this Article, the Administrative Authority shall form a Commission for Inspection of Establishments (hereinafter referred to as: the Commission) in order to establish the compliance with the requirements as laid down by this Law.
- (6) Upon the inspection of the establishment and determining the compliance with the prescribed requirements in terms of infrastructure, equipment, and proper documentation of control put in place by the operator, the Commission shall, upon completion of at least

one direct inspection of the establishment, prepare a protocol with a proposal for the issuance of a conditional approval for a period of three months.

- (7) The Administrative Authority, based on the proposal referred to in paragraph 6 of this Article, shall issue a conditional approval and enter the establishment into the Register.
- (8) When issuing the approval referred to in paragraph 7 of this Article for an establishment operating with food of animal origin, a veterinary control number shall be assigned to it as well.
- (9) Prior to the expiration of the period referred to in paragraph 7 of this Article, the Commission shall re-check the establishment while carrying out the approved activity in order to establish and verify the compliance of other requirements as laid down by this Law.
- (10) Where the re-check referred to in paragraph 9 of this Article shows that the establishment complies with all the requirements as laid down by this Law, the Administrative Authority shall issue the approval for performance of the operations at the establishment, at the proposal of the Commission.
- (11) Where the re-check referred to in paragraph 9 of this Article shows that the establishment has not complied with the requirements as laid down by this Law, the Administrative Authority shall extend the conditional approval for the period not longer than three months, with the exception of ships (factory and refrigerator), flying the flag of Montenegro, for which conditional approval shall be issued for the period no longer than one year.
- (12) Where the re-check upon the expiry of the deadline referred to in paragraph 11 of this Article, shows that not all requirements, as laid down by the Law, have been complied with, the Administrative Authority shall adopt a decision on removal of the establishment from the Register.
- (13) The types of establishments where operations subject to approval are carried out, the form of the request for approval and more detailed content of the documents to be submitted along with the request shall be laid down by a regulation of the Ministry.
- (14) The Administrative Authority shall inform the European Commission and the European Union Member States of the establishments approved.

Revocation of approval

Article 51

- (1) The approval shall be revoked:
 - at the request of food or feed business operators;
 - based on the decision of the inspector on the prohibition of carrying out of business operations in the establishments due to non-compliance with the requirements prescribed for carrying out of business operations for which the approval was issued;
 - based on the information by the food and feed operator or by inspector that the business operations in the establishment concerned have ceased for more than one year.
- (2) Food business operators, whose approval was revoked in accordance with paragraph 1 of this Article, shall be deleted from the Register by a decision.

Changes in approved operation

Article 52

- (1) Food or feed business operator shall notify the Administrative Authority of any change concerning the operator, change in terms of the establishment or with regard to the approval issued, no later than 15 days from the date of change.
- (2) Upon the receiving of notification referred to in paragraph 1 of this Article, the Administrative Authority shall carry out the approval procedure in accordance with Article 50 of this Law.

- (3) Where the food or feed business operator temporarily does not perform one or more of the approved operations in period no later than 6 month for approved is issued, it shall notify the Administrative authority thereof within 15 days from the day of suspension of the operations.
- (4) Where the suspension of one or more of the approved operations lasts for more than six months, the food or feed business operator shall, no later than 15 days before recommencing the operation in the establishment, file a request to the Administrative Authority for approve the establishment referred to Article 50 paragraph 2 of this Law.

Instructions and guides to good practice

Article 53

- (1) In order to facilitate operations and to achieve the food safety requirements as laid down by this Law, the associations of food or feed operators may develop guides to good hygiene practice and the application of HACCP principles.
- (2) In the process of developing the guide to good practices referred to in paragraph 1 of this Article, the associations of food or feed business operators shall:
 - Co-operate with the competent authorities, associations of consumers and other interested persons in the course of implementation of instructions and the guides;
 - take into account the relevant codes of practice of the Codex Alimentarius; and
 - for primary production and related supporting activities, they shall also take into account the instructions on good hygiene practice for risk control.
- (3) The Ministry shall approve of the national guidelines referred to in paragraph 1 of this Article where the guides are:
 - Developed in accordance with the paragraph 2 of this Article;
 - Appropriate for the sectors for which they are intended, and they ensure achieving of compliance with the food or feed hygiene as laid down by this Law;
- (4) The guides referred to in paragraph 1 of this Article may include guidelines for conducting analyses referred to in Article 43, paragraph 4 of this Law.
- (5) The guides referred to in paragraph 1 of this Article shall be regularly revised in order to be adjusted to the food regulations and new knowledge of risks in food or the environment.
- (6) The request for the revision of the guide may be filed by the Ministry or by the association of food or feed business operators.
- (7) The Ministry shall approve of the revised guides.
- (8) The Ministry may provide technical assistance and encourage development and implementation of the guide.
- (9) The Ministry shall keep the register of guides referred to in paragraphs 3 and 7 of this Article and submit these to the European Commission.

Food information for consumers

Article 54

- (1) Food business operator shall at all stages of production, processing and distribution, ensure that the information on food, intended for the final consumer or public eating facilities, concerning health, economic, social and ethical circumstances is delivered to the consumer.
- (2) The food business operator, under whose name or title the food is placed on the market, shall be responsible for the food information, its accuracy and consistency, and where such operator is not based in Montenegro, the food importer shall be responsible.
- (3) The food business operator shall make available to the final consumer, precise, clear and easily understandable information and data on the food, through a label or in some other appropriate manner, that concern the following:
 - 1) Name, type, composition, properties, characteristics and origin of the certain food;
 - 2) Consumers' health protection and safe usage of food which include:

- Food ingredients that may be harmful to health of certain groups of consumers;
 - Food shelf-life, manner and conditions for storage and use of food;
 - Impact on health, including the risks and consequences related to the manner of consumption that may be harmful to health;
- 3) Nutritive properties of food which include also the specific dietary needs, recommended quantities per meal or consumption unit; and
 - 4) Other information deemed necessary by the food business operator.
- (4) The food business operator shall provide information referred to paragraph 3 of this Article, within its operations, for all food intended to final consumer, including food offered by public eating facilities (restaurants, cantinas, hospitality industry facilities, including vehicles, or fixed or mobile stalls, education facilities and hospitals), as well as food intended for supply of the public eating facilities, food supplied by transport companies (catering service), as well as for distance sale of food.
 - (5) Information and data on imported food referred to in paragraphs 3 and 4 of this Article shall be provided in Montenegrin language.
 - (6) More detailed content of information and data on food according to food types and categories, labelling of food and the manner of providing information shall be laid down by a regulation of the Government.

Fair information practices

Article 55

- (1) Food business operator shall not provide food information and data that may mislead the consumer, and in particular:
 - in terms of the characteristics, types, names, properties, composition, quantity, shelf-life, country or place of origin and method of production;
 - attributing to the food the effects or properties that the food does not have;
 - referencing to the specific characteristics of food that belong to similar food, and in particular by emphasizing the presence or absence of certain ingredients and/or nutritional substances;
 - the appearance, description or visual display of the presence of a particular food or ingredients, when that ingredient is either naturally occurring or commonly used in that food, replaced by other components or other ingredient.
- (2) Food business operator shall not provide the information of food refer to the medicinal properties of food, except for natural mineral waters and food for special dietary needs referred to Article 65 paragraph 1 of this Law.
- (3) The provisions of paragraphs 1 and 2 of this Article shall apply also to the advertising and presentation of food (form, packaging, arrangement, appearance, packaging material, the way it is displayed and the environment in which food is displayed).

Nutrition and health claims

Article 56

- (1) The food business operator may use nutritional and health claims in labelling, presentation, advertising of food under the conditions as laid down by this Law.
- (2) The food business operator shall not use nutritional and health claims that are:
 - incorrect, ambiguous or misleading;
 - give rise to suspecting the safety and/or nutritional adequacy of other food;
 - encourage or tolerate the excessive use of certain foods;
 - suggest or indicate that a balanced and diverse nutrition could not offer appropriate quantities of nutrients;
 - indicating changes in body functions.
- (3) It shall be prohibited to use health claims:
 - Indicating that health could be endangered as a result of non-consuming of certain food;

- Indicating the rate or quantity of weight loss.
- (4) The health and nutritive claims, the conditions and manner and restriction of their use and other requirements shall be laid down by a regulation of the Government.

Batch or lot marks

Article 57

- (1) Batch or lot marks is a series of sales units of food that is produced, processed or packed under the same conditions.
- (2) Food shall not be placed on the market unless it is labelled with a mark enabling identification of the batch or lot that the food belongs to.
- (3) Batch or lot marks shall be determined and put by the food business operator who produces, processes or packs, or repacks the food.
- (4) The marks identifying the batch or lot marks that the food belongs to and the manner of marking shall be laid down by a regulation of the Ministry.

Additives

Article 58

- (1) Additive means any substance not normally used as a food, or is a characteristic ingredient of food or feed that is added to food or feed for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage, becoming directly or indirectly a component of such food or feed.
- (2) It shall be prohibited to place on the market food additives or food containing food additives that do not comply with the prescribed requirements.
- (3) The types of additives that may be used and their specification, the conditions of their use and labelling, as well as the manner and conditions for placing on the market shall be laid down by a regulation of the Government.

Food enzymes

Article 59

- (1) Food enzyme means a product obtained from plants, animals or micro-organisms or products thereof including a product obtained by a fermentation process using micro-organisms:
 - 1) containing one or more enzymes capable of catalyzing a specific biochemical reaction; and
 - 2) added to food for a technological purpose at any stage of the manufacturing, processing, preparation, treatment, packaging, transport or storage of food.
- (2) It shall be prohibited to place on the market the food enzymes and food containing food enzymes that fail to comply with the prescribed conditions.
- (3) The types of food enzymes that may be used, the conditions for their use and labelling, as well as the manner and conditions for their placing on the market shall be laid down by a regulation of the Government.

Extraction solvents

Article 60

- (1) Extraction solvent means solvents used in an extraction procedure during the processing of raw materials, of food, or of components or ingredients of these products and which is removed from food after extraction but which may result in the unintentional, but technically unavoidable, presence of residues or derivatives in the food or food ingredient.
- (2) It shall be prohibited to place on the market the food extraction solvents or food containing food extraction solvents that fail to comply with the prescribed conditions.
- (3) The types of food extraction solvents that may be used, the conditions for their use and labelling, as well as the manner and conditions for their placing on the market shall be laid down by a regulation of the Government.

