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## Croatia

### Agricultural Situation

### Croatian Law on Food (English Translation)

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**Report Highlights:**

Following is the English translation of the Croatian Law on Food.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
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# THE FOOD ACT

## I. GENERAL PROVISIONS

### Article 1

This Act shall regulate:

- general principles and requirements relating to the hygiene and sanitary safety of food and feed,
- the obligations of food business operators and feed business operators regarding the hygiene and sanitary safety of food, including feed,
- general requirements relating to food
- general requirements for obtaining the registration of geographical indications and designation of origin or the food and the traditional reputation of the food,
- general requirements relating to the declaration and labelling of food and feed,
- general requirements for placing food and feed on the market,
- general requirements for placing novel foods on the market,
- general requirements for placing on the market food and feed which contains genetically modified organisms or consists of them,
- the system of official control of food and feed,
- the system of authorised testing laboratories and reference laboratories,
- crisis and emergency management,
- foundation of the Croatian Food Agency,
- authority and responsibilities of the competent authorities regarding food and feed produced in the Republic of Croatia or imported and placed on the market of the Republic of Croatia.

### Article 2

This Act shall apply to all stages of production, processing, storage and distribution of food and feed, except for primary production, preparation, handling and storage of food in households intended for personal consumption and feeding of household animals which are not intended for sale on the market.

### Definition of Foodstuff

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1) For the purposes of this Act, the foodstuff shall be every substance or product – processed, partially processed or unprocessed, intended for human consumption or which can be expected to be consumed by humans.

2) The term foodstuff shall also include beverages, chewing gum, food additives and any other substance that is intentionally incorporated into food during its production, preparation or treatment.

3) The term foodstuff shall also include water, namely:

- water used for public supply of the population as potable water,
- water used and/or incorporated into food during its production, preparation or treatment,
- water packed in original packaging as table water, mineral water and source water.

4) The term foodstuff shall not include:

- feed,
- live animals, except if they are prepared for placement on the market as food,
- plants before harvesting, picking, or collecting of fruits,
- medicines and medicinal products defined by a special regulation,
- cosmetics defined by a special regulation,
- tobacco and tobacco products defined by a special regulation,
- narcotics or psychotropic substances within the meaning of the Uniform convention of the United Nations about the Psychotropic Substances, 1971,
- residues and contaminants, as well as natural ingredients of vegetal and animal origin that are harmful to human health.

#### Other Definitions

#### Article 4

For the purposes of this Act, certain terms shall have the following meaning:

1. "food regulations" – shall be this Act, implementing regulations adopted on the basis of this Act and other special regulations (Acts and the pursuant regulations) relating to food, particularly the hygiene and sanitary safety of foodstuffs, including all stages of production, processing and distribution of food and feed for food producing animals or animals used for food production,
2. "food business" – shall mean any undertaking, whether for profit or not and whether public or private, carrying out within the scope of its operations any or all jobs related to any stage of production, processing, storage, transport or distribution of foodstuffs,
3. "food business operator" – shall mean a physical or legal person, registered for performing certain activities relating to food business, responsible for unobstructed implementation of the provisions concerning foodstuffs within the business which it manages,
4. "feed" – shall mean any substance or product, including feed additives, processed, partially processed or unprocessed, intended for feeding of food producing animals, or animals used for food production,;
5. "feed business" – shall mean any undertaking, whether for profit or not and whether public or private, carrying out within the scope of its operations any or all jobs related to any stage of production, processing, storage, transport or distribution of feed, including production, processing or distribution of feed intended for feeding animals on a private property,
6. "feed business operator" – shall mean any physical or legal person, registered for performing certain activities relating to feed business, responsible for ensuring unobstructed implementation of the provisions of feed regulations within the scope of the business it manages,
7. "competent authorities" – shall mean risk managing bodies, namely the Croatian Food Agency, Ministry of Agriculture and Forestry and Ministry of Health
8. "retail trade" – shall mean handling and/or processing of food and/or its processing and/or preparation and storage at the point of sale or delivery to the final consumer, and includes

- catering operations, institutional catering, (hospitals, nursery schools, schools, homes for senior citizens and alike), factory canteens, catering establishments like restaurants and other food service operations, stationary or movable food kiosks, food preparation, sale and catering outlets outside of the premises or location destined for food business, shops and wholesale outlets,
9. “marketing” – shall mean holding of food and feed with the purpose of selling, including offering for sale, selling or any other form of transaction, whether free or not, distribution and other forms of transfer, on the territory of the Republic of Croatia,
  10. “risk” – shall mean the probability and severity of adverse effect of hazards to human health,
  11. “risk analysis” – shall mean a procedure consisting of three interconnected components; risk assessment, risk management and risk notification
  12. “risk assessment” – shall mean a scientifically based procedures consisting of four stages; hazard identification, hazard characterisation, exposure assessment and risk characterisation,
  13. “risk management” – shall mean a procedure by which different possibilities of acting of the competent authorities, relating to risk, are compared, in cooperation with interested participants, taking into account risk assessment and other relevant factors, and, if necessary, the procedure of selecting adequate preventiva and control measures,
  14. “risk notification” – shall mean and interactive exchange of information and opinions during the whole procedure of risk analysis, relating to hazards and risks, competent authorities, consumers, food and feed producers, academic community and other interested parties, including the explanation of findings during risk assessment and the basis for making decisions during risk management,
  15. “hazard” – shall mean a biological, chemical or physical agent in the food and feed or the state of food and feed, with the potential to cause adverse effects to human health,
  16. “traceability” – shall mean the possibility of tracing food, feed, food producing animal or animal serving for food production, raw material or substance intended for incorporation or expected to be incorporated into food or feed, in all stages of production, processing and distribution,
  17. “stage of production, processing and distribution” – shall mean any stage, including import, primary production, processing, storage, transport, selling or supply of final consumer with food, and, where related to it, import, production, manufacturing, storage, transport, distribution, selling of feed and supply with feed,
  18. “primary production” – shall mean the production and rearing or growing primary agricultural products in crop farming, cattle raising or fish farming (pisciculture), including harvesting and picking of fruits, milking and raising animals prior to slaughter, hunting and fishing and collecting self-grown fruits and plants,
  19. “consumer” – shall mean a physical person buying food for fulfilling its own needs, and not using it in any stage of food business,
  20. “official control” – shall mean control of hygiene, safety and quality of food and feed in order to establish whether the provisions of food regulations are met,
  21. “food safety” – shall mean the assurance that food will not cause adverse effects to human health if it is prepared and consumed taking into account its intended use,
  22. “food hygiene” – shall mean measures and conditions necessary for hazard control and assurance of fitness of food for human consumption, in accordance with its intended use,
  23. “feed safety” – shall mean harmlessness of feed for animals to animal health, and indirectly to the health of humans who consume products produced from those animals, with regard to the presence of certain biological, chemical or physical substances in feed,
  24. “contaminant” (or “harmful substance”) – shall mean a biological, chemical and physical substance harmful to human health, which is not added to food on purpose, and the presence thereof in the food is the consequence of procedures during production

- (including the procedures carried out during the cultivation of crops and animals and application of veterinary medicines), processing, preparation, treatment, packaging, transport or storage of that foodstuff, or the consequence of environmental pollution,
25. “residue” (“remaining substance”) - shall mean the remnant of biological or chemical substances that are permitted for using in certain quantities and certain stages of primary production of food, as well as the remnants of their metabolites and products of their decomposing; residues do not include food additives,
  26. “ food additive” - shall mean every substance which is normally not consumed, nor is it a typical ingredient of food, not regarding its nutritional value, and which is added intentionally due to technological and sensory characteristics or food in the technological procedure of production, during preparation, treatment, processing, moulding, packaging, transport and storing,
  27. “feed additive” – shall mean any substance which, incorporated into feed, may affect the characteristics of feed of the cultivation of food producing animals or animals used for the production of food intended for human consumption,
  28. “food quality” – shall mean the overall characteristics of food which add to its ability to satisfy the needs of the final consumer,
  29. “declaration” (or “labelling”) – shall mean placement of written indications, commercial indications, registered trad mark, make, pictoral representations or symbols relating to food or feed, which are placed on the packaging, label or tag or on a conspicuous place for the consumer of unpackaged food,
  30. “objects that come into direct contact with food” – are dishes, accessories, equipment, devices and packaging used in food business,
  31. “novel foods” – shall mean the food and food ingredient that so far haven’t been considerably used for human consumption in the Republic of Croatia,
  32. “genetically modified organism” – shall mean the organism, except for human beings, whose genetic material was intentionally changed in a way that can not be achieved by natural propagation and/or natural recombining,
  33. “food for special dietary needs” (ili “or dietary foodstuff”) – shall mean the food fo special composition or special way of production, different from usual food due to its nutritional characteristics, which may be intended for consumption of infants and small children, people with the disturbances of digestive process or metabolism, and persons who are in special physiological states, for whom it is necessary to achieve special effects by a controlled intake of certain alimentary ingredients.

## **II. GENERAL PRINCIPLES**

### **1. Principles of the Risk Analysis The Risk Analysis Article 5**

1) In order to achieve the main objective, which is the high level of protection of human life and health, the measures which are implemented pursuant to food regulations shall be based on risk assessment, except if it is not suitable due to circumstances or the nature of the measure.

- 2) Risk assessment shall be based upon available scientific proofs and conducted in an independent, objective and transparent way.
- 3) Risk assessment shall be conducted by the Croatian Food Agency.

### **The Risk Notification**

#### **Article 6**

The Risk notification shall be conducted by the Croatian Food Agency in order to provide:

- The Ministry of Agriculture and Forestry and the Ministry of Health, respectively,
  - Food and feed business operators,
  - Consumers, and
  - Other competent institutions and interested parties,
- With timely, reliable, objective and understandable information about the food and feed related hazards and risks, respectively.

### **Risk Management**

#### **Article 7**

- 1) Risk management shall ensure that the preventive and control measures, taken with the objective of reducing, eliminating or preventing risks to human health during food consumption, be efficient, impartial and adequate.
- 2) Risk management shall be performed by the competent authorities.

## **2. The Principle of Precaution**

### **Article 8**

1) Under special circumstances, having identified, after the assessment of all available information, the possibility of adverse effect of a foodstuff on human health, but if there are some scientific doubts, the competent authorities may take provisional measures of risk management, much-needed for ensuring the highest possible level of human health protection to until further scientifically founded information necessary for the overall assessment of the risk is acquired.

2) The measures taken pursuant to the paragraph 1 of this article must be adequate and not restrict trade more than is necessary to achieve high level of human health protection, taking in to account their technical and economical feasibility and the established state of the facts.

3) The measures must be reconsidered in an adequate period of time, depending on the nature of the identified risk for human health and life, and about the type of scientifically founded information necessary for the clarification of scientific doubts, and for the carrying out of the overall risk assessment.

## **3. The Principle of Transparency**

### **Article 9**

1) Croatian Food Agency, directly or through authorised representatives of consumers or other interested groups, during preparation, evaluation and revision of the risk management measures, must carry out open and transparent public consultation, except when the urgency does not permit it.

2) If there is a justified doubt that food or feed could represent a risk for human or animal health, depending upon the nature, seriousness and extent of that risk, the Croatian Food Agency shall take measures for informing the public about the nature of the health risk.

3) In the case of the paragraph 2 of this Article, it is necessary to, as much as possible, to identify food or feed, risk it represents, and the measures taken or which shall be taken in order to prevent, reduce or eliminate that risk.

## 4. The Protection of the Consumers' Interests

### Article 10

- 1) The interest of the consumers must be protected as much as possible,
- 2) The food regulations shall be directed towards the consumer protection and provide the basis for providing complete information about foodstuffs to be consumed by the consumers, and offer them in that way the choice of foodstuffs.
- 3) It is contrary to the interest of the consumers:
  - Production and placement on the market of sanitary unsafe food and the food unfit for the market,
  - Fraud or intentional incorrect carrying out of the procedures in food business,
  - Forging the foodstuff by replacing or leaving out of the basic ingredients which are connected with the certain type of characteristic of foodstuff,
  - Misleading the consumer by providing incorrect information on the declaration,
  - Carrying out or using the procedures (advertising and alike) that can mislead the consumer.

