

## **IV. FOOD SAFETY**

### **1. FOOD SAFETY REQUIREMENTS**

#### **Safe Food Article 22**

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

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

#### **Detailed Requirements for Determining Food Safety Article 23**

When determining food safety, the following shall be considered:

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

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

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

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

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

#### **Unsafe Food Article 24**

Food shall be considered unsafe for human consumption if:

- 1) it contains microorganisms, parasites, bacterial toxins or histamine in larger quantities than prescribed;
- 2) it contains natural toxins or other natural toxic substances in larger quantities than prescribed;
- 3) it contains heavy metals, metalloids, residues of pesticides, veterinary medicines, micro-toxins and other substances in larger quantities than prescribed;
- 4) it contains additives which may not be used in a certain type of food, or if content of allowed additives in the food is higher than prescribed;
- 5) it contains radionuclide above the prescribed limit, or if it is polluted by radiation over the permitted limit;

- 6) the packaging, materials, and articles coming in contact with food do not fulfill prescribed requirements;
- 7) it derives from animals that were not examined before and after slaughter, and when meat was not marked in accordance with the regulations;
- 8) it derives from diseased or dead animals, or animals for which slaughter and further slaughterhouse treatment are not allowed regardless of the reason;
- 9) due to physical, chemical, microbiological or other processes, sensory characteristics of food (taste, smell, color, appearance, structure, etc.) are changed;
- 10) it contains substances which are not toxicologically evaluated, verified, and safe for human consumption;
- 11) it contains mechanical impurities;
- 12) packaging is damaged in such a way that microbiological and chemical changes of food may occur;
- 13) it was not produced, processed, packed, stored or distributed in a prescribed manner;
- 14) it is not labeled and marked in a prescribed manner;
- 15) it does not fulfill prescribed nutrition content requirements.

## **2. FEED SAFETY REQUIREMENTS**

### **Safe Feed Article 25**

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

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

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

### **Unsafe Feed Article 26**

Feed shall be deemed to be unsafe if:

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

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

### **Detailed Requirements for Determining of the Unsafe Feed Article 27**

Feed shall be considered unsafe if:

- 1) it contains microorganisms, parasites, bacterial toxins or histamine in larger quantities than prescribed;
- 2) it contains natural toxins or other natural toxic substances in larger quantities than prescribed;
- 3) it contains heavy metals, metalloids, residues of pesticides, veterinary medicines, micro-toxins and other substances harmful to human and animal health in larger quantities than prescribed;
- 4) it contains additives which may not be used in a certain type of feed, or if content of allowed additives in the feed is higher than prescribed;

- 5) it contains radionuclide above the prescribed limit, or if it is polluted by radiation over the permitted limit;
- 6) the packaging, materials, and articles coming in contact with feed do not fulfill prescribed requirements;
- 7) due to physical, chemical, microbiological or other processes, sensory characteristics of feed (taste, smell, color, appearance, structure, etc.) are changed;
- 8) it contains substances which are not toxicologically evaluated, verified, and safe for animal feeding;
- 9) it contains mechanical impurities;
- 10) packaging is damaged in such a way that microbiological and chemical changes of feed may occur;
- 11) it was not produced, processed, packed, stored or distributed in a prescribed manner;
- 12) it is not labeled and marked in a prescribed manner;
- 13) it does not fulfill prescribed nutrition content requirements.

### **3. PROHIBITION OF CIRCULATION**

#### **Article 28**

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

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

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

### **4. LABELING, MARKING, PRESENTATION AND ADVERTISING**

#### **Labeling and Marking Article 29**

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

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

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

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

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

### **Presentation and Advertising Article 30**

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

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

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

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

### **Article 31**

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

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

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

## **6. FOOD OR FEED ADDITIVES**

### **Article 32**

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

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

## **7. QUICK FROZEN FOOD**

### **Article 33**

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

Temperature within the quick frozen food, following warmth stabilization, shall be constantly maintained at  $-18^{\circ}$  C or below.

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

## **8. DIET FOOD**

### **Article 34**

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

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

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

## **9. NOVEL FOOD**

### **Article 35**

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

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

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

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

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

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

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

## **10. GENETICALLY MODIFIED FOOD AND FEED**

### **Article 36**

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

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

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

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

## **11. REQUIREMENTS FOR WATER**

### **Article 37**

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

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

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

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

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

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

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

### **1. GENERAL RESPONSIBILITIES**

#### **Obligations Article 38**

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

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

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

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

#### **Responsibilities Article 39**

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

#### **Liability for Damages Article 40**

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

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

#### **Traceability Article 41**

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

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

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

### **Withdrawal of Unsafe Food or Feed from Circulation Article 42**

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

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

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

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

### **Article 43**

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

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

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

## **Production and Circulation Requirements Article 44**

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

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

## **3. SPECIFIC HYGIENE REQUIREMENTS FOR FOOD AND FEED**

## **Article 45**

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

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

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

## **4. HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)**

### **Article 46**

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

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

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

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

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

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

## **Manuals, Instructions and Guides**

### **Article 47**

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

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

### **Article 48**

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

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

### **Request for Approval of Facilities Article 49**

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

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

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

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

### **Determining Fulfillment of Requirements Article 50**

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

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

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

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

### **Registers of Approved Facilities Article 51**

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

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

### **Entry in the Register Article 52**

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

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

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

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

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

### **Removal from the Register Article 53**

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

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

## **VII. GENERAL OBLIGATIONS IN THE FOOD AND FEED TRADE**

### **Food and Feed Safety Measures in International Trade**

#### **Article 54**

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

- 1) only to the extent necessary to protect human life and health, and provided they are based on scientific principles and available scientific evidence, international standards, guidelines, and recommendation;

- 2) in such a manner as to avoid arbitrary or unjustified discrimination between countries where identical or similar conditions prevail, including discrimination between the territory of Montenegro and other countries;
- 3) based on the assessment of risk to human life and health conducted in accordance with the risk assessment techniques of international organizations;
- 4) in a manner that would not constitute a disguised restriction on international trade.

#### **Article 55**

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

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

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

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

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

#### **Article 56**

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

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

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

#### **Article 57**

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

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

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

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

#### **Article 58**

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

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

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

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

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

#### **Article 59**

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

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

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

#### **Article 60**

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

- 1) promptly, without any undue delay and discrimination of imported products in respect of similar domestic products;
- 2) based solely on the facts and information necessary to conduct the proceedings in front of the competent authority, including approvals for use of additives, or for determination of the tolerance level for contaminants in food and feed;
- 3) in such a manner as to ensure protection of confidentiality of information;
- 4) taking samples solely in the quantity that is necessary for the control and approval procedures;
- 5) if specification of food and feed changes after the control is performed, the procedure for changes shall be conducted insofar as it is necessary to determine that the food and feed, regardless of the change, comply with the relevant regulations.

## **GENERAL REQUIREMENTS FOR IMPORT**

### **Import of Food and Feed Article 61**

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

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

### **Specific Conditions for Import Article 62**

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

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

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

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

### **Export of Food and Feed Article 63**

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

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

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

#### **Article 64**

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

#### **Documentation Article 65**

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

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

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

#### **Exceptions Article 66**

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

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

### **VIII. SAMPLING AND EXAMINATION**

#### **Taking Samples Article 67**

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

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

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

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

### **Laboratory Examinations Methods Article 68**

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

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

### **Authorized Laboratories Article 69**

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

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

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

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

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

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

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

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

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

### **Reference Laboratories Article 70**

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

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

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

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