Food flavourings

Article 61

- (1) Food flavourings are products that are:
 - 1) Not intended for consumption as such and are added to food in order to achieve change in odour and/or taste;
 - 2) Are produced or consist of: flavouring substances, flavouring products, flavourings obtained by thermic procedures, smoke flavouring, flavouring precursors or other flavourings and mixtures thereof.
- (2) It shall be prohibited to place on the market the food flavourings and food containing food flavourings that fail to comply with the prescribed conditions.
- (3) The types of food flavourings that may be used, the conditions for their use and labelling, as well as the manner and conditions for their placing on the market shall be laid down by a regulation of the Government.

Materials and objects coming into contact with food

Article 62

- (1) Materials and objects coming into contact with food or feed means products in direct contact or coming into contact with food or feed.
- (2) Materials and objects coming into contact with food (including active and intelligent materials and objects), shall be produced in accordance with good manufacturing practice so that under normal and foreseeable conditions of use, these do not transfer their ingredients into or into the food in quantities which could pose hazard to human health or cause an unacceptable change in the composition of food or a deterioration in the sensorial properties of food.
- (3) The labelling, advertising and presentation of materials or products coming into contact with food shall not mislead consumers.
- (4) The objects and materials coming into contact with food shall be made of appropriate raw material that does not have an adverse effect on food safety during production, placing on the market and use.
- (5) The food business operator may use objects and materials coming into contact with food that are approved and marked in accordance with prescribed conditions.
- (6) Legal and natural persons producing and placing on the market objects and materials coming into contact with food shall mark such materials and objects, keep records on production and trade and keep documents for the purpose of ensuring their identification and traceability.
- (7) The traceability of materials and objects shall be ensured at all stages in order to facilitate control, withdraw unfit products, consumer information and for establishing the responsibility.
- (8) Once it is established that the objects and materials coming into contact with food could pose a serious risk to human health or the environment and if the risk could not be prevented with the implementation of appropriate measures, the Ministry shall order, commensurate to the nature or level of risk, one or more measures:
 - A temporary ban on the placing on the market or use of objects and materials coming into contact with food;
 - A temporary ban on imports of objects or materials coming into contact with food from the exporting country or its part;
 - specific handling conditions, or
 - other appropriate measures.
- (9) Objects and materials coming into contact with food which could be used by a food business operator, the manner of their labelling, the conditions for placing on the market and good manufacturing practice shall be laid down by a regulation of the Government.

Supplements

Article 63

- (1) Supplement means food the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, placed on the market in dose form (capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities).
- (2) It shall be forbidden to place on the market supplements that do not comply with the requirements as laid down by this Law.
- (3) It shall be forbidden during labelling, presentation and advertising, to suggest that supplements have the properties of prevention, treating or curing human diseases, and to refer to such properties.
- (4) The supplements may be placed on the market under the name of "dietary supplement" or "supplement" in the original packaging, in a suitable form, provided that they comply with the prescribed requirements.
- (5) The types and forms of vitamins and minerals that may be used in the production of supplements and requirements that must be complied with by vitamins, minerals and supplements and other substance, as well as the manner and conditions for labelling and their placing on the market shall be laid down by a regulation of the Government.

Adding vitamins, minerals and other substances to food

Article 64

- (1) The food business operator may be added to food Vitamins, minerals and other substances in prescribed amounts and under the prescribed conditions.
- (2) It shall be forbidden, during labelling, presentation and advertising of food that vitamins, minerals and other substances have been added to:
 - to indicate that a balanced and diverse nutrition could not provide appropriate quantities of nutrients,
 - mislead or deceive consumers regarding the nutritional value of food that may result from the addition of these ingredients, in any way.
- (3) When placing on the market, it shall be mandatory to declare the nutritional values of products that vitamins and minerals were added to, as well as information of their total quantity added.
- (4) The types and forms of vitamins, minerals and other substances that may be added to food, and requirements that these have to comply with, as well as the manner and conditions for labelling and their placing on the market shall be laid down by a regulation of the Government.

Food for special dietary needs

Article 65

- (1) Food for special dietary needs means:
 - food for infants ('infant formula' and 'follow-on formula');
 - processed cereal-based food and food for young children;
 - dietary food for special medical purposes; and
 - replacement for whole day nutrition in weight reduction diet.
- (2) Food business operators shall not place on the market the food for special dietary needs that is not in its original packaging and that does not comply with the requirements in terms of composition and information.
- (3) The conditions in terms of composition and information and a list of substances that may be added to food referred to in paragraph 1 of this Article as well as the manner and conditions for labelling and their placing on the market shall be laid down by a regulation of the Government.

Quick Frozen Food

Article 66

- (1) 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, while the reached temperature (after thermal stabilization) shall be continuously maintained at a level of -18 C or lower in all points.
- (2) Quick frozen food shall not be considered the ice cream and other edible ice products.
- (3) Quick frozen food may be placed on the market provided that it is marked as "quick frozen".
- (4) Detailed conditions for quick freezing of food, method of temperature control (sampling and analysis methods), and monitoring of temperature in means of transportation and areas for storage and preservation of quick-frozen food as well as the manner and conditions for labelling and their placing on the market shall be laid down by a regulation of the Ministry.

Contaminants

Article 67

- (1) Contaminant means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination.
- (2) Extraneous matters: insect fragments, animal hair and other substances are not considered contaminants, in accordance with specific legislation.
- (3) Food business operators, including the primary production, shall implement measures necessary to prevent the occurrence of contaminants in food.
- (4) The food containing contaminants exceeding the maximum permitted quantities of contaminants, and particularly those toxic and harmful to human health shall not be placed on the market.
- (5) The maximum permitted quantities of contaminants shall be laid down by a regulation of the Government.
- (6) The manner of sampling and the laboratory analysis methods and the monitoring of contaminants shall be laid down by a regulation of the Ministry.

Novel food

Article 68

- (1) Novel food means any food or food ingredient placed on the market accordance with prescribed conditions which have not been used for human consumption to a significant degree.
- (2) Novel food shall include food and food ingredients:
 - That consists of or is isolated from microorganisms, fungi or algae;
 - That consists of or isolated from plants or animals, except for food and food ingredients obtained by traditional propagating or breeding, which is known to be safe for consumption;
 - With a new or intentionally modified primary molecular structure;
 - which is obtained by a production method that have not previously been used, which leads to significant changes in the composition or structure of the food or food ingredients, which affect the nutritional value, metabolism or levels of undesirable substances.
- (3) Novel food shall not include: food additives, flavourings, extraction solvents and food enzymes.
- (4) Food and food ingredients referred to in paragraph 2 of this Article shall not:
 - present a danger to consumers;
 - mislead consumers;

- differ from food or food ingredients with they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.
- (5) The list of novel food that may be used, the manner and conditions for use, labelling and placing on the market shall be laid down by a regulation of the Government.

Food and food ingredients treated with ionizing radiation

Article 69

- (1) It shall be forbidden to produce, place on the market and import food treated with ionizing radiation that does not comply with the prescribed requirements.
- (2) Food, subjected to ionizing radiation shall meet the safety requirements in accordance with this Law.
- (3) Method of treating food with ionizing radiation, the type of food that may be treated and the requirements for facilities where food treatment may take place, the manner and conditions for labelling and placing on the market shall be laid down by a regulation of the Government.

Natural mineral water

Article 70

- (1) Natural mineral water means microbiologically safe water originating from an underground aquifer and springs from one or more natural or drilled water sources.
- (2) Natural mineral water shall be placed on the market only if it complies with the requirements for natural mineral water prescribed by this Law.
- (3) Natural mineral water originating from a single source may not be placed on the market under different brand names.
- (4) Natural mineral water shall not be considered the water:
- water, regarded as a remedy;
 - natural mineral water, used at source for medicinal purposes in thermal and hydrothermal facilities.
- (5) It shall be prohibited to disinfect the natural mineral water by any means, or add bacteriostatic elements or perform other types of treatment that could change the number of living microorganisms in the water.
- (6) The requirements, to be complied with by natural mineral water and springs water, the manner and conditions for its exploitation, treatment and placing on the market shall be laid down by a regulation of the Government.

Genetically modified food or feed

Article 71

- (1) Genetically modified food or feed means a is food or feed which contains, consists or it is produced from genetically modified organism (hereinafter referred to as: GMO).
- (2) Food referred to in paragraph 1 of this Article shall not:
- 1) be harmful to human and animal health;
 - 2) mislead the consumers or buyers;
 - 3) differ from food or feed or food ingredients or feed, intended to be replaced, to the extent that brings into question its nutritional value and safety.
- (3) It shall be forbidden to place on the market the GMO for use in food or use ofgenetically modified food if don't full fill conditions from paragraph 4 of this Article.
- (4) The list of GMO food or feed that may be placed on the market, the manner and conditions for use and labelling shall be laid down by a regulation of the Government.

VIII. SPECIFIC RULES FOR FEED

General obligations

Article 72

- (1) Feed business operator shall ensure that all stages of production, processing and distribution of feed within its business and which is under its control are carried out in accordance with this Law.
- (2) Animal keeper shall undertake all measures and implement procedures aimed at minimising the hazard of biological, chemical and physical contamination of feed, animals and products of animal origin when feeding food-producing animals.
- (3) The animal keeper referred to in paragraph 2 of this Article keeping food-producing animals shall apply the good feeding practices for such animals.
- (4) The good feeding practices shall be laid down by a regulation of the Ministry.