## III. SANITARY SAFETY OF THE FOOD

### 1. The Conditions for Determining Food Safety

#### Article 11

- 1) Food shall be considered sanitary safe if it cannot cause adverse effects to human health, if it is produced, prepared and consumed according to its intended use.
- 2) The placement on the market of unsafe food shall not be permitted.
- 3) The food shall be considered sanitary unsafe if it is:
  - Harmful to human health
  - Unfit for human consumption

#### Article 12

- 1) When deciding whether some foodstuff is sanitary safe, the following shall be taken into account:
  - The conditions at every stage of production, processing and distribution of food, and the conditions of preserving and holding the food until selling it to the final consumer, as well
  - Information given to the final consumer, including the details on the declaration and the information which is generally available to the final consumer, relating to the avoidance of specific adverse effects to human health of a certain food or food category.
- 2) When deciding whether certain foodstuff is harmful to human health, the following shall be taken into account:

- Possible direct or indirect, short-term or long-term adverse effects of that food on the health of the person that consumes it and the effects upon future generations,
- Possible cumulative toxic effect,
- Special sanitary sensitivity of a special category of consumers, intended of that category of consumers.

3) When deciding whether a foodstuff is unfit for human consumption, it should be taken into account whether this foodstuff is unacceptable for its intended use because of its contamination, whether by an external agent or in some other way, due to putrefaction, decaying or decomposition.

4) When the food, which is established to be unsafe, is a part of a production party, series or shipment which is equal by category and description, all food in that production party, series or shipment is considered to be unsafe, except if, having performed laboratory analysis and/or superanalysis, the opposite is established.

### Article 13

1) A foodstuff shall be considered harmful to human health if:

- it contains microorganisms or tissue parasites harmful for human health, bacterial toxins, micotoxines, histamine and histamine-like substances and other microorganisms or tissue parasites in larger quantities than permitted,
- contains natural toxins or other natural toxic substances in larger quantities than permitted,
- contains residues of pesticides, veterinary medicines, metals and metalloids and other substances harmful for human health in larger quantities than permitted,
- contains food additives which may not be used in a certain type of food, or if the quantity of the food additives present in the food is larger than permitted,
- contains radionuclides in over the laid down limit, or if it is polluted by radiation over the permitted limit,
- the packaging contains microorganisms or other substances that may have influence on the increasing of the contents of substances which are harmful to human health in food.
- it is derived from dead animals or animals for which the slaughterhouse treatment is not permitted, from any reason.

2) A foodstuff shall be considered unfit for human health if:

- the sensory characteristics of the foodstuff are so changed due to physical, chemical, microbiological or other processes, that the foodstuff is not fit for human consumption,
- contains substances or raw materials which are not toxicologically evaluated, verified and safe for human use,
- contains mechanical impurities and admixtures which may be harmful for human health,
- the packaging is so harmed that microbiological and chemical changes of foodstuffs are possible beyond the permitted limits.

### Article 14

The restrictive measures for placing the food on the market and the request for withdrawing the food from the market, if there are reasons for doubt that the food is unsafe, shall be adopted by the Minister of Agriculture and Forestry and the Minister of Health, respectively, according to food types, pursuant to the list of supervising contained in the Annex of this Act, which is its integral part.



### Article 15

1) The foodstuff validity date thereof has expired, if determined to be safe by laboratory examination, and with the permission issued by the Ministry of Agriculture and Forestry and the Ministry of Health, depending on their respective competences, may in the timeframe determined by the permission:

- be reused in food production
- sold, or
- donated

2) The foodstuff from the paragraph 1 of this Article intended for donation or selling must have a special note on a conspicuous place, that it is a foodstuff the validity date thereof has expired, but which is still sanitary safe.

3) The way of submitting the request for the conditions for the permission set out in the paragraph 1 of this Article shall be laid down by the Minister of Health with the agreement of the Minister of Agriculture and Forestry.

## 2. Implementing Regulations Relating to Food Safety and Hygiene

### Article 16

1) The Minister of Health, with the agreement of the Minister of Agriculture and Forestry shall adopt the regulations:

- by which certain types and quantities of toxins, microorganisms, ions of heavy metals and non-metals, residues of pesticides, veterinary medicines, radionuclides and other substances harmful to human health, like toxicologically evaluated food additives, substances that influence on the nutritional value of the food intended for special nutritional needs may be permitted or forbidden
- concerning the sanitary safety of the objects that come to the direct contact with foodstuffs,
- concerning the treatment and removal of the food that does not meet the laid down requirements of sanitary safety,
- concerning the implementation of food monitoring with the objective of determining the level of nutrients, contaminants, additives and other food ingredients, and whose objective is to determine the intake in the organism of certain ingredients or substances and the assessment of the danger for the health of the population,
- concerning the way of sampling depending on the methods for performing the food analysis.

2) The Minister of Health with the previously obtained opinion of the Minister of Agriculture and Forestry shall adopt the regulations:

- Concerning the sanitary safety of the potable water, table water, mineral and source water and the water for the production of the food intended for placing on the market,
- Concerning the sanitary and hygienic conditions which must be met by the persons coming into the direct contact with food, as well as about the requirements for work clothes and the clothes necessary for the protection of the sanitary safety of the food,
- Concerning the restriction or prohibition of certain conditions of placing the food intended for human consumption on the market, excluding the food of predominantly animal origin,
- Concerning the restriction or prohibition of use of certain raw materials, excluding the raw materials of predominantly animal origin, its nature, subsequent treatment or other characteristics.

3) The Minister of Agriculture and Forestry, with the agreement of the Minister of Health adopts the regulations concerning the implementation of any procedure in the production and preparation of food which may affect the hygiene and sanitary safety.

4) The Minister of Agriculture and Forestry, pursuant to the previously obtained opinion of the Minister of Health adopts the regulations;

- Concerning the restriction or prohibition of certain conditions of placing the food of predominantly animal origin intended for human consumption on the market,
- Concerning the restriction or prohibition of use of certain raw materials of predominantly animal origin in the production of food, which originate from specific sources, be it regarding the type of the animal, place of origin, its nature, posterior treatment or other characteristics.

5) The regulations set out in this Article and the regulations set out in the Article 26, paragraph 1, 2, 4 and 5, Article 29 (6) and Article 74 (2) and (5) of this Act are adopted by the competent Minister pursuant to a previously acquired opinion of the Croatian Food Agency.

#### **IV. IMPORT AND EXPORT OF FOODSTUFFS**

##### **Import**

##### **Article 17**

1) Foodstuffs which imported into the Republic of Croatia to be placed on the market, must meet the requirements of food regulations.

2) By the way of derogation from the paragraph 1 of this Article, if there is a special international agreement concluded between the Republic of Croatia and the exporting country, the foodstuff that is imported into the Republic of Croatia in order to be placed on the market must meet the requirements contained in the agreement.

##### **Export**

##### **Article 18**

1) Foodstuffs exported from the Republic of Croatia, for the purpose of being placed on the market of another country, must meet the provisions of the food regulations.

2) By way of derogation from paragraphs 1 and 2 of this Article, exported from the Republic of Croatia, must meet the requirements determined by the Acts that are in force in the importing country.

3) By way of derogation of paragraphs 1 and 2 of this Article, if there is an existing international agreement concluded between the Republic of Croatia and the importing country, the foodstuffs exported from the Republic of Croatia must meet the conditions contained in the agreement.

#### **The Supervision of the Sanitary Safety of Foodstuffs upon Import**

##### **Article 19**

1) The food importer must apply to the border veterinary inspector of the Ministry of Agriculture and Forestry, namely the border sanitary inspector of the Ministry of Health, for a

request to examine the food consignment that has been imported for the purpose of establishing sanitary safety.

2) By way of derogation of the responsibilities established in the Annex, the Croatian Food Agency, in cooperation with the Minister of Agriculture and Forestry and the Minister of Health shall establish the products within the marked tariff indications from the Annex, for which discrepancies from the responsibilities of the inspections established in the Annex shall be determined.

3) Examination of the consignment for the purpose of establishing the sanitary safety of food is carried out at border veterinary crossings by the border veterinary inspector and in other places by the border sanitary inspector.

4) Border veterinary crossings from paragraph 2 of this Article are established through an enforced regulation by the Minister of Agriculture and Forestry and in other places where examinations of consignments take place by the Minister of Health.

### **Article 20**

1) The customs office, the respective customs outpost, cannot carry out the customs procedure of clearing the food consignments through customs until the border veterinary inspector, the respective border sanitary inspector, according to the division of responsibilities in Annex 1, shall establish sanitary safety of the consignment and through an arrangement approves its import.

2) It shall be the customs office's duty within its rights and responsibilities to enable the authorised border inspector from Article 19 of this Act, access to documentation and free performance of control of sanitary safety of food.

3) Until the completion of the procedure of establishing the sanitary safety of food, and before the completion of the customs procedure, the consignments may be kept in storage in customs warehouses which meet the requirements from Articles 22 and 26 of this Act.

4) The competent border veterinary inspector, the respective border sanitary inspector, for the purpose of verifying the sanitary safety of food being imported, shall reserve the right to take samples and have them examined in authorised laboratories.

5) The expenses of the consignment examination fee, the issuing of the arrangement from paragraph 1 of this Article and the expenses of laboratory examinations shall be covered by the importer.

### **Article 21**

1) Upon the import of food, which according to the Regulations on Food shall be required to have an obligatory certificate on sanitary safety, the consignments must contain a regulated international certificate on the sanitary safety of the consignment, if it has not been determined otherwise by an international convention.

2) For the food being imported, international certificates on the sanitary safety of the consignment can be recognised based on bilateral and multilateral conventions, issued by the competent authority of the exporting country.

3) If the conventions from paragraph 2 of this Article are non-existent, the recognition of international certificates and other documents shall be carried out through enforced regulations which are adopted by the Minister of Agriculture and Forestry and the Minister of Health, respectively.

4) The international certificates and other documents on sanitary safety must be in both Croatian and latin script, and the language of the country they originate from.

## V THE RECORD BOOK AND THE APPROVAL OF FACILITIES

### Article 22

1) The facility not used in the primary production of food must be registered in the Record Book of the Ministry of Agriculture and Forestry.

2) Facilities used in the production, processing and storage of food must be registered in the Record Book of the Ministry of Agriculture and Forestry, the respective Ministry of Health, according to the responsibilities in the provision of general or specific food hygiene conditions from Article 26, paragraph 2 of this Act.

3) Facilities used in the preparation, processing or treatment of food at a retail outlet, including movable and/or temporary space (stationary or movable food kiosks, places of sale on the market, movable vehicles for sale) must be registered in the records of the Ministry of Agriculture and Forestry, the respective Ministry of Health according to the responsibilities in the provision of general or specific food hygiene conditions from Article 26, paragraphs 4 and 5 of this Act.

4) For the purpose of registering into evidence from paragraph 3 of this Article, the competent offices of the State Directorate, the Economic Office, after the adoption of the arrangement on met conditions established by special regulations, must deliver a copy of the arrangement to the Ministry of Agriculture and Forestry, the Ministry of Health respectively.

5) The facilities in which the production, processing and storage of food of animal origins take place must be approved according to the regulations on veterinary medicine.

6) The Minister of Health can within the frame of his duties provided by Article 26, paragraph 2, sub-paragraph 2, paragraph 4, sub-paragraph 2 and paragraph 5 of this Act, adopt an enforced regulation by which the type of the facilities that need to be approved and the date by which the operators already engaged in the food trade in the facilities subject to the procedure of approval shall be established, which shall meet the conditions laid down by this Act and the regulations adopted and based on this Act.

7) In facilities subject to the procedure of approval, the performance of the activities cannot be begun without authorisation. The competent authority shall approve only those objects for which professional supervision has been carried out for the purpose of meeting the established conditions.

8) The competent Ministries in the procedure of registering into the Record Book issue an arrangement about registering in the Record Book and assign a registration number or approval number to every facility from paragraphs 1 and 2 of this Article.

9) The food business operators, apart from those on the retail level, shall ensure that the foodstuffs that they produce are marked with a registration number or approval number from the Record Book.