Feed hygiene requirements

Article 73

- (1) The food business operator shall implement measures in order to comply with the feed hygiene requirements at all stages of production, processing and distribution of feed, starting from the primary production of feed until its placing on the market, when feeding food-producing animals as well as in imports and exports in accordance with this Law.
- (2) Feed hygiene means a set of measures and conditions needed for control of hazard and ensuring the appropriateness of feed in animal nutrition, in accordance with its intended purpose.
- (3) The feed business operator may carry out the operations of production, processing and distribution of feed only in registered or approved establishments complying with the hygiene requirements for the establishment, equipment, including the storage and transport and having a person responsible for production and an appropriate number of employees, depending on the type of operations.
- (4) The feed business operator placing on the market the fats, oils or products obtained from fats and oils and if it is used in animal nutrition, including feeding mixtures, shall control that fats and oils or products obtained from fats and oils for presence of dioxin or dioxin-like polychlorinated biphenyls (hereinafter referred to as: the PCBs).
- (5) More detailed requirements for feed hygiene at the primary production level with supporting activities and after primary production, establishment, equipment, staff, production, quality control, monitoring of dioxins, sampling and laboratory analysis methods, contents, manner of keeping and keeping of records referred to in Article 75 paragraph 4 of this Law, good hygiene practice, including storage and transport shall be laid down by a regulation of the Government.

Derogations from feed hygiene requirements

Article 74

- (1) The feed hygiene requirements referred to in Article 73 of this Law shall not apply to:
 - 1) production of feed for private domestic needs:
 - for food producing animals for private domestic consumption;
 - for animals not kept for food production.
 - 2) feeding of food producing animals for private domestic needs;
 - 3) feeding of animals that are not kept for food production;
 - 4) direct supply of small quantities of feed from the primary production by the producers at the local level, for use in local agricultural holdings;
 - 5) retail sales of pet food.
- (2) The food hygiene requirements referred to in paragraph 1 of this Article, according to the type of businesses, small amounts and criteria for the determination of small amounts of feed from the primary production and local markets referred to in paragraph 1 item 4 of this Article shall be laid down by a regulation of the Government.

Specific obligations

Article 75

- (1) Feed business operator shall, at all stages of primary production of feed ensure compliance with the specific microbiological criteria for feed and undertake measures and implement procedures guaranteeing feed safety.
- (2) The feed business operator, including the family agricultural holdings shall feed food-producing animals only with feed originating from establishments registered and/or approved in accordance with this Law.
- (3) The feed business operator in primary production of feed with supporting activities shall keep records on hazard control measures.
- (4) The feed business operator following the primary production of feed, including traders who do not keep feed in their own establishments shall keep records on production, supply and sale of feed in order to ensure traceability from receipt to delivery, including the imports.

Hazard Analysis and Critical Control points

Article 76

- (1) Feed business operator shall, except for primary feed production with supporting activities, put in place, implement and continuously maintain the procedures based on HACCP principles at all stages of production, processing and distribution of feed in accordance with Article 41 of this Law.
- (2) When making any change in a product, process or any stage of production, processing, storage and distribution, the feed business operator shall review the processes put in place referred to in paragraph 1 of this Article for the purpose of their harmonisation with the changes made.
- (3) For implementation of procedures based on HACCP principles, the feed business operators may use guides of good practices along with the guides on HACCP implementation.

Placing on the market and use of feed

Article 77

- (1) Only safe feed without adverse effect on environment or animal welfare may be placed on the market.
- (2) The feed business operator placing feed on the market shall, in addition to paragraph 1 of this Article, ensure also that feed:
 - is fit, original, unadulterated and appropriate for its intended purpose, of appropriate quality, labelled, packaged and presented in accordance with this law; and
 - complies with other requirements concerning animal nutrition as laid down by specific legislation.
- (3) Feed, referred to in paragraph 1 of this Article, shall not contain or consist of substances whose placing on the market or use for animal nutrition is restricted or prohibited.
- (4) Feed material and feeding mixtures may be placed on the market and used in animal nutrition under the conditions and in a way as laid down by this law.
- (5) Feed material and feeding mixtures determined and marked in compliance with the feed material catalogue may be placed on the market and used.
- (6) The feed business operator placing for the first time the feed material not listed in the feed material catalogue shall immediately notify the Administrative Authority of its use.
- (7) The feed referred to in paragraph 1 of this Article shall not contain undesirable substances above the maximum permitted quantities.
- (8) More detailed requirements for placing on the market and use of feed intended for food-producing and for non-food-producing animals, including the requirements in terms of labelling, packaging and presentation, substances placing on the market of which or use in feeding animals is restricted or prohibited, the maximum permitted quantities of unauthorised and undesirable substances in feed shall be laid down by a regulation of the Government.

(9) The feed material catalogue, laboratory method and method of sampling feed and the programme of monitoring for certain undesirable substances in feed shall be laid down by a regulation of the Ministry.

Placing on the market of feed for specific dietary needs

Article 78

(1) Feed for specific dietary needs is feed, other than medicated feed, that may satisfy a specific nutritive need of an animal with its specific composition, production procedure and that distinctively differs from common feed.

(2) Feed for specific dietary needs may be placed on the market provided that it complies with the elementary nutritive properties for specific dietary needs and provided that its intended use is in accordance with the list of intended use of feed for specific dietary needs.

(3) The detailed requirements for production and placing on the market and use of feed for special nutritive needs and lists of use of that food shall be prescribed by the Government.

Feed labelling, presentation and packaging

Article 79

(1) Labelling and presentation of feed shall not mislead the buyer or animal keeper, in particular:

- 1) concerning the intended use or properties of feed, and particularly the nature, treatment or production method, properties, composition, quantity, shelf-life, species or category of animals it is intended for;
- 2) by attributing non-existent effects or properties to feed or by highlighting specific properties of feed where common feed for animals of that particular species has such properties; or
- 3) concerning the labelling in the feed material catalogue and the guide for good practices in labelling certain feed types.

(2) Feed materials and feeding mixtures placed on the market shall be marked in accordance with the catalogue of feed materials.

Claims

Article 80

(1) When labelling and presenting feed materials and feeding mixtures, presence or absence of certain substances in feed may be pointed at, as well as specific nutritive properties or effects or specific functions provide that:

- 1) such claims are objective, verifiable and understandable to feed user (animal keeper);
- 2) such claims are scientifically proved, either through publicly available scientific evidence or through a documented research of the feed operator.

(2) The claim referred to in paragraph 1 of this Article shall be available at the time of placing feed at the market.

Guide to good labelling practice

Article 81

(1) Guides to good labelling practice may be developed separately for pet feed and feeding mixtures for food-producing animals and feeding mixtures for fur animals.

(2) Use of guides is voluntary, and where the feed business operator states the use of the guide on the feed label, the food business operator shall adhere to all the provisions of the guide.

(3) Guides referred to in paragraph 1 of this Article shall be approved by the Ministry.

Feed additives

Article 82

- (1) Feed additives means substances, microorganisms or products, other than feed materials and pre-mixtures, intentionally added to feed or water for the purpose of:
 - 1) achieving favourable effect on properties of feed and products of animal origin and on colour of ornamental fish and birds,
 - 2) satisfying the nutritional needs of animals,
 - 3) achieving a favourable effect on environment during animal production,
 - 4) achieving a favourable effect of animal production, performance or welfare, particularly by effect on gastro-intestinal flora or digestion; or
 - 5) achieving coccidiostatic or histomonostatic effect.
- (2) Antibiotics, other than coccidiostatics or histomonostats may not be used as feed additives.
- (3) Substances not authorised for use in feed, other than antibiotics, may be used for experimental and scientific purposes provided that these experiments are carried out under official supervision and in accordance with the specific regulation governing the protection of welfare of animals used in experiments or for other scientific purposes.
- (4) The animals referred to in paragraph 3 of this Article may be used for production of food only if it is established on the basis of a risk assessment that these animals do not have an adverse effect on health of animals, humans or environment.
- (5) Feed additives and pre-mixtures that may be placed on the market, their categories, labelling and packaging shall be laid down by a regulation of the Government.

Undesirable substances in feed

Article 83

- (1) Undesirable substances in animal feed means any substance or product, other than pathogenic substances, that is present in and/or on the product intended for feed and posing a potential hazard to human health, animal health or the environment, or may have a harmful effect on livestock production.
- (2) It is prohibited that, products intended for feed, containing undesirable substances in quantities higher than the maximum permitted quantity mixed for the purpose of their dilution, with the same or other products intended for feed.
- (3) The undesirable substances in feed, the maximum permitted levels of undesirable substances, the manner of procedure in determining the sources of certain undesirable substances, the monitoring programmes for undesirable substances aimed at reducing the presence of certain undesirable substances shall be laid down by a regulation of the Government.

Medicated feed

Article 84

- (1) Medicated feed may be produced in an approved establishment complying with the requirements as laid down by this Law and with the requirements for storage of medicated premixes, intermediate products and medicated feed.
- (2) The distributor of medicated feed and/or intermediate product may deliver the medicated feed and/or intermediary product exclusively on the basis of a prescription issued, in the original packaging and in the quantity as specified by the prescription, directly to:
 - 1) the establishment producing medicated feed, including the establishment on an agricultural holding in the case of delivery of the intermediate product, or
 - 2) to the animal owner or keeper, in the case of delivery of medicated feed.
- (3) Feed business operator which engages in the distribution of medicated feed and / or intermediate products shall keep a record and that is at least five years from the date of the last track, as well as recipes on the basis of which is delivered medicated feed and /

or intermediate product and certificates that accompanied the shipment of medicated feed during import.

- (4) More detailed requirements concerning production and placing on the market of medicated feed and/or intermediate product, labelling and packaging of medicated feed, imports of medicated feed, as well as supervision over production, trade and use of medicated feed shall be laid down by a regulation of the Government.
- (5) The form and the content of the prescription for medicated feed, forms and contents of the accompanying document shall be laid down by a regulation of the Ministry.

IX. OFFICIAL CONTROLS

Scope of application

Article 85

- (1) Official controls verify the compliance with the requirements for food and feed set out in this law and the law governing the inspection surveillance, animal health, animal welfare and plant health protection, with a view to:
 - preventing, eliminating or reducing to acceptable levels risks to human and animal health, either directly or through the environment;
 - guaranteeing free trade and trade under same conditions food or feed and protecting consumer interests including information on food and feed.
- (2) Official controls of products of animal origin intended for human consumption shall be performed in accordance with this law and the law governing veterinary affairs.
- (3) More detailed rules and the manner of performing official controls referred to in paragraph 2 of this Article shall be laid down by a regulation of the Ministry.

Methods and techniques of official controls

Article 86

Official controls shall be implemented using appropriate control methods and techniques as follows: inspection, monitoring, surveillance, verification (checks), audit, sampling and laboratory analyses.

Organisation of official controls

Article 87

- (1) Official controls over implementation of this law concerning monitoring, verification (compliance checks) of conditions as laid down by this law, the audit and where necessary, the sampling for laboratory analyses shall be carried out by the Administrative Authority.
- (2) The official controls referring to inspectorial surveillance shall be carried out by the Administrative Authority through food inspectors, official veterinarians on borders and border phytosanitary inspectors.
- (3) The Administrative Authority referred to in paragraph 1 of this Article shall:
 - ensure the effectiveness and appropriateness of official controls of live animals, food and feed at all stages of production, processing and distribution, including of the primary production of food and feed with supporting activities, as well as of the use of food and feed;
 - implement contingency plans, where necessary;
 - ensure impartiality, quality and consistency of official controls at all levels;
 - organize and carry out official controls in accordance with the Article 88 of this law, and make the information on official controls carried out available to the public as soon as possible, except for information regarded as confidential in accordance with the law;
 - ensure efficient coordination and cooperation for carrying out official controls;
 - put in place a system of official controls at imports;
 - provide for financial resources for carrying out official controls;
 - take administrative measures and actions in accordance with this Law;

- cooperate with the European Commission, and
- carry out other activities in accordance with the law.

Organisation of official controls

Article 88

(1) Official controls shall be carried out regularly, at appropriate frequency, based on a risk assessment, taking account of:

- identified risks associated with animals, feed or food, food or feed business operators, the use of food or feed or in any process, material, substance, activity or operation that may affect food or feed safety, animal health or animal welfare;
- historical data on operations of food or feed business operator in terms of compliance of food or feed with this Law, the law governing animal health and animal welfare protection, the law governing plant nutrition and plant protection;
- the reliability of the checks that the food or feed business operator is carrying out on its own; and
- any other information that might indicate operations in contravention of the law.

(2) The official controls shall be carried out without prior announcement, except in cases of audits where prior notification of the food or feed business operator is necessary also official controls may also be carried out on an *ad hoc* basis.

(3) Official controls shall be carried out at all the stages of production, processing and distribution of food or feed and on animals and products of animal origin.

(4) Official controls referred to in paragraph 3 of this Article include controls of food and feed business operations, on the use of food and feed, on the storage of food or feed, on any processes, materials, substances, activities or operations, including transport of food, feed and live animals

(5) Official controls of food and feed in exports shall be organized in the same way as official controls at the moment of placing on the market of Montenegro and imports in Montenegro.

(6) Products intended for dispatch to the Member State of the European Union are controlled in the same way as products intended for marketing within the territory of Montenegro.

(7) When Montenegro place of destination of products from other Member States of the European Union, the Administrative Authority may carry out non-discriminatory checks to establish compliance with the conditions stipulated by this law and required that food and feed business operators which products are delivered from other Member States informed about the arrival of such products.

(8) When the checks referred to in paragraph 7 of this article, discrepancy at destination or during storage or transport, Administrative Authority shall take appropriate measures which may include the return of the shipment in the Member State of the European Union that is a state of origin.

Official controls procedures

Article 89

(1) Official controls shall be carried out in accordance with the procedures included in instructions for persons performing official controls.

(2) The procedures referred to in paragraph 1 of this Article shall contain the following:

- the organisation of official controls;
- objectives to be achieved;
- tasks, responsibilities and duties of persons performing the official controls;
- sampling procedures, control methods and techniques, interpretation of results and decisions arising from these;
- measures to be taken following official controls;
- verification of appropriateness of methods of sampling, methods of analysis and tests;

- any other activity required for the efficient execution of official controls.
- (3) The efficiency of official controls is verified by the Administrative Authority through audits, in order to undertake corrective action where necessary and to review procedures referred to in paragraph 1 of this Article.
- (4) Instructions and guidelines for official controls may be adopted by the Administrative Authority for:
 - implementation of HACCP;
 - other control systems put in place by the food and feed business operators with a view to more efficient compliance with the requirements set;
 - on microbiological, physical and chemical safety of food and feed.
- (5) The person performing official control shall produce the protocol on official control carried out, including the subject and objective of the official control, the technique or control method applied, the result of the official control and where necessary, the actions and measures that the food or feed business operator shall undertake in case non-compliances are identified.
- (6) The protocol referred to in paragraph 5 of this Article shall be produced in three copies, of which one copy shall be delivered to the food business operator and signed by the person carrying out the official control, and the food or feed business operator.
- (7) The procedures referred to in paragraph 1 of this Article shall be laid down by a regulation of the Ministry.

Transparency and confidentiality

Article 90

- (1) The person carrying out the official control shall not reveal to the public the data it obtained in the course of carrying out the official control that are, by its nature, considered the business secret.
- (2) The business secret referred to in paragraph 1 of this Article shall not be publishing of information referred to in Article 17 of this Law, except for the personal data in accordance with the Law.
- (3) The data considered a business secret include: confidentiality of the ongoing process, personal data, documents and data protected as business secret.

Methods and laboratory analyses

Article 91

- (1) Sampling and laboratory analysis of food and feed during official controls shall be performed using appropriate methods in accordance with the standards.
- (2) In absence of the standards and methods referred to in paragraph 1 of this Article, internationally recognized methods or protocols or methods developed in accordance with scientific protocols of international institutions may be used
- (3) Validation of methods referred to in paragraph 2 of this Article shall take place in accordance with the internationally accepted protocol.
- (4) The methods of sampling and laboratory analyses of food and feed shall be laid down by a regulation of the Ministry.

Sampling

Article 92

- (1) Samples taken during official controls shall be delivered to the authorised laboratory (hereinafter referred to as: the official laboratory) for laboratory analysis.
- (2) When taking samples of food or feed for laboratory analysis the inspector shall:
 - take three identical samples: the official sample, the sample for the second opinion for the needs of the food or feed business operators and the third reference sample (sample needed for carrying out further testing if the results of the official sample analysis differ from the results of the analysis carried out by the food and feed business operator);

- take samples referred to in indent 1 of this paragraph in the prescribed quantity and the number necessary for the analysis, under the same conditions and at the same time, from the same batch or lot of food or feed, seal the samples and duly mark them at the place of sampling;
 - produce a protocol on sampling signed by the authorised person of the food and feed business operator subjected to the control, who is given one copy of the protocol;
 - keep taken samples from damage, and if necessary, on appropriate temperature regime until its delivery to the official laboratory;
 - deliver the official sample to the official laboratory without delay;
 - seal and mark the sample for second expert opinion, which is left at food or feed business operator, at the place of sampling and enter those data in the protocol along with the instructions for proper keeping of the sample;
 - keep the reference sample under appropriate conditions in the official premises or in other place and enter that data in the protocol.
- (3) Where the official laboratory does not perform certain analysis, the inspector shall send the official sample to the laboratory accredited for such testing.
 - (4) Food or feed business operators are entitled to requesting the analysis of the reference sample, within 15 days from the day of sampling, provided that they performed the analysis and delivered the results of the second sample, taken for the needs of establishment, to the inspector.
 - (5) Inspector shall notify without delay the food or feed business operator of the results of the analysis.
 - (6) The results of the analysis of the reference sample shall be relevant for further actions.
 - (7) Food or feed business operator may waive their right to taking sample for the second expert opinion at the moment of sampling, by waiving the protocol on sampling.
 - (8) The reference sample shall not be taken for perishable food and testing of microbiological criteria, and the results of the analysis of the official sample shall be considered relevant for further actions.
 - (9) Food or feed business operator whose products are subject to sampling and analysis are entitled to requesting further expert opinion, without prejudice to the obligation of the competent authority to take prompt actions in case of emergency.
 - (10) In the event referred to in paragraph 9 of this Article, a sufficient number of samples shall be provided for further expert opinion, with the exception of highly perishable products or very small quantities of products.
 - (11) The samples shall be appropriately handled and labelled on prescribed way, so as to guarantee both their integrity and analytical suitability.

Official laboratories

Article 93

- (1) The analysis of samples taken during official controls and monitoring of food and feed and material coming into contact with food shall be carried out by official laboratories authorised by the Ministry.
- (2) The authorisation referred to in paragraph 1 of this Article may be granted to the laboratory that operates as a legal entity and is accredited in accordance with the following standards:
 - ISO/IEC 17025 – “General requirements for the competence of testing and calibration laboratories”;
 - ISO/IEC 17011 -”General requirements for accreditation bodies accrediting conformity assessment bodies”;
 - for method or methods for which the laboratory can prove that it regularly and successfully participates in inter-laboratory testing programmes.
- (3) The laboratory shall be authorised based on the request and proof of accreditation referred to in paragraph 2 of this Article.

- (4) The Ministry may revoke the authorisation issued to the laboratory referred to in paragraph 1 of this Article if it ceases to comply with the conditions referred to in paragraph 2 of this Article.
- (5) In the case that Montenegro does not have official laboratories to carry out specific analyses, the Ministry shall designate an accredited laboratory of a Member State of the European Union.
- (6) The list of laboratories referred to in paragraph 1 of this Article shall be published by the Ministry in the "Official Gazette of Montenegro".

Obligations of the official laboratory

Article 94

- (1) The official laboratory shall:
 - prepare and analyse the official samples and produce the report on results;
 - commence the analysis immediately upon receiving the samples, and upon completion of the analysis produce the report and deliver it to the inspector who delivered the sample;
 - where, after completion of the analyses, the sample fails to comply with the values prescribed, it shall deliver the report on results to the inspector immediately, and no later than 48 hours from the completion of the analysis.
- (2) The report referred to in paragraph 1 of this Article shall contain: name of the sample with information on food or feed or product, date of delivery, date of commencement and completion of laboratory testing, description of the sample submitted and the temperature it was submitted at if necessary, method of laboratory testing, statement of compliance with the regulation.

National reference laboratories

Article 95

- (1) For specific types of food and specific analyses of food and feed, the Ministry shall designate one laboratory as the national reference laboratory for such testing (hereinafter referred to as: the reference laboratory)/
- (2) One laboratory may be designated as reference laboratory for several types of testing.
- (3) In the case that Montenegro does not have the laboratory for specific area, which complies with the requirements laid down by this law, the Ministry may designate a reference laboratory of the Member State of the European Union or of the European Free Trade Association (EFTA).
- (4) Types of food and feed and type of analysis for which the national reference laboratory is designated for, the process of designation and the conditions for the laboratory referred to paragraph 1 of this Article shall be laid down by a regulation of the Ministry.
- (5) The list of reference laboratories referred to in paragraphs 1 and 2 of this Article shall be published by the Ministry in the "Official Gazette of Montenegro" and delivered to the European Commission, the reference laboratories of the European Union and the Member States of the European Union.