10) The Ministry of Agriculture and Forestry, the respective Ministry of Health, keep records from paragraph 3 of this Article and Record Books of registered or approved facilities from paragraphs 1 and 2 of this Article, and deliver this list to the Croatian Food Agency.

11) The Ministry of Agriculture and Forestry, the respective Ministry of health shall through this agreement and at his request, erase the food business operator registered in the Record Book from paragraph 10 of this Article, namely when it has been established that the operator has stopped meeting the conditions prescribed by the food regulations.

12) The content, form and way of keeping records and the Record Book of registered or approved facilities and the procedure of marking with a registered number or approval number are provided for by the Minister of Agriculture and Forestry, the Minister of Health, respectively.

***Temporary prohibition of business operations***  
**Article 23**

The Ministry of Agriculture and Forestry, the Ministry of Health respectively, may temporarily prohibit the performance of operations in facilities from Article 22 of this Act in the following cases:

- 1) When during inspectoral supervision it is established that the facility had been used contrary to the provisions of food regulations,
- 2) When such a procedure is crucial or effective in order to ensure the sanitary safety of food.

**The expenses for the procedure of facilities approval**

**Article 24**

- 1) For the facilities from Article 22, paragraphs 5 and 6 of this Act which are subject to the procedure of approval, the competent Minister shall establish a Professional Commission.
- 2) The expenses for the Commission's activities from paragraph 1 of this Article shall be determined by the competent Minister and covered by the applicant of the request.

**VI THE OBLIGATIONS OF THE FOOD BUSINESS OPERATORS**

**General Responsibility for Hygiene and Sanitary Safety of Food**

**Article 25**

For every harm to human health caused due to consumption of sanitary unsafe food, the food business operators in all phases of production, processing, distribution and sales shall be held responsible.

**General and Specific Conditions of Food Hygiene**

**Article 26**

- 1) The food business operators on the level of primary production must ensure systematical implementation of general and specific conditions of food hygiene determined by the Minister of Agriculture and Forestry through an enforced regulation.
- 2) The operators in the production, processing, storage and transport of food must ensure systematic implementation of general and specific conditions of food hygiene which are determined by shall mean of enforced regulations by:
  - the Minister of Health for the rest of the food.

3) The operators in retail trade must meet the general and minimal and technical conditions determined by trade regulations.

4) The operators that prepare, process or treat and refrigerate and/or store foodstuffs in retail space must ensure systematic implementation of specific hygiene conditions determined by shall mean of enforced regulations by:

- The Minister of Agriculture and Forestry for foodstuffs of predominantly animal origins;
- The Minister of Health for the rest of the foodstuffs.

5) Food business operators in catering must ensure systematic implementation of general and/or specific hygiene conditions determined by shall mean of an enforced regulation by the Minister of Health in accordance with the Minister of Tourism.

### **Responsibilities Regarding fFod Not meeting the Provided Requirements**

#### **Article 27**

1) If the food business operator is aware of or has reasonable doubt that the food he imported, produced, placed on the market or distributed does not meet the sanitary safety requirements, it shall be the obligation thereof to immediately begin the procedure of preventing the placement of such food on the market, namely the withdrawal of such food from the market in cases when the product is no longer under his immediate control and consequently inform the Ministry of Agriculture and Forestry or the Ministry of Health respectively about this matter.

2) If the food has already reached the consumer, the food business operator must effectively and accurately inform the consumers about the reasons for the withdrawal of the food and if necessary require the consumer to return the food already acquired, when other measures are not enough to achieve a high level of health safety.

3) The food business operator in retail or distributional activities which does not have direct influence on the packaging, declaration, sanitary safety of food within the frames of its activities must begin the procedure of withdrawal of food from the market which does not meet the requirements on sanitary safety when it receives a notification or a decision which orders the measures to be taken respectively on this matter.

4) The food business operator must give crucial information for tracing the food to the competent authorities.

5) The food business operator must cooperate and must not prevent another person from cooperating with the competent authorities in the measures taken in order to decrease the risk that is the result of the food that they supply or supplied the market with.

### **R equirements Regarding the Traceability of Food**

#### **Article 28**

1) The traceability must be determined on all levels of production, processing and distribution of foodstuffs, raw materials of vegetable and animal origins, food producing animals or animals used in food production, including the tracing of any other sort of material intended for incorporation or which shall be incorporated into food.

2) The food business operators must establish a system of keeping records, namely the data base and ensure the procedures, which will enable them to identify at any given moment every legal and natural person that has supplied them with food, animals producing food or that serve to produce food or any other materials intended for the production or that can be expected to be used in the production of food.

3) The food business operators must establish a data base and ensure the procedures which shall enable them to identify other food business operators to which they delivered food at any given moment.

4) The food business operators must keep the information from paragraphs 2 and 3 for three years and upon request make them available to the competent authorities.

5) The food placed on the market or most likely to be placed on the market, must be declared or identified in some other way through provided documentation or other information in order to ensure the traceability.

## Requirements Regarding the Self-Control System

### Article 29

1) The food business operators, apart from the level of primary production must establish and enforce regular control of hygienic conditions of production in every object under his control by means of enforcing of the preventive procedure of self-control, developed according to the following principles of system's analysis of danger and critical control points ( hereinafter referred to as: HACCP):

- to identify all dangers which must be prevented, eliminated or diminished to an acceptable level
- to identify the critical control points in places where control is essential for preventing or the removal of dangers or their decreasing to an acceptable level;
- to determine the critical limits on the critical control points which separate the acceptable from the unacceptable for the prevention, removal and decreasing of identified dangers;
- to determine and enforce effective procedures of systematic monitoring of critical control points;
- to determine corrective procedures when the monitoring system warns that the critical control point is not under control;
- to determine the verification procedures for the purpose of establishing the effectiveness of enforcing the measures specified in sub-paragraphs 1 to 5 of this paragraph; the verification procedures must regularly be carried out by the objects and the competent inspectors in the objects;
- to determine the documents and records suitable to the nature and scope of the work which will present an effective implementation of the measures specified in sub-paragraphs 1 to 6 of this paragraph..

2) The food business operator on the level of primary production must establish and enforce regular control of hygienic conditions of production in every object under his control by enforcing the preventive procedure of self-control, developed according to good production practices.

3) The initial harmonisation verification of the HAACP plans for objects from paragraph 1 of this Article shall be carried out by the Ministry of Agriculture and Forestry, the Ministry of Health respectively, according to the authorities determined in article 26, paragraphs 2, 4 and 5 of this Act.

4) If the results of the self-controls specified in paragraph 1 of this Article reveal the existence of health risks for people, the food does not meet the requirements provided by the requirements of sanitary safety and the food business operator must take measures according to Article 27 of this Act.

5) The conditions for the implementation of the self-control system in objects from paragraphs 1 and 2 of this Article shall be determined through enforced regulations by the

Minister of Agriculture and Forestry, the Minister of Health respectively, according to the authorities determined in Article 26, paragraphs 2 and 4 of this Act.

6) The Minister of Agriculture and Forestry, the Minister of Health respectively, can in the implemented regulations from paragraph 5 of this Article establish exceptions from the provisions from paragraph 1 of this Article for specific food business operators, especially small operators, specific categories of operators in retail and the production of traditional products under the condition that the primary level of hygiene is ensured through the implementation of the self-control procedure, developed according to good production practices.

## VII NOVEL FOODS

### The Categories of Novel Foods

#### Article 30

1) The following categories shall be considered part of the novel foods:

- food and food ingredients which contain genetically modified organisms or are composed of such ( hereinafter referred to as :GMO);
- food and food ingredients, excluding food additives (aromas and enzymes), produced from the GMO, but which do not contain any GMOs;
- food or food ingredients with new or intentionally modified primary molecular structure;
- food and food ingredients which consist of micro-organisms, fungi or algae or are isolated from them;
- food or food ingredients which consist of animals or vegetables, mineral or synthetic materials or have been derived from them, excluding food and food ingredients resulting from traditional ways of reproduction or for which it has been long for a long time that they are safe to be consummated;
- food and food ingredients which have undergone a production procedure which is no longer being used, and in cases when it causes significant changes in the system or structure of food or food ingredients which have an effect on their food value, the metabolism or the level of undesirable materials.

2) The categories of novel foods specified in paragraph 1 of this Article must not :

- present a danger for the consumer,
- mislead the consumer,
- differ from foods or food ingredients which they are intended to replace in such and extent that their normal consumption would be nutritionally disadvantageous for the consumer.

3) The provisions of this Act and special regulations shall be applied on the categories of new food from paragraph 1, sub-paragraphs 1 and 2 of this Article.

### The Marketing of Novel Foods



### Article 31

1) For the marketing of novel foods for the first time in the Republic of Croatia, the applicant must obtain an approval according to the provisions of this Act and the special regulation.

2) The approval from paragraph 1 of this Article shall be issued by the Minister of Health in accordance with the Minister of Agriculture and Forestry and based on the previously obtained scientific expert statement of the Croatian Food Agency.

3) The approval for placing the food and food ingredients on the market which contain or consist of GMO and food and food ingredients produced from GMO but not necessarily containing them, shall be issued by the Minister of Health in accordance with the Minister of Agriculture and Forestry and based on the previously obtained scientific opinion of the Croatian Food Agency..

4) The conditions and the procedure for issuing the approval set out in paragraph 1 of this Article shall be provided by the Minister of Health in accordance with the Minister of Agriculture and Forestry.

### The Record Book on Issued Approvals for Placing Novel Food on the Market

#### Article 32

1) The Ministry of Health shall keep the Record Book on the issued approvals for placing novel food on the market.

2) The content, form and way of keeping the Record Book from paragraph 1 of this Article are provided by the Minister of Health.

### The Prohibition of Novel Food Marketing

#### Article 33

1) If there are any scientific discrepancies regarding the harmful effect of novel foods on the people's health, especially food and food ingredients containing genetically modified organisms or consisting of them, the Minister of Health in accordance with the Minister of Agriculture and Forestry can temporarily prohibit the marketing of such food for the purpose of preventing or decreasing the possibility of negative influences on the health of the people.

2) The Minister of Health in accordance with the Minister of Agriculture and Forestry shall permanently prohibit the placement of new food on the market, especially food and food ingredients containing genetically modified organisms or consisting of such, if based on the scientific risk estimate it is established as harmful to the health of the people.

3) The Government of the Republic of Croatia, upon the suggestion of the Ministry of Agriculture and Forestry, the Ministry of Health or the Croatian Food Agency, may temporarily or permanently prohibit the import of novel foods containing genetically modified organisms in case of lack of the relevant scientific information and knowledge about the possible extent of the negative consequences to human life and health.

## Harmless Removal of Novel Foods

### Article 34

Novel foods, especially food and food ingredients containing genetically modified organisms or consisting of them, that do not meet the requirements of sanitary safety provided by this Act, must harmlessly be removed pursuant to a special regulation.

## VIII FOOD QUALITY

### Article 35

1) Food business operators shall be allowed to produce and place on the market foodstuffs of compulsory quality, including the foodstuffs without provided quality requirements, if the food meets the requirements of the provisions on sanitary safety and the information in the declaration.

2) The Minister of Agriculture and Forestry with a previously received expert statement from the Minister of Health shall adopt the implemented regulations which regulate food quality for the purpose of:

- protecting the interests of the consumer;
- enabling the consumers to make a selection regarding the food which they consume;

3) The implemented regulations from paragraph 2 of this Article shall establish the requirements regarding:

- the classification, categorisation and terminology of foodstuffs,
- the sensor characteristics and composition of foodstuffs,
- the sort and quality of raw materials, additives and other materials used in the production and processing of foodstuffs,
- technological procedures applied in the production and processing of foodstuffs,
- methods of sampling and analytical methods for the purpose of controlling food quality,
- additional or specific data that needs to be specified on the food declaration.

## IX THE INDICATION OF THE TRADITIONAL REPUTATION OF FOOD

### Article 36

1) Food (foodstuff) may be marked with the indication "traditional reputation", if it is produced through the use of traditional raw materials or has a traditional composition or has been produced or processed in the traditional way and it is distinguished by its special characteristics regarding other similar food from the same category.

2) Foodstuffs from paragraph 1 of this Article shall be determined with an implemented regulation by the Minister of Agriculture and Forestry.