Obligations of the Reference laboratory

Article 96

The reference laboratory shall:

- collaborate with the European Union's reference laboratory within its area of competence;
- coordinate the activities of authorised laboratories responsible for laboratory analysis of samples;
- where appropriate, organise inter-laboratory testing for authorised laboratories;

- disseminate information from reference laboratories of the European Union to the competent authorities and authorised laboratories;
- provide scientific and technical assistance to the Ministry in implementation of emergency measures;
- carries out other activities in accordance with the law.

X. OFFICIAL CONTROLS ON THE IMPORT OF FOOD AND FEED

Border control

Article 97

- (1) Food and feed may be imported in Montenegro only through designated border inspection posts where veterinary surveillance was put in place, i.e. through designated point of entry where phytosanitary surveillance and customs supervision have been put in place in accordance with the law.
- (2) The list of designated border inspection posts and points of entry referred to in paragraph 1 of this Article shall be published at the Ministry's web site.

Cooperation of competent authorities on the border

Article 98

- (1) In border inspection posts and points of entry referred to in Article 97, paragraph 1 of this Law, the inspectors referred to in Articles 115, paragraphs 4 and 5 of this Law shall cooperate with officers of the administrative authority in charge of customs affairs in carrying out of official controls.
- (2) The administration authority in charge of customs affairs shall not allow the entry or circulation in free zones or free warehouses of food and feed of animal origin as well as food and feed referred to in Article 100, paragraph 4 of this law, without the checks by the border inspector.
- (3) Where samples of food or feed of animal origin are taken for laboratory testing, the official border veterinarian or border phytosanitary inspector shall inform the administrative authority in charge of customs services and the food or feed business operators or person responsible for the consignment and decide whether the consignment may be released into circulation before the results of the analysis of the samples are available, provided that the traceability of the consignment is ensured.
- (4) In the case of release of the consignment referred to in paragraph 3 of this Article for free circulation, the inspectors referred to in Article 115, paragraphs 4 and 5 of this law and customs services shall cooperate in accordance with the law.

Official controls of food and feed of animal origin

Article 99

- (1) Official controls of food of animal origin and feed of animal origin, feed materials of animal origin, medicated feed, pre-mixtures and feed additives, feed materials with feed additives, milk substitutes for animal nutrition, and feed for specific dietary needs subjected to veterinary checks at the border inspection posts at import shall be performed in accordance with the law governing veterinary issues.
- (2) The official controls of food of animal origin and feed of animal origin shall be carried out in accordance with control plans referred to in Article 110 of this Law.

Official controls of food and feed of non-animal origin

Article 100

- (1) Official controls of food of non-animal origin and feed of non-animal origin shall be performed in accordance with the control plans referred to in Article 110 of this law.
- (2) Official controls of food referred to in paragraph 1 of this Article may be carried out at the point of entry of the consignment, point of release into free circulation, warehouse, business premises of the food or feed business operator.

- (3) The controls referred to in paragraph 1 of this Article shall be carried out on food or feed of non-animal origin that is:
- placed under one of the customs procedures (transit, customs warehousing, inward processing, processing under customs supervision, temporary imports); or
 - entered into free zones or free warehouses in accordance with customs regulations.
- (4) Checks of food and feed consignments referred to in paragraph 1 of this Article for which there is a known or emerging risk and which are subject to an increased level of official controls shall be performed by border phytosanitary inspector at the border inspection post at the point of entry, referred to in Article 102 paragraph 1 of this Law.
- (5) The list of food referred in paragraph 4 of this Article shall be laid down by a regulation of the Ministry.

Control methods for food and feed of non-animal origin

Article 101

- (1) The official controls of food of non-animal origin and feed of non-animal origin shall include documentary check, random identity check and, as appropriate physical check.
- (2) The frequency of physical checks shall depend on:
- the risks associated with different types of food or feed;
 - the history of compliance with the requirements for food or feed imported, establishment of consignment origin as well as food and feed business operators importing or exporting the products;
 - the controls that the food or feed business operators importing the products has carried out;
 - the guarantees that the competent authority of the country from which food or feed is imported, has given.
- (3) The official control method for food or feed of non-animal origin that is imported and frequency of official controls shall be laid down by a regulation of the Ministry.

Point of entry

Article 102

- (1) Official control of consignments of food of non-animal origin and feed of non-animal at imports shall be performed at the point of entry designated in accordance with the law governing the plant health protection.
- (2) More detailed requirements that the point of entry referred to in paragraph 1 of this Article shall meet shall be laid down by a regulation of the Ministry.

Common Entry Document

Article 103

- (1) Business operator of food of non-animal origin or feed of non-animal origin or the person responsible for the consignment shall notify the consignment for the checks.
- (2) The costs of consignment checks and the implementation of measures upon the orders of the border phytosanitary inspector shall be borne by the person responsible for the consignment.
- (3) The notification of the consignment referred to in paragraph 1 of this Article shall be done through the Common Entry Document (hereinafter referred to as: CED), at least one working day prior to the physical arrival of the consignment to the point of entry.
- (4) The types of consignment for which CED is issued, CED form and the reporting procedure for consignment check shall be laid down by a regulation of the Ministry.

Action in case of suspicion

Article 104

In case the border inspector suspects that food or feed imported does not comply with the requirements laid down by the law, that the identity or the actual destination of the consignment do not correspond and that the certificate accompanying the consignment is not

appropriate, he/she shall temporarily prohibit its placing on the market pending the obtaining of evidence on the basis of which he/she shall either confirm or eliminate the suspected non-compliance.

Actions following official controls of food and feed from imports

Article 105

- (1) For the food or feed imported that does not comply with the requirements as laid down by the law, the border inspector shall order placing the consignment under the official detention and order taking of one of the following measures:
 - destroying of such food or feed;
 - subjecting it to a specific treatment in accordance with Article 106 of this Law;
 - return of the consignment to the supplier outside the territory of Montenegro in accordance with Article 107 of this law;
 - use of food or feed for purposes other than those for which they were originally intended.
- (2) In case the food or feed referred to in paragraph 1 of this Article has already been placed on the market, the border inspector shall order surveillance or, if necessary, order its recall or withdrawal before taking one of the measures referred to in paragraph 1 of this Article.
- (3) During the implementation of measures referred to in paragraph 1 and 2 of this Article, the border inspectors shall ensure that food or feed does not have adverse effects on human or animal health, either directly or through the environment.
- (4) If it is established by official controls referred to in Articles 99, 100 and 101 of this law that:
 - the food or feed is unsafe or harmful to human and animal health, the border inspector shall place the consignment in question under official surveillance (official detention of the consignment) pending its destruction or any other appropriate measure necessary to protect human and animal health;
 - the consignment of food or feed of non-animal origin, for which an increased level of official control has been laid down in accordance with the Article 100, paragraph 4 of this Law, is not notified for control in accordance with article 103 of this Law, the competent border inspector shall order, without delay its withdrawal from the market and placing under the official surveillance and its destruction or re-dispatching in accordance with the Article 107 of this Law.
- (5) Where the border inspector prohibits the import of food or feed consignment, he/she shall notify the administrative authority in charge of customs affairs and the Administrative Authority.
- (6) The Ministry shall notify the European Commission and the Member States of the European Union of the prohibition of import of consignment, findings, identity and final destination of the consignment using RASFF.

Actions concerning non-compliant food

Article 106

- (1) Food and feed referred to in Article 105 of this law that does not comply with the requirements may be:
 - treated or processed in order to harmonise it with the requirements laid down by this Law or the requirements of other country that the food or feed consignment is re-despatched to, including, where necessary, decontamination, other than by dilution;
 - processed in any other suitable manner for purposes other than human or animal consumption.
- (2) The actions referred to in paragraph 1 of this Article shall take place in the establishments under inspector's supervision.
- (3) The taking actions referred to in paragraph 1 of this Article shall be laid down by a regulation of the Ministry.

Return and re-dispatch of food or feed consignments

Article 107

- (1) The non-compliant food or feed consignment may be returned to the country of origin/dispatch or re-dispatched to another country only:
 - where the destination of the consignment has been agreed with the person responsible for the consignment;
 - when the person responsible for the consignment of food or feed, has previously notified the competent authority of the country of origin or of destination, if different, of the reasons and circumstances preventing the placing on the market of the food or feed concerned, and
 - after receiving guarantees from the competent authority of the country of origin or of destination on acceptance of the consignment.
- (2) Return or re-dispatch of the consignment of food or feed of animal origin shall take place in accordance with the law governing veterinary issues.
- (3) Return or re-dispatch of the consignment of food or feed of non-animal origin shall take place no more than 60 days from the day of designation of the destination for re-dispatch of the consignment.
- (4) If the re-dispatch of consignment did not take place within the deadline referred to in paragraph 3 of this Article, the consignment shall be destroyed at the expense of the person responsible for the consignment, with the exception of a justified delay, which is ascertained by the border inspector.
- (5) The border inspector shall impose the measure of placing the consignment under official surveillance within the deadline referred to in paragraph 3 of this Article, or confirmation of the reasons for rejection, and notify the administrative authority in charge of customs affairs and the Administrative Authority thereof.
- (6) The Ministry shall notify the European Commission and the Member States of the European Union on findings, identity and final destination of the consignment as provided for in the Article 31 paragraph 3 of this Law, in order to prevent re-introduction of a rejected consignment.
- (7) The person responsible for the consignment shall bear the costs incurred by the implementation of measures referred to in Articles 104, 105 and 106 of this Law.

XI. CHARGES

Charges and fees

Article 108

- (1) The financial resources for laboratory analysis of official samples taken based on annual official controls plan and monitoring plans shall be provided from the Budget of Montenegro.
- (2) Where the results of testing of official samples taken based on annual official controls plan fail to comply with the values prescribed, the costs of testing shall be borne by the food or feed business operator that the sample has been taken from.
- (3) The costs of delivery and testing of the reference sample and costs of delivering and testing samples at imports of food and feed regardless of the results shall be borne by the food or feed business operator or the person responsible for the consignment.
- (4) The food or feed business operator shall pay the fee for issuance of the decision on compliance with the requirements for carrying out the business operations in establishments subject to approval or registration in accordance with the law governing the administrative fees and for consignments of food of non-animal origin and feed of non-animal origin at imports, or exports and transit, as appropriate.
- (5) Fees for performed official controls of food and feed of animal origin shall be paid in accordance with the law governing veterinary issues.
- (6) Fees and charges referred to in paragraph 4 of this Article shall be the revenues of the Budget of Montenegro.

- (7) The amount of the fee and the charges referred to in paragraphs 1 to 5 of this Article may not be higher than actual procedure costs and may not represent an indirect protection of domestic products or indirect taxation of imports, or exports, as appropriate.
- (8) When setting the fee referred to in paragraphs 4 and 5 of this Article, the following shall be taken into account:
- the type of business operations of the operator and relevant risk factors;
 - production volume;
 - traditional methods used for production, processing and distribution;
 - geographical area of the business operations.
- (9) The criteria for setting the amount of the fees for checks referred to in paragraph 4 of this Article, the methods of their calculation and payment shall be set by the Government.

Conditions for specific food types

Article 109

The Ministry shall prescribe detailed requirements for:

- food and feed imported or placed under one of the customs procedures (transit, bonded warehouse, inward production, processing under customs supervision, temporary import);
- food for the supply of the crew and passengers in international means of transport;
- food and feed ordered by mail, by telephone or via the internet and delivered to the consumer;
- feed intended for pets or horses and food carried by passengers and crew of international means of transport;
- consignments originating from the European Union returned from a third country;
- documents that have to accompany consignments when taking samples;
- forms of certificates and requirements for certification of certain foods and feed.

XII. CONTROL PLANS

Multi-annual official control plans

Article 110

- (1) Official controls of food and feed shall be carried out on the basis of multi-annual control plan (hereinafter referred to as: the multi-annual plan) adopted by the Ministry.
- (2) Multi-annual plan shall contain the information on the structure and organisation of food and feed control, control of animal health and animal welfare, and plant health, and in particular on:
- the strategic objectives of the plan and control priorities;
 - the risk categorization by the activities concerned;
 - competent authorities and their tasks and responsibilities and available resources;
 - the general organisation of official controls, including official controls in individual establishments;
 - control systems applied and coordination in different areas;
 - methods and techniques of official controls;
 - organization of training for persons carrying out official controls;
 - implementation of procedures for official controls;
 - the organisation and implementation of contingency plans and measures in case of animal diseases or food-borne disease, food and feed contamination and other risks to human health.
- (3) Multi-annual plans are reviewed during their implementation taking account of:
- new regulations;
 - the emergence of new diseases or other health risks;
 - significant changes to the structure, management or operation of the competent authorities;

- the results of official controls;
 - the results of controls carried out by the European Commission;
 - any amendments to the instructions;
 - scientific findings;
 - results of the audit; and
 - other relevant data.
- (4) The multiannual plan shall be presented to the European Commission, at request.

Development of multi-annual plans

Article 111

- (1) The multi-annual plan shall be adopted by the Ministry using:
- 1) consistent, comprehensive and integrated approach to official controls of food and feed, animal health and animal welfare and all sectors and stages in the food and feed chain, including imports;
 - 2) identification of priorities based on risks and criteria for the risk assessment in specific operations and the most effective control procedures;
 - 3) identification of all stages of production, processing and distribution of food and feed, and the use of feed, in order to provide the most reliable and indicative information about compliance with food and feed regulations;
 - 4) best practices at all levels of the control system:
 - development of effective traceability systems;
 - setting up the system of records on controls performed and results of controls;
 - audit criteria;
 - data from annual reports;
 - indicators of effectiveness used when evaluating multiannual national control plans.
- (2) The annual report on implementation of the multiannual plan is produced by the Ministry and delivered to the Government and the European Commission no later than 30 June of the current year for the previous year.
- (3) The report on implementation of the multiannual plan referred to in paragraph 2 of this Article shall include in particular the data on the following:
- 1) changes to the multiannual plan;
 - 2) results of official controls and audits made in the previous year in accordance with the multiannual plan;
 - 3) type and number of non-compliance cases identified;
 - 4) measures ensuring efficient implementation of the multiannual plan, including the measures of prohibitions, restrictions and results of such measures.
- (4) The guidelines for development of plans and reports referred to in paragraphs 1 and 2 of this Article shall be adopted by the Ministry.

Monitoring

Article 112

- (1) Monitoring of food and feed safety in accordance with this law, the veterinary law and the law on plant nutrition and plant protection products shall be carried out by the Administrative Authority on the basis of the monitoring programme of:
- microbiological hazards;
 - contaminants;
 - residues of plant nutrition and plant protection products;
 - pharmacologically active substances of veterinary medicinal products;
 - unauthorised substances and other hazards concerning food and feed.
- (2) The programmes referred to in paragraph 1 of this Article shall be adopted by the Ministry.
- (3) The programmes referred to in paragraph 1 of this Article shall include the types of hazards concerning food and feed, conditions and manner of implementation of

monitoring, control methods, conditions, manner and method of taking and keeping samples, keeping the records of samples and methods of laboratory analyses.

- (4) The monitoring program referred to in paragraph 1 of this Article shall include also the funds necessary for financing of the programme, measures to be undertaken in the event of existence of a hazard, the structure of authorities and organizations for implementation of the programme and other parameters of relevance for implementation of the programme.
- (5) The monitoring programme referred to in paragraph 1 of this Article shall be adopted by the end of the current year for the following year.
- (6) The funds for implementation of the programme referred to in paragraph 1 of this Article shall be provided from the Budget of Montenegro.

Audit

Article 113

- (1) For the purpose of control of implementation of the official controls plan, the measures planned and for checking the efficiency and appropriateness of measures undertaken, the Administrative Authority shall establish an independent organisational unit to carry out independent audit.
- (2) The unit referred to in paragraph 1 of this Article shall review the state of affairs, produce the report and propose actions to be taken in accordance with the audit findings in order to ensure the achievement of objectives of this Law.
- (3) The audit is carried out on the basis of the annual internal audit plan developed by the unit referred to in paragraph 1 of this Article.
- (4) More detailed manner of performing the audit referred to in paragraph 1 of this Article shall be laid down by a regulation of the Ministry.

Official certification

Article 114

- (1) For consignments for which certificates are issued in accordance with the veterinary law and the law on plant health protection, additional certification may be sought.
- (2) In cases referred to in paragraph 1 of this Article, when additional certification is sought, the following has to be ensured:
 - 1) existence of a connection between the certificate and the consignment;
 - 2) that the data in the certificate are accurate and genuine.
- (3) Food types and cases in which additional certification may be sought, the manner of issuing certificates, shall be laid down by a regulation of the Ministry.

XIII. SUPERVISION

Article 115

- (1) Supervision over the implementation of this Law and legislation adopted on the basis of this Law shall be done by the Ministry.
- (2) The inspection supervision over the implementation of this Law and legislation adopted on the basis of this Law shall be done by the Administrative Authority through food inspectors, border official veterinarians and border phytosanitary inspectors, in accordance with the law.
- (3) The food inspector shall carry out the inspection supervision:
 - at the level of primary production of food and feed and supporting activities;
 - at the level of production, processing and distribution of food, feed and materials coming into contact with food;
 - in imports of food of non-animal origin that is not subject to more stringent official controls at the point of release into free circulation, warehouse, business premises of the food or feed business operator;
 - GMO food and feed;
 - in imports of food and feed.

- (4) Border official veterinarian shall perform inspection supervision:
- in imports and transit of products of animal origin and feed in accordance with the law governing veterinary affairs.
- (5) Border phytosanitary inspector shall perform inspection supervision:
- in imports and transit of food of plant origin (fruit, vegetables, cereals and other food of plant origin subjected to simple processing by grinding, drying, etc.) food of non-animal origin subject to more stringent official controls at the point of entry and feed of plant origin.

Requirements for food inspectors

Article 116

- (1) In addition to general and specific requirements laid down by the Law on Civil Servants and State Employees, the Veterinary Law and the Law on Plant Health Protection, the inspectors performing official controls shall:
- 1) be trained to carry out appropriate official controls;
 - 2) receive regular additional training in their area of competence;
 - 3) have multidisciplinary cooperation abilities.
- (2) Depending on the subject of supervision, the food inspectors may be persons with VII degree of vocational education in the following areas: veterinary, medicine, biology, chemistry, food technology, agricultural sciences in the field of plant production and livestock production, and in addition to general and specific requirements as laid down by the Law on Civil Servants and State Employees, also have passed state qualifying exam for work in public administration bodies.
- (3) The trainings referred to in paragraph 1, item 1 of this Article shall be organised by the Ministry.
- (4) The training programme and methods of implementation of the training referred to in paragraph 1 of this Article shall be defined by the Ministry.

Duties and powers of inspectors

Article 117

- (1) In carrying out official controls, the inspectors referred to in Article 115 of this Law shall, in addition to duties and powers laid down by the Law on Inspection Surveillance, shall also have the right and duty to:
- 1) carry out official controls in accordance with this Law;
 - 2) take samples in accordance with the Article 92 of this Law;
 - 3) check control systems put in place by food and feed business operators and the results obtained;
 - 4) inspect:
 - establishments where food and feed business operations take place, including primary production, surroundings, premises, equipment, means of transport, food and feed;
 - raw materials, ingredients, auxiliary substances used during the processing and treatment and other products used in food and feed preparation and production;
 - semi-processed products, materials and objects coming into contact with food;
 - processes and products for cleaning and maintenance as well as the use of pesticides;
 - food labelling, presentation and advertising;
 - 5) check the food hygiene requirements in establishments where food and feed business operations take place;
 - 6) make assessment of procedures put in place by food and feed business operators: Good Manufacturing Practice, Good Hygiene Practices, Good Farming Practices, HACCP system, traceability system, procedures for withdrawal of unsafe food or feed, taking into consideration the use of instructions and guides developed in accordance with this Law;

- 7) check the sampling of food and feed by food and feed business operators and assess the results and frequency of sampling;
- 8) check documentation and other records that may be of relevance for assessment of compliance with food and feed regulations;
- 9) read the values recorded on measuring instruments in establishments of food and feed business operators;
- 10) perform control using equipment in order to confirm the results obtained by measurement carried out by food or feed business operator;
- 11) carry out any other official activity necessary in order to ensure accomplishing of the objectives of this Law.