3) The producers and processors and the Associations of Producers and/or Processors (hereinafter referred to as: Associations) shall have the right to apply for a request to receive the indication "traditional reputation", regardless of the legal form or composition of the Association,

which produce or process such food (foodstuffs). The applicants must enclose along with the request a specification for the food product.

4) The Minister of Agriculture and Forestry shall provide conditions and procedure for recognising special food (foodstuff) characteristics, the contents of the specification and establishes a Commission for issuing the "traditional reputation" indication.

### **Article 37**

1) The Ministry of Agriculture and Forestry keeps a Record Book of food products which refer to the "traditional reputation" indication.

2) The content, form and way of keeping the Record Book from paragraph 1 of this Article, is provided for by the Minister of Agriculture and Forestry.

### **Article 38**

1) The Ministry of Agriculture and Forestry shall establish an arrangement on entering items into the Record Book from Article 37 of this Act based on the request of the Association, if the compulsory conditions are met.

2) The Ministry of Agriculture and Forestry shall through an arrangement erase from the Record Book the food product established to have stopped meeting the compulsory conditions

## **X DESIGNATION OF ORIGIN AND GEOGRAPHICAL INDICATIONS OF FOOD**

### **1 Designation of Origin**

#### **Article 39**

1) A designation of origin shall be the name of a region, specific place or, in exceptional cases, the name of the country used in indicating the food (foodstuff):

- which originates from that region, the respective place or from that country, and
- whose quality and characteristics, essentially or exclusively incur under the influence of special natural and human factors of a specific geographical environment and its production, processing and preparation in its entirety take place in that geographical area.

2) By way of derogation from the provisions from paragraph 1 of this Article, the geographical indications that have a proven traditional characteristics, an exceptional reputation and are well known shall be registered as indications of authenticity, when the raw materials for the food product originate from a wider or different area from the processing area, under the condition:

- that the area of the production of raw materials is limited,
- that special conditions exist for the production of the raw materials,

3) That the raw materials from paragraph 2 of this Article shall be only live animals, meat and milk.

4) That the Minister of Agriculture and Forestry establishes those foods which may have the designation of origin with a compulsory regulation.

5) That the areas and conditions from paragraphs 1 and 2 of this Article and the methods of control are closely determined by shall mean of a compulsory regulation by the Minister of Agriculture and Forestry.

## 2 The Geographical Indication

### Article 40

1) The geographical indication shall be considered the name of the region, specific place or, in special cases, the name of the country used in indicating foods:

- Which originates from that region, the respective place or from that country and,
- which has specific quality, reputation or some other characteristic which is assigned to its geographical origins, and its production and/or processing and/or preparation takes place in that geographical area.

2) The foods that may have the geographical indication shall be determined by the Minister of Agriculture and Forestry by a compulsory regulation.

3) The areas and conditions from paragraph 1 of this Article and methods of control are closely shall be provided for by a compulsory regulation by the Minister of Agriculture and Forestry.

## 3 The Registration of Traditional Geographical and Non-geographical Terms

### Article 41

Traditional geographical or non-geographical terms used for indicating food (food products) that originate from a specific region or another specific place can be registered as indications of authenticity, if that food product meets the conditions specified in Article 39, paragraph 2 of this Act.

## 4 Terms that cannot be registered

### Article 42

1) The following cannot be registered as an indication of authenticity or a geographical indication:

- the term which does not meet the requirements provided by this Act,
- the term whose registration could due to its reputation, familiarity and length of usage mark usage be misleading to the consumers about the true identity of the food product,
- the term which is inconsistent with the term of the plant sort or animal sort which may mislead the public and the consumers about the origins of the food product concerned,
- the term which, although it refers to a specific place or specific region in which the food product was originally produced or placed on the market, has become a common term for that product (generic term).

2) When establishing if one term has become generic in the sense of the provisions of paragraph 1, sub-paragraph 4 of this Article, all factors have to be considered, especially the existing situation in the geographical area from which this term originates and the areas where this product is used.

10) During the period of protection, registered terms cannot become generic terms.

## 5 Registration Procedure

### Article 43

1) The procedure for the registration of origin designation or geographical indications shall be carried out by the Ministry of Agriculture and Forestry.

2) The procedure set out in paragraph 1 of this Article shall begin by submitting a registration application.

3) In the procedure from paragraph 1 of this Article the reimbursement of costs for the procedure shall be paid as provided by the Minister of Agriculture and Forestry.

4) A complaint cannot be filed against the arrangements and conclusions established in the procedure from paragraph 1 of this Article, however an administrative lawsuit can be filed.

5) The Ministry of Agriculture and Forestry shall establish a Commission for the registration of designation of origin and geographical indications.

### Persons Authorised for Submitting the Registration Application

#### Article 44

1) The registration application for the designation of origin or geographical indications for an individual food product may be submitted by a group of producers and/or processors of that product.

2) The term group from paragraph 1 of this Article shall include every association of producers and/or processors of a specific food product (hereinafter referred to as: Association), regardless of the legal status that Association may have.

3) An individual producer and/or processor, regardless of whether it is a legal or natural person, may submit a request from paragraph 1 of this Article only if:

- during the period that the request is submitted he is the only producer, the respective processor of the food product for which he is requesting the registration of the designation of origin or geographical indication in a specific geographical area;
- it is the only one using authentic and unchangeable local procedures;
- the geographical area has characteristics that greatly differ from the characteristics of neighbouring areas and/or if the characteristics of the product are different.

### The Contents of the rRegistration Form

#### Article 45

1) The registration form shall contain:

- a registration request for indications of authenticity or geographical indications containing, in particular: information about the applicant, including information about the Association submitting the request and about each individual producer, the respective processor who is a member of that Association, with evidence showing that the conditions have been met which are provided by this Act;
- the specification of the product.

2) Information that the request contains and the content of the specification from paragraph 1 of this Article shall be closely determined by a compulsory regulation by the Minister of Agriculture and Forestry.

## 6 The Geographical Indications and Designation of oOigin Records

### Article 46

1) The designation of origin and geographical indications shall be entered into the Register of the designation of origin and the respective Register of geographical indications kept by the Ministry of Agriculture and Forestry on the day the arrangement on the adoption of the registration request comes into effect.

2) The content, form and method of keeping the Register from paragraph 1 of this Article shall be provided for by the Minister of Agriculture and Forestry.

## 7 The Right to Use Registered Indications

### Article 47

1) All producers and processors of the food product for which the indication has been registered shall have the right to use registered designation of origin or geographical indication provided they meet the conditions specified by this Act and regulations established and based on this Act (authorised users).

2) Authorised users from paragraph 1 of this Article shall have the right to use registered indications only for indicating that product which meets the requirements of the specification from Article 45, paragraph 1, sub-paragraph 2 of this Act.

3) It shall be prohibited to use registered indications contrary to paragraphs 1 and 2 of this Article.

4) Authorised users from paragraph 1 of this Article shall be entered into the Record Book of Users of Registered Designation of Origin or into the Record Book of Users of Registered Geographical Indications kept by the Ministry of Agriculture and Forestry.

5) The procedure of entering and erasing users and the content, form and method of keeping the Record Book from paragraph 4 of this Article shall be determined by a compulsory regulation by the Minister of Agriculture and Forestry.

### Article 48

- 1) The terms registered as the designation of origin or geographical indications must not :
- be used for commercial purposes, directly or indirectly, for indicating those food products which are not included in the registration, if such products are comparable to products which are included in the registration, or if the reputation of the protected term is used through such usage;
  - misuse, imitate or use for the purpose of creating misunderstandings, even if the right origins of the food product are specified, including the usage of the protected term in the translation or accompanied by such expressions as: «style», «type», «method», «produced in», «imitation» and such;
  - be used in a way which creates misunderstandings about the origins, authenticity, sort or crucial characteristics of the food product on the outer or inner packaging, the advertising material or the documents regarding the product also on the container of the packaged products which could draw the wrong conclusion about its origins;
  - be used in any other way that could mislead the public about the true origins of the food product.

2) If the registered term contains in itself the term of the food product which is considered to be a generic term, the usage of that generic term on the appropriate food products shall not be considered to be the type of usage described in paragraph 1, sub-paragraphs 1 and 2 of this Article.

## 8 Relations Towards the Brand Names

### Article 49

The registered designation of origin or geographical indication bears no influence on the value and the usage of the brand name which was in good faith registered before the date the registration request for that indication had been filed.

## 9 International Registration

### Article 50

1) The international registration of designation of origin or geographical indications shall be carried out based on the International Agreement on the Mutual Protection of Designation of Origin and Geographical Indications, which is binding on the Republic of Croatia.

2) An unregistered term or one no longer used in the country of its origins, cannot be registered as an designation of origin or a geographical indication in the Republic of Croatia

## 10 The Civil Law Protection

### Article 51

The provisions of the Act which determines the geographical indications of the product and services shall be applied to the civil law protection of the registered indications of authenticity or geographical indications.

## XI DECLARATION OR LABELLING AND ADVERTISING OF FOOD

### General Requirements for Declaration or Labelling of Food

#### Article 52

1) The food which is placed on the market of the Republic of Croatia must have a declaration.

2) The declaration shall include all written indications, a market indication, trade mark, brand name, picture or symbol referring to the food and is placed on the packaging, a sticker or tag should be placed on the documents and all notifications that accompany or refer to that food.

3) The declaration must be written in Croatian, in Latin script, must be visible, legible and understandable.

- 4) The declaration must contain the following information:
- the name of the food under which it is sold;
  - the List of ingredients;
  - the quantity of specific ingredients or the category of the ingredients;
  - the Net quality for the packaged food;
  - the Expiry date;
  - storage conditions, where necessary, whether they can influence on the duration of the food, respectively;
  - the name and address of the producer or the person who packages the food and/or places it on the market;
  - for imported products, one must put next to the name and address of the producer, the name and address of the importer's head office and the country of origin;
  - the details about the place of origin if the absence of this information could be misleading for the consumer about the true origins of the food;
  - instructions and usage where necessary for proper handling;
  - for beverages containing more than 1,2% vol. of alcohol, and the true strength of the alcohol by the volume.

### **Food Inappropriate for the Market**

#### **Article 53**

- 1) It shall be prohibited to place on the market food which is inappropriate for the market.
- 2) Food shall be considered to be inappropriate if:
- The declaration does not have an expiry date provided for by the producers, if the expiry date is illegible or if it has run out;
  - The components of the nutritious materials in the food do not correspond with the indications on the declaration;
  - It contains approved materials or ingredients bigger or smaller quantities than those prescribed in the enforced regulations.

### **The Declaration or Labelling of Food**

#### **Article 54**

- 1) The information on the declaration and method of declaring and food labelling must not be misleading for the consumer and especially:
- regarding the food characteristics, its nature, identity, components, quantity, duration, origins, methods its of production;
  - regarding the attribution of effects and characteristics to the food that does not have them;
  - by creating misconceptions that the food has some special characteristics and that all similar food has such characteristics.
- 2) Not all food can be attributed the characteristics of preventing, healing or recovering from diseases or refer to such characteristics through declaration and methods of declaring.
- 3) Prohibitions and restrictions from paragraph 1 of this Article shall also refer to:
- the presentation of food, especially its shape, appearance or packaging, the materials used for the packaging, the method and place on which it is displayed and exhibited;
  - food advertising



## The Regulations on Food Declaration

### Article 55

1) The Minister of Agriculture and Forestry in accordance with the Minister of Health shall adopt an enforced regulation which shall provide the method of declaring or indicating, presenting and advertising and specifying the nutritional values of food.

2) The Minister of Health shall establish the enforced regulation by which he provides for the indication of food for special food requirements (diet food) in accordance with the food regulations.

3) The Minister of Agriculture and Forestry shall provide for special indications of products of animal origins pursuant to this Act and the regulations on veterinary medicine.

4) The Minister of Agriculture and Forestry, the respective Minister of Health upon establishing the regulations from paragraphs 1,2 and 3 of this Article can specify:

- that certain information regarding food be put on the declaration for packaged food or specified in some other way for food which is not packaged;
- that special information regarding food be declared in another way;
- that common meanings of terms under which the food is placed on the market are established;
- special requirements regarding the declaration or indication of only specific groups of products.

## Advertising Alcoholic Beverages

### Article 56

1) It shall be prohibited to advertise alcoholic beverages through the press, the public media, all forms of advertising in public places, objects and traffic vehicles, books, magazines, calendars and clothes, also stickers, posters and leaflets if those stickers, posters and leaflets are separated from the packaging of the alcoholic beverages.

2) By way of derogation from paragraph 1 of this Article, advertising of beer, wine and fruit wine shall be permitted in accordance with a special regulation.

3) Advertising from paragraph 1 of this Article shall be considered to be all forms of direct and indirect advertising, including the distinguishing of the name of the producer of the alcoholic beverages for advertising purposes including the distribution of alcoholic beverages for advertising purposes.

4) The provision of paragraph 1 of this Article shall not refer to professional books, magazines and other professional publications which publish information about the characteristics of alcoholic beverages if those professional publications are intended exclusively for the producers or the vendors of those products.

5) The provision of paragraph 1 of this Article shall not refer to the situation of consumer's being informed about the characteristics of alcoholic beverages in objects in which they are sold. The Minister of Health shall establish an enforced regulation by which he shall specify the conditions and methods of informing the consumers about the characteristics of alcoholic beverages which isn't considered to be advertising in the sense specified in paragraph 1 of this Article.

## The Declaration or Labelling of Novel Foods

### Article 57

1) Novel foods placed on the market of the Republic of Croatia, apart from the general declaration or indication requirements from Article 42 of this Act, must also contain on the declaration additional special information to keep the consumers informed about all the characteristics and features by which the novel food or its ingredient no longer corresponds to the existing food or food ingredient.

2) In that case the declaration must contain information about the changed characteristics or features including the method used to get that indication or characteristic.

3) The food and food ingredients containing or consisting of GMOs, must have a visible indication that it contains or consists of GMOs including the term GMO.

4) The indication must clearly state “genetically modified organisms” or contain the sentence “This product contains genetically modified organisms.”

5) The food and food ingredients originating from GMOs but not containing them must have a visible indication that they originate from GMOs.

6) The requirements regarding the declaration of novel food shall be provided for by an enforced regulation by the Minister of Health in accordance with the Minister of Agriculture and Forestry.

## **XII OFFICIAL CONTROL OF SANITARY SAFETY AND FOOD HYGIENE**

### **Official Control of Sanitary Safety and Food Hygiene**

#### **Article 58**

Official control of sanitary safety and food hygiene includes one or more of the following activities:

- inspectoral control;
- sampling and analysis;
- inspection of declarations, documentation and official records;
- inspection of records from Article 28 of this Act;
- inspection of enforcement and effectiveness of the self-control system of the object based on the inspection of the records and documentation specified in Article 29 of this Act.

#### **The Inspectoral Control**

##### ***Article 59***

1) The inspectoral control for the purpose of official control of sanitary safety and food hygiene shall be enforced by sanitary inspectors and border sanitary inspectors, the respective veterinary inspectors and border veterinary inspectors and other state officials who are authorised for this by the competent Minister.

2) The inspectoral control from paragraph 1 of this Article shall be enforced pursuant to the provisions of this Act and special regulations if they are not contrary to the provisions of this Act.

#### ***The general Principles of Inspectoral Control***

##### **Article 60**

1) The inspectoral control of sanitary safety and food hygiene from Article 59 of this Act shall be enforced:

- Regularly and in accordance with the priorities established by the risk estimate;
  - Always when there is reason to believe that the provided requirements have not been met.
- 2) Inspectoral control must be enforced by using the appropriate measures for the future goal
- 3) Inspectoral control must cover all levels of production, processing and distribution.
- 4) Inspectoral control should be enforced without being previously announced.

### ***The Contents of Inspectoral Control***

#### **Article 61**

*The following shall be subject to inspectoral control which is enforced for the purpose of official control of sanitary safety and food hygiene:*

- the position of the object- locations, condition of the object, the office, the environment, the production plants, transportation vehicles used in the food trade, especially the conditions established in Articles 22 and 26 of this Act;
- an inspection of health and hygienic state of the personnel and objects that come in direct contact with food;
- raw materials, ingredients, technological tools and other things used in the preparation and production of food;
- half-products;
- ready made food;
- cleaning and maintenance substances used in procedures that are applied in the food trade;
- procedures applied production or processing of food;
- canning methods

### **Sampling for Laboratory Analysis**

#### **Article 62**

1) For the purpose of official control of sanitary safety of food samples of raw materials, ingredients, technological tools and other materials used in the preparation and production of food, half-products, ready food, objects that come in direct contact with food including substances for cleaning and maintenance that are used in the food trade can be taken.

2) The food business operators must for the purpose of sampling enable free access to the necessary quantities of food, objects and substances from paragraph 1 of this Article.

### **XIII OFFICIAL CONTROL OF FOOD QUALITY**

#### ***Official Control of Food Quality***

#### **Article 63**

Official control of food quality shall include one or more of the following activities:

- inspectoral control;
- sampling and analysis;
- inspection of the contents of declarations, written materials and documents.

## ***The Inspectoral Control***

### **Article 64**

1) Inspectoral control for the purpose of official control of food quality shall be enforced in retail.

2) Inspectoral control from paragraph 1 of this Article shall be enforced by the sanitary, the respective veterinary inspectors depending on the authorities established in Appendix 1 of this Act.

3) The inspection of the contents of the declaration for the purpose of official control of food quality in retail shall be carried out by economic inspectors of the State Inspectorate. In exceptional cases that imply the possibility of violation of the provisions on food quality, the economic inspectors of the State Inspectorate can while inspecting the contents of the declaration also implement sampling and analysis.

4) By way of derogation from paragraph 1 of this Article, the inspectoral control for the purpose of official control of food quality with a protected geographical indication, indication of authenticity and indication of traditional reputation, including the food for which this has been provided for by a special regulation shall be implemented also in production.

5) The inspectoral control in production and retail for the purpose of official control of food quality with a protected geographical indication, indication of authenticity and an indication of traditional reputation shall be implemented by the economic inspectors of the State Inspectorate.

6) The Minister of Agriculture and Forestry can authorise legal persons for estimating the conformity of production and processing of food and products with a geographical indication, an indication of authenticity and an indication of traditional reputation.

7) The Minister of Agriculture and Forestry, in accordance with the Director of the State Bureau of Standards and Metrology shall issue an enforced regulation which determines the system of determining the conformity and the conditions which must be met by the legal persons in order to implement the procedure of estimating the conformity from paragraph 5 of this Article.

## **The General Principles of Inspectoral Control**

### **Article 65**

1) Inspectoral control for the purpose of official control of food quality shall be implemented:

- regularly;
- inspectoral control must be implemented through the use of appropriate measures for the goal.

2) Inspectoral control should be implemented without it being previously announced.

## ***The Contents of Inspectoral Control***

### **Article 66**

1) *Inspectoral control from Article 64, paragraph 2 of this Act which shall be implemented for the purpose of official control of food quality includes:*

- the verification of the information and meeting the compulsory requirements regarding the declarations or indications, including the claims on the characteristics of the food based on the written material and documents including the declaration of food;
- inspecting the components of the ready food.

2) The inspectoral control from Article 64 paragraph 3 of this Act which is being implemented for the purpose of official control of food quality includes the inspection of the declaration for the purpose of checking the general declaration requirements specified in Article 52, paragraphs 1, 3 and 4 of this Act, and as an exception the inspection of the components of ready food.

3) The inspectoral control from Article 64, paragraph 64 of this Act which is being implemented for the purpose of official control of food quality includes:

- the control of production and processing conditions when regarding food quality;
- the control of the origins of raw materials and ingredients used in the production and preparation of food;
- the control of food components;
- the control of technological procedures applied in the production and preparation of food;
- inspections of declarations, written materials, records and documents.

### **Sampling for Laboratory Analysis**

#### **Article 67**

1) For the purpose of official control of food quality in retail trade, sanitary, the respective veterinary inspectors can for laboratory purposes of analysis take food samples.

2) For the purpose of official control of food quality set out in the Article 64, paragraphs 3 and 4 of this Act, economic inspectors of the State Inspectorate can for laboratory purposes of analysis take food samples.

3) Food business operators must for the purpose of sampling enable free access to the necessary food qualities from paragraphs 1 and 2 of this Article.

## **XIV GENERAL PROVISIONS GOVERNING THE OFFICIAL FOOD CONTROL**

### **General Provisions**

#### **Article 68**

1) When the competent inspector during inspectoral control shall discovers or has reason to suspect that there has been a violation of the food provisions, he shall take all the necessary measures so that the food business operator corrects the established irregularities.

2) The owner, proprietor, the responsible person, the employee in the facility or another person that found himself in the facility that the competent inspector has entered must not:

- Keep information from the inspector or not provide the required assistance,
- Consciously give out a false statement.

3) No one must disturb the inspector in the performance of his duties.

4) No one without a written permit from the competent inspector can take any measures determined by the food regulations with the aim of correcting the established irregularities.

5) The competent inspector must implement inspectoral control according to the authorisations, duties and responsibilities given to him by this Act including the special regulations if they are not contrary to this Act.

***Authorisations of the Authorised Inspector***  
**Article 69**

The authorised inspector can:

- at any time, even when work operations are being carried out enter and object he considers to be a place where food is produced, processed, packaged or stored and conduct inspectoral control in order to establish the existence, nature and scope of any trade concerning food;
- prohibit the use of space, machines, equipment, plants and tools in the object;
- inspect any food in any object that he considers to be subject to the food provisions, take samples of food and inspect anything that he considers to be used or could be used for the production of food;
- prohibit import of unhealthy, inappropriate food and determine the procedures when dealing with such food;
- stop, search or detain a vehicle, ship or airplane that he believes to be carrying food, examine the food and take samples of the food;
- open and inspect a container or package that he believes contains food, examine the contents and take samples;
- request inspection of books, documents or other records kept in any medium that he believes contains any information that is important for implementing the provisions of this Act regarding any sort of food, make copies or take extracts from those documents;
- seize and keep the food if he believes that the provisions of this Act or the conditions of the approval issued pursuant to this Act have been violated;
- perform another activity for which he is authorised through special regulations.

**Responsibilities of the Authoprised Inspector**

**Article 70**

The authorised inspector during the process of enforcing the authorisation determined in Article 69 of this Act and upon the request of the person that those actions regard must:

- return the food which he confiscated when it is certain that it meets the requirements of the provisions of this Act;
- if the food does not meet the requirements of the provisions of this Act and if the owner or proprietor of the food agrees to have it destroyed or eliminated, determine a way of eliminating or destroying it;
- to determine the measures for harmless destruction of food/feed containing genetically modified organisms;
- if he does not receive approval from sub-paragraph 2 f this Act, after a written noticed has been delivered to the owner or proprietor, he must organise the destruction or elimination of that food.

***The responsibilities of the authorised inspector***  
**Article 71**

No information regarding the business of the food business operators which has been obtained during official controls by the authorised inspector or which refers to risk analysis must be revealed without written consent of the food business operators, except in cases when:

- it is crucial for the enforcement of this Act and when it has been approved by the Minister of Agriculture and Forestry, the respective Minister of Health;
- it is necessary in order to conduct the procedure based on a submitted report after the inspectoral control has been carried out.

## **The Annual Programme of Inspections and Reports**

### **Article 72**

1) In order to carry out inspectoral control, annual programs for enforcing official controls shall be developed which contain the following:

- the number and type of inspectoral controls that are going to be carried out;
- the number and type of objects that will be included in the inspectoral control;
- the criteria applied to the construction of the program;
- the required financial assets.

2) In order to conduct inspectoral control, annual reports on the conducted official controls shall be developed which contain the following:

- the number and type of carried out inspectoral controls;
- the number and type of objects in which the inspectoral control was carried out; information on violations and criminal offences;
- the measures taken in cases where the requirements determined and based on this Act.

3) The programs and reports from paragraphs 1 and 2 of this Act regarding official control of food safety shall be developed by the Ministry of Agriculture and Forestry and the Ministry of Health, depending on the responsibility, and are approved by the Administrative Council of the Croatian Food Agency.