Administrative measures and actions

Article 118

- (1) In addition to administrative measures and actions laid down by the law governing the inspection surveillance, the inspectors referred to in Article 115 paragraph 2 of this Law, after establishing non-compliance with the requirements as laid down by this Law or other regulations, shall have the duty and powers to:
- prohibit placing on the market of food for which risk assessment procedure has not been implemented (Article 11, paragraphs 1 and 2);
 - order temporary precaution measures (Article 14);
 - order destruction of unsafe food (Article 20);
 - order withdrawal of food from the market or restrict placing food on the market if there are reasons to suspect its safety (Article 21, paragraph 5);
 - order withdrawal of food or feed or restrict placing food or feed on the market where food or feed complies with the requirements as laid down by this Law but its safety is suspected (Article 25);
 - prohibit placing on the market of food, temporarily prohibit the production and placing on the market of food suspected of non-compliance with the food hygiene requirements as laid down by this Law (Article 37 paragraph 1);
 - prohibit work of persons handling and coming into contact with food or feed who do not comply with the requirements prescribed in terms of personal hygiene (Article 39 paragraph 1);
 - order the food business operators at all stages of production, processing and distribution to ensure that persons responsible for the development and maintenance procedures based on HACCP principles and application of appropriate guide, receive training on the application of the principles of HACCP (Article 40, paragraph 1 item 2);
 - order establishing, implementation and continuous maintenance of procedures based on HACCP principles at all stages of production, processing and distribution of food after primary production and supporting activities (Article 41 paragraph 1);
 - order, where necessary, implementation of study food testing (Article 43 paragraph 4);
 - prohibit business operations in establishments not approved for operations (Article 50 paragraph 1);
 - prohibit the subject of supervision the provision of information and data on food that may mislead the consumer (Article 55 paragraph 1);
 - prohibit the use of objects and materials coming into contact with food and that could pose hazard to human health or cause unacceptable change in composition of food or cause deterioration of sensorial food properties (Article 62 paragraph 2);
 - prohibit the trade in quick frozen food not labelled as “quick frozen” (Article 66 paragraph 3);

- order implementation of measures needed for prevention of occurrence of contaminants in food (Article 67 paragraph 3);
- prohibit production, placing on the market and import of treated by ionising radiation that does not comply with the requirements as laid down by this law and safety requirements (Article 69 paragraphs 1 and 2);
- order implementation of measures in order to comply with the feed hygiene requirements at all stages of production, processing and distribution of feed, starting from primary production to placing on the market when feeding food-producing animals as well as in imports and exports (Article 73 paragraph 1);
- order elimination of non-compliances identified by official control (Article 89 paragraph 5);
- take other measures in accordance with the law.

(2) Inspectors referred to in paragraph 1 of this Article shall have the right and duty to issue an oral decision for the enforcement of certain measures as a precaution and due to urgency:

- when the risk to human health identified during the official control requires immediate implementation of a particular measure without delay;
- where there is a risk of concealing, replacement or destruction food or feed or evidence if the measure is not immediately undertaken.

(3) During the performance of official controls, inspectors shall have the right and duty to order immediate enforcement of the oral decision, which is entered into the protocol on the control carried out.

(4) In addition to administrative measures and actions as laid by the law governing inspection surveillance, the inspectors referred to in Article 115 paragraph 2 of this law, who perform inspection surveillance at border inspection point, point of entry or the place of final destination of consignment (bonded warehouse), after establishing the non-compliance with the requirements laid down by this law and other regulations of the consignment that is either imported in or in transit through the territory of Montenegro, shall undertake measures in accordance with Articles 104-107 of this law.

(5) The inspectors, referred to in paragraph 1 of this Article, if necessary, upon undertaking measures referred to in paragraphs 1 and 2 of this Article, may also request an opinion and take into consideration the risk assessment issued by the European Food Safety Authority, the Administrative Authority referred to in Article 6, paragraph 2 of this Law or authorised technical and scientific institution.

(6) The inspectors referred to in paragraph 1 of this Article shall keep as strictly confidential the identity of the persons presenting an initiative indicating the violation of this Law.

XIV. PENALTY PROVISIONS

Article 119

(1) A pecuniary fine ranging from 500 to 20,000 EUR shall be imposed for an offence on a legal entity if it:

- 1) fails to put in place traceability at all stages of production, processing and distribution of food and/or feed and /or food-producing animals and/or substances added in food or feed (Article 27, paragraph 1);
- 2) fails to put in place the traceability system and the procedures to identify the persons from which he supply food and/or feed and/or food-producing animals and/or substances that are added to food or feed and/or to whom the products are supplied (Article 27, paragraph 2);
- 3) fail to labelled food or feed which is placed on the market to enable traceability through relevant documentation or information (Article 27, paragraph 3);
- 4) food has reached the consumer and shall immediately not inform the consumers of the reasons for the withdrawal of food and/or , if Administrative Authority found that is

- necessary, don't ask from consumer the food that has already been delivered (Article 28, paragraph 2);
- 5) does not immediately inform the owner or animal keeper about the reason for the withdrawal of animal feed and/or if the Administration Authority has determined that it is necessary not require return of the delivered feed (Article 29, paragraph 3);
 - 6) in all stages of production and/or processing and/or distribution does not provide that persons who are virus carriers and/or have infected wounds and/or diarrhea that do not handle with food and not to enter in the spaces in which food is handled, if there is any danger of direct or indirect contamination (Article 39 paragraph 2);
 - 7) in all stages of production and/or processing and/or distribution does not provide that persons who come into direct contact with food are supervised and/or receive instructions and/or training regarding the rules of food hygiene related activities they perform (Article 40, paragraph 1, paragraph 1);
 - 8) in all stages of production and/or processing and/or distribution does not ensure that persons responsible for the development and maintenance procedures based on HACCP principles or application of appropriate guide, receive training on the application of the principles of HACCP (Article 40 paragraph 1, paragraph 2);
 - 9) fail to establish and/or does not apply, and/or does not continuously maintain procedures based on HACCP principles in all stages of production and/or processing and/or distribution of food after primary production and associated activities (Article 41, paragraph 1);
 - 10) when replacing the product and/or process and/or production stages do not make changes of established procedures (Article 41, paragraph 3);
 - 11) fails to make a sampling plan prepared meals and/or surface swabs order to validate their actions (Article 43, paragraph 3);
 - 12) put the prescribed identification mark to a product of animal origin produced in the house which is not approved in accordance with Article 50 of this Law (Article 46, paragraph 2);
 - 13) carries out the activity of production and/or processing and/or distribution of food or feed in unregistered or unapproved facility (Article 47, paragraph 1);
 - 14) fails to submit an application for registration of the object to the Administration Authority prior to the commencement of activities for the facility at which it performs the activity which is subject to registration (Article 48 paragraph 1);
 - 15) fails to notify the Administration Authority of any change of subject and/or changes in the establishment and/or the business operations compared to the approval issues no later than 15 days from the day of change (Article 52 paragraphs 1);
 - 16) fails to notify the Administration Authority within 15 days of the cessation of activities that temporary carries out one and/or more activities up to six months, which approval was issued (Article 52, paragraph 3);
 - 17) fails to submit to the Administration Authority request for approval of the facility at least 15 days prior to the restart of the activity in the object, when the cessation of activities and/or more of the activities for which the approval was issued lasted more than six months (Article 52, paragraph 4);
 - 18) do not write on the Montenegrin information and data for food referred to Article 54 par. 3 and 4, is being imported (Article 54, paragraph 5);
 - 19) provides information and/or data on food that may mislead the consumer in terms of features in terms of characteristics and/or species and/or name and/or properties and/or composition and/or quantity and/or shelf life and/or the country or place of origin and/or mode of production and/or attributing to the foodstuff effects or properties which the food don't have and/or reference to the special characteristics of the food that has similar food, in particular by emphasizing the presence or absence of certain ingredients and/or nutrients and/or appearance, description or visual display of the presence of a particular food or ingredient when this ingredient or naturally present or commonly used in the food, replaced by other components or other ingredient (Article 54 paragraph 1);

- 20) provides information about the food that point to the healing properties of the food, except for natural mineral waters and foods for particular nutritional needs prescribed in Article 65, paragraph 1 of this Law (Article 55, paragraph 2);
- 21) during the advertising and/or presentation of food (shape, packaging, arrangement, appearance, packaging material, the way it is arranged and the setting in which it is exposed food) provides information and/or data about the food that consumers can be misleading regarding the characteristics and/or the type and/or name and/or properties and/or composition and/or quantity and/or shelf life and/or the country or place of origin and/or mode of production and/or attributing to the food effects or properties which the food don't have and/or reference to the special characteristics of the food that has similar food, in particular by emphasizing the presence or absence of certain ingredients and/or nutrients and/or appearance, description or visual display of the presence of a particular food or ingredient when this ingredient or naturally present or commonly used in the food, replaced by another integral part or second component and/or information about food that point to the healing properties of the food, except for natural mineral waters and foods for particular nutritional needs prescribed in Article 65, paragraph 1 of this Law (Article 55, paragraph 3);
- 22) uses nutritive and health claims that are incorrect and/or ambiguous or misleading and/or give rise to suspecting the safety and/or dietary appropriateness of other food and/or encourage and/or tolerate the excessive use of certain food and/or suggest or indicate that a balanced and diverse nutrition cannot provide adequate quantities of nutrients and/or indicate the changes in body functions (Article 56 paragraph 2);
- 23) uses health claims indicating that health could be endangered as a result of not consuming certain food and/or indicating the rate or quantity of weight loss (Article 56 paragraph 3);
- 24) places on the market food that is not marked with a mark enabling identification of a batch or lot that the food belongs to (Article 57 paragraph 2);
- 25) during labelling and/or presentation and/or advertising indicates that supplements do have properties of preventing and/or treating and/or curing human diseases and/or indicate such properties (Article 63 paragraph 3);
- 26) during labelling and/or presentation and/or advertising of food that vitamins and/or minerals and/or other substances have been added to, indicates that a balanced and diverse nutrition cannot provide sufficient quantities of nutrients and/or misleading the consumer in terms of nutritive value of the food that may be a result of adding such ingredients, in any way (Article 64 paragraph 2);
- 27) during placing on the market, fails to indicate the nutritive value of the product that vitamins and minerals were added to, as well as the information on the total quantities added (Article 64 paragraph 3);
- 28) places on the market quick frozen food that is not marked as "quick frozen" (Article 66 paragraph 3);
- 29) places on the market natural mineral water originating from a single source under different brand names (Article 70 paragraph 3);
- 30) does not control the fat and/or oil and/or products derived from fats and/or oils in the presence of dioxins or dioxin-like PCBs and placing on the market of fat and/or oil and/or products derived from fats and oils, which are used in animal feed, including compound feed (Article 73, paragraph 4);
- 31) fails to put in place and/or implement and/or continuously maintain the procedures based on HACCP principles at all stages of production and/or processing and/or distribution of feed other than primary production of feed with supporting activities in accordance with Article 41 of this Law (Article 76 paragraph 1);
- 32) used antibiotics, which are not coccidiostats and/or histomonostats as additives in animal feed (Article 82, paragraph 2);
- 33) does not keep records and/or is not at least five years from the date of the last track, and/or keep the recipes on the basis of which is delivered medicated feed and/or

intermediate product and/or keep the certificates that accompanied the shipment of medicated feed for on the importation of animals (Article 84, paragraph 3).