4) The programs and reports from paragraphs 1 and 2 of this Act regarding the official control of food quality shall be developed by the Ministry of Health, the Ministry of Agriculture and Forestry, and the State Inspectorate and are approved by the Administrative Council of the Croatian Food Agency.

## **XV THE AUTHORISED TESTING AND REFERENCE LABORATORIES**

### ***The Authorised Testing Laboratories***

#### **Article 73**

1) Laboratory analyses of the samples from Articles 20, 62 and 67 of this Act, taken for the purpose of official food control, shall be carried out by laboratories authorised by the Minister of Agriculture and Forestry and the Minister of Health, depending on the responsibility.

2) The samples shall be taken and delivered to an authorised testing laboratory by the authorised inspector.

3) The costs of the performed analyses of food produced in the Republic of Croatia shall be covered by the competent authority and if the food does not meet compulsory requirements based on this Act and/or the information specified on the declaration, the food business operator who either produces and/or places the food on the market shall cover the costs.

4) The list of testing laboratories which states the type of laboratories and the analyses they are authorised to perform shall be published in the Official Gazette once a year.

#### **Article 74**

1) The authorised testing laboratories from Article 73, paragraph 1 of this Act can be authorised to perform the following:

- basic activities;
- specialised activities;
- specialised activities with the possibility of publishing international certificates.

2) Testing laboratories authorised to perform the basic activities must meet the conditions determined by the enforced regulations which are based on this Act and which shall be adopted by the Minister of Agriculture and Forestry, the respective Minister of Health.

3) The testing laboratories authorised to perform specialised activities must meet the conditions determined by good laboratory practice.

4) The testing laboratories authorised to perform specialised activities to issue international certificates must meet the conditions determined by the appropriate standards and must be accredited by an independent institution.

5) The Minister of Agriculture and Forestry, the respective Minister of Health can also determine special conditions that must be met by the testing laboratories from paragraph 1, subparagraphs 2 and 3 of this Article.

6) The assessment and authorisation procedure of testing laboratories from paragraph 1 of this Article shall be regulated by the Minister of Agriculture and Forestry, the respective Minister of Health through enforced regulations with the opinion of the Director of the State Bureau of Standards and Metrology. The accreditation, assessment and authorisation of testing laboratories can refer to individual analysis or groups of analyses and for individual food groups.

7) The authorised testing laboratories must participate in the appropriate programs of testing of qualification.

### **Reference Laboratories**

#### ***Article 75***

1) For each analysis performed for the purpose of official control of food safety or the quality of food, the Minister of Agriculture and Forestry, the respective Minister of Health shall authorise one laboratory as a reference laboratory for that analysis. One laboratory can be a reference laboratory for more analyses.

2) The reference laboratories must meet the conditions determined by the appropriate standards and must be accredited by an independent institution.

3) The reference laboratories from paragraph 1 of this Article shall:

- counsel the Ministry of Agriculture and Forestry and the Ministry of Health, depending on the responsibility, when authorising laboratories equipped to perform analyses for the purpose of official control;
- coordinate and offer support, including training and other services for laboratory activities concerning technical standards and methodologies of analyses which they perform;
- organise matched tests of standardised samples and participate in them on a national and international level for the purpose of monitoring the qualifications of the testing laboratories;
- make sure that the laboratories use the inner system of the work quality insurance system (including evaluation methods, keeping records, storage of reagents, the safety and routine calibration of equipment).

4) The costs of financing reference laboratories for performing the activities stated in paragraph 3 of this Article shall be covered by the Ministry of Agriculture and Forestry, the respective Ministry of Health.

5) The list of reference laboratories which specifies the analyses for which they are authorised as reference laboratories to perform, shall be published in the "Official Gazette" once a year.



**XVI CRISIS AND EMERGENCY MANAGEMENT**  
***Urgent Measures for Ensuring Food Safety***  
**Article 76**

1) When the competent Ministers from Article 16 of this Act shall establish that the food presents a serious hazard for the health of the people or the environment and that such a risk cannot be eliminated in a satisfactory way, they can depending on the gravity of the situation order one or more measures from paragraphs 3 and 4 of this Article.

2) The competent Minister can order the measures from paragraphs 3 and 4 of this Article without the accordance or opinion of another Minister, if the urgency of the situation does not allow it to be any different.

3) If the food is of domestic origins, the measures from paragraph 1 of this Article can be::

- the temporary prohibition of marketing or using the food;
- determining special conditions for the specified food;
- determining the measures for harmless elimination of the specified food;
- other, appropriate temporary measures.

4) If the food originates from import, the measures from paragraph 1 of this Article can be:

- the temporary prohibition of import of food from the exporting country or parts of the exporting country or the country of transit;
- determining special measures for the specified food from the exporting country or parts of the exporting country or the country of transit;
- determining the measures for harmless elimination of the specified food;
- other, appropriate temporary measures.

***The General Plan for Crisis Management***  
**Article 77**

1) The Croatian Food Agency in cooperation with the Ministry of Agriculture and Forestry and the Ministry of health can construct a general plan for dealing with a crisis in the field of food safety.

2) The plan from paragraph 1 of this Article, adopted by the Government of the Republic of Croatia shall determine the types of risks originating from food which can directly or indirectly be hazardous for the health of the people and which are not likely to be eliminated or reduced to an acceptable level through the application of the existing provisions of this Act or which cannot be regulated in the appropriate way through the application of the provisions from chapter XII of this Act.

3) The plan from paragraph 1 of this Article shall determine the practical procedures which are crucial when dealing with a crisis, including the organisation of a crisis unit in the competent authorities, staffing equipping it with staff through the application of the principles of transparency and determining the communication strategy between the Croatian Food Agency, the Ministry of Agriculture and Forestry, the Ministry of Health, other competent authorities of the State Directorate and institutions, the consumers and the food business operators.

**XVII FEED**

**Requirements Regarding Feed Safety**

### Article 78

- 1) It shall be prohibited to place unsafe feed on the market.
- 2) Feed shall be considered to be unsafe for usage if it is harmful for the health of the animals that produce food or are used in the production of food; therefore the food produced from these animals is considered to be unsafe for human consumption.
- 3) When the feed which does not meet the requirements of food safety is a part of a production series or consignment of the same feed, it shall be assumed that all feed in that production series or consignment is also defective, unless after laboratory analysis and super-analysis it is established to be otherwise.

### Article 79

- 1) When there are grounds for suspicion that the feed is unsafe, the Ministry of Agriculture and Forestry shall take measures of restricting the marketing of the feed, its withdrawal from the market respectively.
- 2) The Minister of Agriculture and Forestry shall adopt enforced regulations which shall determine:
  - requirements regarding feed safety;
  - hygienic conditions when dealing with feed;
  - introduction of the system of self-control and its application on the feed business operators for the purpose of ensuring the safety of the feed being placed on the market;
  - conditions regarding professional employees, space and equipment which must be met by the laboratories in order to perform analyses and super analyses of the feed;
  - prohibition or restriction of using specific raw materials in the production of feed which originate from specific sources, either according to the animal sort, origins of the meat, its nature, retrospective processing or other characteristics;
  - other conditions regarding feed considered to be crucial in order to ensure that the feed meets all the requirements of feed safety.

## The Import and Export of Feed

### Article 80

- 1) The provisions of Articles 17 and 18 of this Act shall apply to the import and export of feed in the Republic of Croatia.
- 2) The feed importer must submit a request for the examination of the food consignment he is importing to the border veterinary inspector of the Ministry of Agriculture and Forestry to determine the feed safety.
- 3) The customs office, the respective customs branch office cannot perform the procedure of clearing the feed consignment through customs until the border veterinary inspector establishes the sanitary safety of the consignment and with an arrangement approves its import.
- 4) The customs office must within its rights and duties enable the border veterinary inspector access to all documentation and undisturbed control of feed safety.
- 5) Until the end of the procedure of establishing the feed safety and before the customs procedure, the consignments can be stored in the customs warehouses.

6) The border veterinary inspector, for the purpose of verifying the safety of the feed being imported, shall have the right to take samples and have them analysed in authorised laboratories.

7) The reimbursement of costs for the examination of the consignment, the issuing of the arrangement from paragraph 3 of this Article and the costs of laboratory testing are covered by the importer.

### **The Registration into the Record Book of the Facilities**

#### **Article 81**

The provisions of the Regulations on Veterinary Medicine shall apply to the registration into the Record Book (registration and/or approval) of the facilities in which feed is produced or stored.

### **The Obligations and Responsibilities of Feed Business Operators**

#### **Article 82**

The obligations and responsibilities of feed business operators regarding:

- hygiene and food/feed safety;
- necessary procedures that need to be taken if the feed does not meet the compulsory requirements;
- introduction of the system of self-control in objects used in the feed business;
- introduction of a system that shall enable feed tracing;

shall be in accordance with commitments and responsibilities of the food business operators provided in Chapter VI of this Act.

### **Marketing Feed Consists of or Containing GMOs**

#### **Article 83**

1) When placing feed and feed ingredients that consist of or contain GMOs, the request applicant must obtain an approval that is in accordance with the provisions of this Act and a special regulation.

2) The approval from paragraph 1 of this Article shall be issued by the Ministry of Agriculture and Forestry and based on the previously obtained scientific opinion of the Croatian Food Agency.

3) The conditions and procedure for issuing the approval from paragraph 1 of this Article shall be provided for by the Minister of Agriculture and Forestry in accordance with the Minister of Environmental Protection and Physical Planning.

4) The Ministry of Agriculture and Forestry shall keep a Record Book on issued approvals for marketing feed and feed ingredients containing or consisting of GMOs.

5) The contents form and methods of keeping the Record Book from paragraph 4 of this Article shall be provided for by the Minister of Agriculture and Forestry.

6) The Government of the Republic of Croatia on the proposition of the Ministry of Agriculture and Forestry, the Ministry of Health or the Croatian Food Agency can prohibit temporary or permanent import of feed containing genetically modified organisms if there is a lack of scientific information and knowledge on the possible proportions of negative consequences on the life and health of people.

## **Harmless Elimination of Feed Containing GMOs**

### **Article 84**

Feed and feed ingredients containing or consisting of GMOs, which have been established not to meet the requirements of sanitary safety provided by this Act, must be harmlessly eliminated in accordance with the special regulations.

## **Declaration and Indication of Feed**

### **Article 85**

Feed declaration must meet the general requirements from Article 52 of this Act and the regulation adopted by the Minister of Agriculture and Forestry.

## **Declaration and Indication of Feed Containing or Consisting of GMOs**

### **Article 86**

1) Feed and feed ingredients containing or consisting of GMOs marketed in the Republic of Croatia, among the general declaration or indication requirements from Article 52 of this Act must contain on the declaration, packaging and accompanying documentation a visible indication that it contains or consists of GMOs and which GMO or its contents it contains.

2) The indication must clearly state the following” This products contains a genetically modified organism.”

3) More detailed requirements regarding feed and feed ingredients declaration containing or consisting of GMOs shall be provided for by an enforced regulation by the Minister of Agriculture and Forestry.

## **Official Feed Control**

### **Article 87**

1) Official feed safety and hygiene control shall include activities from Article 58 of this Act.

2) Inspectoral control of feed safety and hygiene control including feed additives shall be conducted by the veterinary and border veterinary inspection.

3) Inspectoral control from paragraph 2 of this Article shall be conducted in accordance with the provisions of this Act and special regulations if they are not contrary to the provisions of this Act.

4) Inspectoral control from paragraph 2 of this Article must include all levels of production, processing and distribution.

5) The provisions of Articles 60 and 61 of this Act shall be applied to both the inspectoral control and the inspectoral control contents of feed.

6) The general provisions contained in chapter XIV of this Act shall be applied to official feed control.

### **Taking Samples for Laboratory Analysis of Feed**

#### **Article 88**

1) Samples of raw materials, ingredients, technological tools and other materials used in the preparation and production of feed, ready feed, objects coming in direct contact with feed, including cleaning and maintenance substances used in the feed business can be taken in order to officially control feed safety and for the purpose of laboratory analyses.

2) The feed business operators must for the purpose of sampling, enable free access to the necessary quantities of the feed, objects and instruments from paragraph 1 of this Article.