- (2) For the offense referred to in paragraph 1 of this Article, a natural person and responsible person in the legal entity shall be fined in the amount of 30 euros to 2,000 euros.
- (3) For the offense referred to in paragraph 1 of this Article shall be fined in the amount of 150 euros to 6,000 euros.

Article 120

In the case of a repeated misdemeanour referred to in Article 119 of this Law, in addition to the fine, a protective measure of prohibition of business operations for the period of 6 month may be imposed on the food or feed operator.

XV. TRANSITIONAL AND FINAL PROVISIONS

Adoption of regulations

Article 121

- 1) The secondary legislation from article 9 points 6, 7, 8, 10, 11, 13, 14, 15, 17, 19, 20 i 21, article 37 paragraph 6, article 38 paragraph 2, article 43 paragraph 5, article 44 par. 6 i 7, article 45 paragraph 2, article 46 paragraph 3, article 54 paragraph 6, article 56 paragraph 4, article 58 paragraph 3, article 59 paragraph 3, article 60 paragraph 3, article 61 paragraph 3, article 62 paragraph 9, article 63 paragraph 5, article 64 paragraph 4, article 65 paragraph 3, article 67 paragraph 5, article 68 paragraph 5, article 70 paragraph 6, article 73 paragraph 5, article 77 paragraph 8, article 82 paragraph 5, article 83 paragraph 3 and article 84 paragraph 4 of this Law zakona donijeće se u roku od šest mjeseci od dana stupanja na snagu ovog zakona.
- 2) Podzakonski akti iz člana 11 stav 6, člana 21 stav 6, člana 27 stav 4, člana 31 stav 3, člana 34 stav 5, člana 42 stav 3, člana 47 stav 4, člana 48 stav 3, člana 50 stav 13, člana 57 stav 4, člana 66 stav 4, člana 67 stav 6, člana 69 stav 3, člana 71 stav 4, člana 72 stav 4, člana 74 stav 2, člana 77 stav 9, člana 78 stav 3, člana 84 stav 5, člana 85 stav 3, člana 89 stav 7, člana 91 stav 4, člana 100 stav 5, člana 101 stav 3, člana 102 stav 2, člana 103 stav 4, člana 106 stav 3, člana 108 stav 9, člana 109, člana 111 stav 4, člana 113 stav 4, člana 114 stav 3, člana 115 stav 4 ovog zakona shall be adopted within four years from the day of entry of this Law into force.
- 3) Pending the adoption of legislation referred to in paragraph 1 and 2 of this Article, the legislation adopted pursuant to the Food Safety Law (Official Gazette of Montenegro 14/07) and the Veterinary Law (Official Gazette of Montenegro 30/12) shall apply, provided they are not in contravention of this Law.

Harmonisation of operations

Article 122

- (1) Food business operators, at all stages of production, processing and distribution who, by entry into force of this Law, performed their business operations on the basis of the approval of operations shall file a request for approval issuing within 60 days from the day of receipt of the notification on category from the administrative authority.
- (2) The food business operator whose establishment was, based on the assessment of the establishment's conditions by entry into force of this law, classified into category I on the basis of the assessment report, shall be issued with an approval for operations within 30 days from the day of filing the request referred to in paragraph 1 this Article.
- (3) The food business operator whose establishment was, based on the assessment of the establishment's conditions by entry into force of this law, classified into category II on the basis of the assessment report, shall be issued with a conditional approval for operations for the period of six months, within 30 days from the day of filing the request referred to in paragraph 1 of this Article.

(4) The operator referred to in paragraph 3 of this Article shall eliminate the non-compliances noted by the expiry of the period for which the conditional approval was issued.

(5) Upon expiration of the period referred to in paragraph 3 of this Article, the Commission shall carry out on-the-spot inspection of the establishment for the assessment of the condition of the establishment in terms of non-compliances identified and shall deliver a report on findings to the Administrative authority.

(6) The establishment of the operator who eliminated the non-compliances in accordance with the paragraph 5 of this Article, shall be classified into the category I and issued with the approval for operations.

(7) The establishment of the operator who failed to eliminate the non-compliances in accordance with the paragraph 5 of this Article, shall be classified into the category III.

Conditional approval

Article 123

(1) Food business operators whose establishments were classified into the category III based on the assessment of the condition by the day of entry into force of this law on the basis of the assessment report due to established major non-compliances, elimination of which requires longer time and operators referred to in Article 122, paragraph 7 of this Law, shall file the application for issuing of conditional approval and the plan for elimination of non-compliances with deadlines for their elimination (hereinafter referred to as: the improvement plan), within 180 days from the day of the receipt of the notification referred to in Article 121, paragraph 1 of this Law.

(2) The conditional approval referred to in paragraph 1 of this Article, shall be issued upon the assessment and issuing of approval to the improvement plan, within 90 days from the day of submission of the request and the improvement plan.

(3) The food or feed business operator, who eliminated all non-compliances in accordance with the improvement plan shall be classified into the category I and issued with approval for operations.

(4) The Administrative authority shall revoke the conditional approval referred to in paragraph 3 of this Article where the controls made establish that the food business operator is failing to eliminate the non-compliances identified within the deadlines set by the improvement plan.

(5) The Administrative authority monitors the implementation of improvements in the facility.

(6) The content of the Plan of improvements referred to in paragraph 1 of this Article, the assessment procedure and for approving the Plan improvements referred to in paragraph 2 of this Article, the longest period for the authorization referred to in paragraph 3 of this Article, the procedure for revoking the temporary approval referred to in paragraph 4 above, the method of monitoring implementation improvements in the facility shall be prescribed by the Ministry.

Marking of food of animal origin

Article 124

Food of animal origin originating from establishments issued with the conditional approval referred to in Article 123 of this Law shall be marked in accordance with a regulation of the Ministry.

Request for registration of establishments

Article 125

(1) Food and feed business operators that have been approved, and carry out activities that are subject to registration in accordance with Article 48, paragraph 3 and which are entered in the Register prior to the entry into force of this law, shall submit an application for registration 60 days from the date of entry into force of the provisions of Article 48, paragraph 3 of this law.

(2) Food and feed business operators that, to the entry into force of this Law, perform activities that are subject to registration and which are entered in the Register, are obliged to apply for re-registration.

(3) The Administrative authority within six months of receipt of the request from par. 1 and 2 of this Article issued a administrative decision and registered in the Register referred to in Article 47 of this Law.

(4) Food and feed business operators par. 1 and 2 are obliged to harmonize their business by the deadline designated by the administrative decision referred to in paragraph 3 above.

Putting the system in place

Article 126

The RASFF system shall be put in place within the period of three years from the day of entry of this Law into force.

Obligations from the day of accession

Article 127

As of the day of accession to the European Union:

- export shall be considered delivery of food and feed to countries other than Member States of the European Union (hereinafter referred to as: the third countries);
- consignment shall be a consignment of food or feed imported from third countries;
- the Ministry shall notify the European Commission of approved establishments;
- the Ministry shall present to European Commission the guides referred to in Article 53, paragraphs 3 and 7 of this Law;
- the Ministry shall notify the European Commission, the relevant reference laboratories of the European Commission and Member States of the European Commission of national reference laboratories;
- the Ministry shall, in co-operation with the European Commission, develop contingency plans referred to in Article 33 of this Law;
- the Ministry shall present to the European Commission the reports on implementation of the multiannual official controls plan;
- import shall be considered introduction and placing on the market of food and feed from third countries;
- dispatch of consignments of food and feed shall be deemed uploading within Member States.

Obligations of the Ministry

Article 128

As of the day of entry into force of this Law, the Ministry shall:

- present the European Commission with legislation adopted on the basis of this Law;
- enable the European Commission to conduct surveillance on the territory of Montenegro and provide assistance in reviewing the enforcement of this law.

Deadline for adoption of the plan

Article 129

(1) The multiannual official controls plan shall be adopted within two years from the day of entry into force of this Law.

(2) Pending the adoption of the plan referred to in paragraph 1 of this Article, the official controls shall be made based on annual control plans adopted by the Administrative Authority.

Start applications

Article 130

The provisions of Article 88 para. 6 through 8 of this Law shall apply from the date of accession to the European Union.

Repeal
Article 131

On the effective date of this Law, the Law on Food Safety ("Official Gazette of MN", no.14/07), Law on health monitoring of food and items of general use ("Official Gazette of SRCG", no. 26/73), the provisions of Art. 112 to 115 of the Veterinary Act ("Official Gazette of MN", no. 30/12), Article 106 of the Law on Amendments to the Act which are prescribed fines for violations ("Official Gazette of MN", no. 40/11) and stops application of the provisions of the Law on health safety of foodstuff and objects for general use related on food ("Official Gazette of SFRY", No. 53/91).

Entry into force
Article 132

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