### **Authorised Testing and Reference Laboratories**

#### **Article 89**

1) Laboratory analyses of samples from Article 88 of this Act taken for the purpose of official feed control shall be conducted by testing laboratories authorised by the Minister of Agriculture and Forestry.

2) The samples shall be taken and delivered to the authorised laboratory by the authorised inspector.

3) The costs of the performed analyses of feed produced in the Republic of Croatia shall be covered by the competent authority, if the feed does not meet the requirements provided for and based on this Act and/or the specified information on the declaration, the costs shall be covered by the feed business operator who produces and/or places it on the market.

4) The list of testing laboratories containing the type of laboratories and analyses for which they are authorised, shall be issued by the Ministry of Agriculture and Forestry in the Official Journal, once a year.

5) The provisions of Article 24 of this Act shall be applied to the authorised testing laboratories from paragraph 1 of this Article.

6) The Minister of Agriculture and Forestry shall appoint one laboratory for each analysis performed for the purpose of official feed safety control as a reference laboratory for that analysis.

7) The reference laboratories must meet the conditions determined by the appropriate standards and must be accredited by an independent institution.

8) The reference laboratories from paragraph 1 of this Article shall:

- counsel the Ministry of Agriculture and Forestry when authorising the laboratories trained to perform analyses for the purpose of official control;
- coordinate and offer support, including training and other services to the laboratory activities regarding technical standards and methodologies of analyses which they perform;
- organise matched tests of standardised samples and participate in them on a national and international level for the purpose of monitoring the qualifications of the testing laboratories;

- make sure that the laboratories use the inner system of ensuring the work quality (including evaluation methods, keeping records, storage reagents, safety and routine calibration of equipment).

9) The costs of financing reference laboratories for performing the activities specified in paragraph 8 of this Article shall be covered by the Ministry of Agriculture and Forestry.

10) The list of reference laboratories which specifies the analyses they are authorised to perform as reference laboratories shall be issued by the Ministry of Agriculture and Forestry in the Official Gazette, once a year.

## **Dealing with a Crisis and Emergencies**

### **Article 90**

The provisions of Articles 76 and 77 of this Act shall be applied to urgent measures for ensuring feed safety and the construction of a general plan for dealing with a crisis in the field of feed safety.

## **XVIII THE CROATIAN FOOD AGENCY**

### **General Provisions**

#### ***Article 91***

1) This Act hereby shall establish the Croatian Food Agency (hereinafter referred to as: the Agency). The Agency shall conduct scientific and professional business in the sense of this Act regarding feed safety and hygiene.

2) The Agency shall serve as a legal person with rights and obligations provided by this Act and the Agency Statute.

3) The head office of the Agency shall be in Zagreb.

4) The Agency shall be entered to the judicial records.

5) The Administrative Council of the Agency shall adopt a Statute in accordance with the Government of the Republic of Croatia.

6) The Agency shall report to the Government of the Republic of Croatia that exercises rights and obligations of the Republic of Croatia as its founder.

7) The Agency can, with previous authorisation of the Ministry of Agriculture and Forestry and the Ministry of Health, entrust the Croatian National Institute of Public Health and the Croatian Veterinary Institute and other legal persons with public authorities as provided for by the special regulations to perform individual official activities from its scope of activity.

8) The funds for performing the work of the Agency shall be provided from the State Budget of the Republic of Croatia.

9) The Agency shall have its own proceeds from other activities which it organises and implements within the activity.

10) The Agency shall be a non-profit legal person.

11) The means for establishing and starting up the Agency are ensured from the State Budget of the Republic of Croatia for the year 2003 in the amount of 9.000.000,00 kunas.

12) The Institutions Act shall be applied to those issues which are not regulated by this Act.

### ***Activity of the Agency***

#### **Article 92**

- 1) The activity of the Agency shall be to analyse risks regarding food/feed safety:
1. within the activities of risk assessment, the Agency shall :
    - look for, collects and analyses scientific and technical information for the purpose of distinguishing and monitoring risks that have direct or indirect influence on the hygiene and safety of food /feed and for that purpose it establishes a system of departments of the State Directorate, institutions and other legal persons that are active in the field of scientific food/feed safety;
    - in cooperation with the Croatian National Institute for Public Health and the Croatian Veterinary Institute and other authorised legal persons enforce monitoring of food/feed safety;
    - perform activities for the purpose of identifying and distinguishing the risks that appear regarding food/feed safety;
    - constructs scientific studies necessary for promoting risk assessments in the field of food/feed safety;
    - establishes unique methodologies of risk assessment on all levels of production, processing and distribution of food/feed;
  2. within the frame of risk notification, the Agency shall:
    - inform on the risks and offers professional and scientific opinions to the Ministry of Agriculture and Forestry and the Ministry of Health, the food/feed business operators, the consumers and other legal persons concerning the hazards and safety of food/feed;
    - establish a system of fast alarming and for that purpose accepts and forwards all information regarding food hazards and establishes a central information system for exchanging information;
  3. Within the frame of risk management, the Agency shall together with the Ministry of Agriculture and Forestry and the Ministry of Health coordinate those activities regarding the official control of food/feed safety and the development and formation of regulations in the field of food/feed.
- 2) Apart from performing the activities from paragraph 1 of this Article, the Agency shall also:
- develop guide books for good production practices, guide books for the application of the HACCP system and guide books for good laboratory practice;
  - offer scientific opinion regarding the nourishment of people, feed and other issues regarding the health and well-being of animals and the health of plants;
  - cooperate with international institutions and organisations that deal in issues of food and nourishment.
- 3) The Agency shall perform other activities determined by this Act, Statute and other regulations.

## **The Bodies of the Agency**

### **Article 93**

The Bodies of the Agency shall be:

- Management Board,
- Director,
- Advisory Council
- Scientific Council and scientific committees

***The Structure and Mandate of the Management Board***  
**Article 94**

1) The Management Board of the Agency shall have seven members, appointed by the Government of the Republic of Croatia upon the joint proposal of the Minister of Agriculture and Forestry and the Minister of Health.

2) The Management Board of the Agency shall consist of the Assistant Minister of the Minister of Agriculture and Forestry for the veterinary issues, the Assistant Minister of the Ministry of Agriculture and Forestry for agri-food policy issues, the Assistant Minister of the Ministry of Health for sanitary control and the representative of the Croatian Institute of Public Health, and the remaining three members of the Management Board shall be appointed by the Government of the Republic of Croatia on the basis of a public tender.

3) The mandate of the members of the Management Board shall be four years.

4) The President of the Management Board shall be elected by the members of the Board among themselves for the period of three years.

***The Tasks and the Way of Operating of the Management Board***  
**Article 95**

- 1) The Management Board of the Agency shall:
- approve and adopt, respectively, the internal regulations of the Agency and its integral parts,
  - adopt the opinion about the regulations in the food and feed area laid down by the Ministry of Agriculture and Forestry and the Ministry of Health,
  - adopt the financial regulations of the Agency that establish the procedure of the withdrawal of funds and the fulfilment of the Agency's budget from the State Budget, pursuant to the Act about the fulfilment of the State Budget of the Republic of Croatia,
  - ensure that the Agency performs its functions and exercises the tasks which are assigned to it pursuant to this Act,
  - ensure that the working programmes of the Agency be pursuant to the regulations and the policy of priorities of the Government in the area of food safety and food hygiene,
  - provide the public, , with the access to agendas, minutes and other documents from the meetings of the Management Board, including the internal regulations of the Agency, procedural regulations of the Management board and the financial regulations of the Agency, in as short a period as possible
  - adopt the Programme of activities for a maximum period of four years
  - adopt, before January 31 every year, the Program of Agency's Work for the period until December 31 of the following year,
  - adopt the General Report on the Agency's Work in the previous year, before March 30, every year.

2) The Management Board of the Agency adopts decisions by the majority of the votes of its members.

3) The Management Board of the Agency meets at the call of the President or the Director or at the joint call or request of three of their members.

**The Director**

**Article 96**



1) The director and the deputy director of the Agency shall be appointed by the Management Board of the Agency from the candidates that are nominated by the Minister of Agriculture and Forestry, with the approval of the Minister of Health, following a public tender.

2) The mandate of the director and the deputy director shall be five years.

3) The director shall manage+ the Agency's business, represent and act on behalf of the Agency, be responsible for the business and the legality of the Agency's business, submit proposals for the Agency's documents to the Management Board, with the purpose of their adoption, fulfill the decisions of the Management Board, and perform other jobs within the competence thereof, pursuant to the Law, Statute or other official acts.

#### **Advisory Council**

##### **Article 97**

1) The advisory council shall have thirteen members, including: two representatives of the competent Ministry for agriculture and food industry and for veterinary affairs, two representatives of the competent Ministry of health, one representative competent for environmental protection and eight members from the institutions, associations of consumers, chambers and associations which have interests in the area of hygiene and food safety of food and feed.

2) The members of the Advisory council from the ministries shall be appointed by the Management Board upon proposal of the competent ministers, and the other members shall be selected on the basis of a public tender.

3) The members of the Advisory council may not be the members of the Management Board,, Scientific Council or scientific committees.

4) The Advisory Council shall advise the director on conducting the Agency's business.

5) The tasks and the way of working of the Advisory Council, headed by the director of the Agency, shall be laid down by the Statute and other general official acts of the Agency.

#### **Scientific Council and Scientific Committees**

##### **Article 98**

1) The Agency shall have the Scientific Council and scientific committees, as expert bodies for determining scientific opinions within the scope of the Agency.

2) The scope and the number of the members of the Scientific Council, and the scope, number of the scientific committees with the number of its members, and the procedure and the way of working shall be laid down by the Statute and other general official acts of the Agency, pursuant to the international rules and regulations.

#### **Scientific Expert Statements**

##### **Article 99**

1) The Scientific council shall provide scientific expert statements :

- At the request of the Management Board, in relation to any issue within its competence, and in all cases for which the national legislation provides for the consultation with the Scientific Council,
- At its own initiative, about the issues within its competence.

2) The requests set out in the paragraph 1, subparagraph 1 of this Article must be accompanied by all necessary information explaining which scientific issue is addressed.

3) The Scientific Council shall issue its scientific opinion within the period which is set out in the request for the opinion, except if objective circumstances prevent it.

4) If more different requests were submitted in relation to the same issue, or if the request is not pursuant to the paragraph 2 of this Article, if it is unclear, or if the Scientific Council has already given its opinion about a particular issue and concluded that there is no new information

that should be considered, it can either refuse the request, or propose that it be amended in agreement with the director. The refusal must be explained to the Management Board.

***Remunerations and Expenses***  
***Article 100.***

The members of the Management Board, Advisory Council, Scientific council and scientific committees of the Agency shall be entitled to the remuneration for their work and the compensation for the work-related expenses, and the amount of the compensation and remuneration is established by the Government of the Republic of Croatia.

**XIX. PENAL PROVISIONS**

**Article 101**

- 1) Any legal person shall be punished by a fine of 100.000,00 to 500.000,00 kn if:
- It places novel foods on the market contrary to the Article 31 (1) of this Act,
  - Declares or labels novel foods contrary to the Article 57 of this Act,
  - Places feed on the market contrary to the Article 83 (1) of this Act,
  - Declares or labels feed contrary to the Article 86 of this Act.
- 2) For the offences set out in the paragraph 1 of this Article, the person responsible within the legal person shall be punished by a fine from 5.000,00 to 10.000,00 kn.
- 3) For the offences set out in the paragraph 1 of this Article, a physical person shall be punished by a fine of 5.000,00 to 10.000,00 kn.

**Article 102**

- 1) Any legal person shall be punished for the offence by a fine from kaznom od 50.000,00 to 100.000,00 kn, if it:
- Places food on the market contrary to the Article 11 (2) of this Act,
  - Imports food contrary to the Article 17 (1) of this Act,
  - Performs its business in an unregistered facility contrary to the Article 22 (2) of this Act,
  - Performs actions contrary to Article 27 of this Act,
  - Performs actions contrary to the Article 29 (1), (2) and (5) of this Act,
  - Places feed on the market contrary to the Article 78 (1) of this Act.
- 2) For the offences set out in the paragraph 1 of this Article, the person responsible within the legal person shall be punished by a fine from 5.000,00 to 10.000,00 kn.
- 3) For the offences set out in the paragraph 1 of this Article, a physical person shall be fined by a fine from 5.000,00 to 10.000,00 kn.

**Article 103**

- 1) A legal person shall be punished by a fine of 30.000,00 to 70.000,00 kn, if it:
- Performs the actions contrary to the Article 15 (2) of this Act,
  - Performs its activity in an unregistered facility contrary to the Article 22 (1) of this Act,
  - Performs the actions contrary to the Article 25 (1) of this Act,
  - Performs the activities contrary to the Article 28 of this Act,

- Uses the indication «traditional reputation» contrary to the Article 36 of this Act,
- Uses the geographical indications and designations of origin contrary to the Article 47 (1) and (2) of this Act,
- Performs actions contrary to the Article 48 (1) of this Act,
- Declares food contrary to the Article 52 of this Act,
- performs activities contrary to the Article 53 paragraph 1 of this Act;
- declares of labels food contrary to the Article 54 of this Act.

2) For the offences set out in the paragraph 1 of this Article, the person responsible within the legal person shall be punished by a fine from 5.000,00 to 10.000,00 kn.

3) For the offences set out in the paragraph 1 of this Article, a physical person shall be punished by a fine of 5.000,00 to 10.000,00 kn.

#### **Article 104**

Any physical person that shall act contrary to the Article 68(2), (3) and (4) of this Act shall be punished for this offence by a fine from 5.000,00 to 10.000,00 kn.

### XX. TRANSITIONAL AND FINAL PROVISIONS

#### **Article 105**

1) The Minister of Agriculture and Forestry shall, within the period of one year following the day of entering in force of this Act, adopt the regulations pursuant to:

- Article 55 (1) and (3),
- Article 79 (2),
- Article 83 (3) and (5),
- Article 85,
- Article 86 (3) of this Act

2) The Minister of Health shall, within the period of one year following the day of entering in force of this Act adopt the regulations pursuant to:

- Article 15 (3),
- Article 31 (4),
- Article 32 (2),
- Article 55. (2),
- Article 56 (6),
- Article 57 (7) of this Act

#### **Article 106**

1) The Minister of Agriculture and Forestry shall, within the period of two years following the day of entering into force of this Act, adopt the regulations pursuant to:

- Article 26 (1),
- Article 35 (2) of this Act.

2) The Minister of Health shall, in the period of two years following the day of entering into force of this Act, adopt the regulations pursuant to the Article 26 (5) of this Act.

3) The Minister of Agriculture and Forestry and the Minister of Health, respectively, shall, within the period of two years following the day of entering into force of this Act adopt the regulation pursuant to:

- Article 16,

- Article 21 (3),
- Article 22 (6) and (12),
- Article 26 (2) and (4),
- Article 29 (6) of this Act.

### **Article 107**

The Minister of Agriculture and Forestry and the Minister of Health shall, within the period of three years following the day of entering into force of this Act adopt the regulations pursuant to:

- Article 36 (4),
- Article 37 (2),
- Article 39 (5),
- Article 40 (3),
- Article 45 (2),
- Article 46 (2),
- Article 47 (5),
- Article 64 (7),
- Article 74 (2), (5), and (6) of this Act.

### **Article 108**

Implementing regulations set out in the Article 105, 106 and 107 of this Act, except for regulations set out in Article 106 (3) (3) and Article 107 (1) to (8) of this Act shall be adopted following the previous opinion of the Agency.

### **Article 109**

1) The Government of the Republic of Croatia shall appoint members of the Management Board of the Agency and the provisional director of the Agency within the term of three months following the day of entering in force of this Act.

2) The Management Board of the Agency shall be committed to adopt the Statute within the period of four months, and other general documents within the period of six months, respectively, following the day of appointment.

3) The provisional director of the Agency shall be committed to make the preparations for the commencement of the work of the Agency and to submit the application for entering the Agency into the court registrar within the period of three months following the day of appointment.

### **Article 110**

The permits for placing on the market novel foods set out in the Article 31 of this Act and feed which contains or consists of GMO, set out in the Article 83 of this Act, shall not be issued until the adoption of the implementing regulations laid down in the Article 31 (4) and Article 83 (3) and (5) of this Act..

**Article 111**

Until the adoption of implementing regulations pursuant to the Articles 105, 106 and 107 of this Act, the regulations adopted on the basis of the Act about Sanitary Safety and Sanitary Control of Foodstuffs and General Purpose Objects, ("Official Gazette" No 1/97), Veterinary Act ("Official Gazette", 70/97 and 105/01), Standardisation Act ("Official Gazette", 55/96), Cattle Breeding Act ("Official Gazette", 70/97) and the Act about the geographical indications of products and services ("Official Gazette"; 78/99)

**Article 112**

On the day of entering in force of this Act, the provisions of the Act about Sanitary Safety and Sanitary Control of Foodstuffs and General Purposes Objects, ("Official Gazette" No 1/97) shall cease to be applicable in its part referring to foodstuffs and objects that come into immediate contact with food.

**Article 113**

This Act shall enter into force on the eighth day after its publishing in "Official Journal", except for the provisions of the Article 29, Article 74 (4), and Article 75 of this Act which become applicable from the day of expiration of the term of 3 years since the day of entering in force of this Act.

**Annex 1**  
**DIVISION OF THE CONTROL COMPETENCE OF THE SANITARY AND VETERINARY**  
**INSPECTION**

V – VETERINARY INSPECTION - veterinary inspector for production and retail trade  
 - border veterinary inspector upon import

S – SANITARY INSPECTION – sanitary inspector for production and retail trade  
 - border sanitary inspector upon import

| Tariff<br>CN Code | DESCRIPTION   | PRODUCTION | RETAIL | IMPORT |
|-------------------|---|------------|--------|--------|
| 0201              | Meat of bovine animals, fresh or chilled:   | V          | V      | V      |
| 0202              | Meat of bovine animals, frozen:   | V          | V      | V      |
| 0203              | Meat of swine, fresh, chilled or frozen:  | V          | V      | V      |
| 0204              | Meat of sheep and goats, fresh, chilled or frozen:  | V          | V      | V      |
| 020500            | Meat of horses, asses, mules and hinnies, fresh, chilled or frozen:   | V          | V      | V      |
| 0206              | Edible meat offal of the following animal species: bovine animals, swine, sheep, goats, horses, donkeys, mules, hinnies fresh, chilled or frozen: | V          | V      | V      |
| 0207              | Meat and edible internal organs (offal) of the poultry of heading 0105, fresh, chilled or frozen:   | V          | V      | V      |
| 0208              | Other meat and edible meat offal, fresh, chilled or frozen:   | V          | V      | V      |
| 020900            | Pig fat, free of lean meat and poultry fat, not rendered or otherwise extracted, frozen, salted, in brine, dried or                               | V          | S      | V      |

|                           |   |                   |               |               |
|---------------------------|---|-------------------|---------------|---------------|
|                           | smoked:   |                   |               |               |
| 0210                      | Meat and edible meat offal, salted, in brine, dried or smoked; edible flour and meals of meat or meat offal:  | V                 | S             | V             |
| 0301                      | Live fish   | V                 | V             | V             |
| 0302                      | Fish, fresh or chilled, excluding fish filets and other fish meat of heading 0304   | V                 | V             | V             |
| 0303                      | Fish, frozen, excluding fish filets and other fish meat of heading 0304:  | V                 | V             | V             |
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>  | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 0304                      | Fish filets and other fish meat (whether or not ground or minced), fresh, chilled or frozen:  | V                 | V             | V             |
| 0305*                     | Fish, dried, salted or in brine; smoked fish, whether or not cooked before or during the smoking process; flours, meals and pellets of fish, fit for human consumption:   | V                 | S             | V             |
| 0306*                     | Crustaceans (crabs) whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine; crustaceans (crabs) in shell and cooked by steaming or boiling in water, whether or not chilled, dried, salted or in brine; flours, meals | V                 | S             | V             |

|       |   |   |   |   |
|-------|---|---|---|---|
|       | and pellets of crustaceans, fit for human consumption   |   |   |   |
| 0307* | Molluscs whether or not in shell, live, fresh, chilled, frozen, salted or in brine; aquatic non-vertebrates, excluding crustaceans and molluscs, live, fresh, chilled, frozen, dried, salted or in brine; flours, meals and pellets of aquatic invertebrates: | V | S | V |
| 0401  | Milk and cream, non-concentrated and without sugar or other sweeteners added:   | V | S | V |
| 0402  | Milk and cream, concentrated or with sugar and other sweeteners added:  | V | S | V |
| 0403* | Buttermilk, curdled milk and cream, yoghurt, kephir and other fermented or acidified milk and cream, whether or not concentrated, or containing added sugar or other sweetening matter, or flavoured or containing added fruit, nuts or cocoa:                | V | S | V |
| 0404  | Whey, whether or not concentrated, or containing added sugar or other sweetening matter; products which consist of natural milk constituents, whether or not containing   | V | S | V |



|                           | added sugar or other sweetening matter:, not elsewhere specified or included:  |                   |               |               |
|---------------------------|--|-------------------|---------------|---------------|
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>   | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 0405*                     | Butter and other fats and oils derived from milk; dairy spreads:   | V                 | S             | V             |
| 0406                      | Cheese and curd:   | V                 | S             | V             |
| 040700                    | Poultry and birds' eggs, in shell, fresh, preserved or cooked:   | V                 | V             | V             |
| 0408*                     | Poultry and birds' eggs, not in shell and egg yolks, fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or other sweetening matter:: | V                 | S             | S             |
| 04090000                  | Natural honey  | V                 | S             | V             |
| 04100000*                 | Edible products of animal origin, not elsewhere specified or included  | V                 | S             | V             |
| 05040000                  | Guts, bladders and stomachs of animals (other than fish), whole and pieces thereof, fresh, chilled, frozen, salted, in brine, dried or smoked  | V                 | S             | V             |
| 0701                      | Potato, fresh or chilled:  | S                 | S             | S             |
| 07020000                  | Tomato, fresh or chilled:  | S                 | S             | S             |
| 0703                      | Onion, shallot, garlic, leek and other alliaceous vegetables.  | S                 | S             | S             |

|                           |   |                   |               |               |
|---------------------------|---|-------------------|---------------|---------------|
|                           | alliaceous vegetables, fresh or chilled:  |                   |               |               |
| 0704                      | Cabbage, cauliflower, kohlrabi, kale and similar edible brassicas, fresh or chilled:  | S                 | S             | S             |
| 0705                      | Lettuce( <i>Lactuca sativa</i> ) and chicory ( <i>Cichorium spp.</i> ), fresh or chilled:   | S                 | S             | S             |
| 0706                      | Carrots, turnips, red beet, salsify, celeriac, radish and other similar edible roots, fresh or chilled:   | S                 | S             | S             |
| 070700                    | Cucumbers and gherkins, fresh or chilled  | S                 | S             | S             |
| 0708                      | Leguminous vegetables, shelled or unshelled, fresh or chilled   | S                 | S             | S             |
| 0709                      | Other vegetables, fresh or chilled:   | S                 | S             | S             |
| 0710                      | Vegetables (non-cooked or cooked in water or steamed), frozen:  | S                 | S             | S             |
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>  | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 0711                      | Provisionally preserved vegetables (e.g. with sulphur dioxide, in salted water, in sulphur water or in other preservative solutions), but unsuitable in that state for immediate consumption: | S                 | S             | S             |
| 0712                      | Dried vegetables, whole, in cuts, in wedges, broken or in powder, but still   | S                 | S             | S             |

|        |   |   |   |   |
|--------|---|---|---|---|
|        | unprepared:   |   |   |   |
| 0713   | Dried leguminous vegetables, in peas, peeled, unpeeled or broken:   | S | S | S |
| 0714   | Manioc, arrowroot, salep, Jerusalem artichokes, sweet potato or similar roots and tubers with high starch or inulin content, fresh, chilled, frozen or dried, whole or cut or in pellets; the sap of sago tree: | S | S | S |
| 0801   | Coconuts, Brazil nuts, cashew nuts, fresh or dried, peeled or unpeeled:   | S | S | S |
| 0802   | Other nuts, fresh or dried, peeled or unpeeled:   | S | S | S |
| 080300 | Bananas, including plantains, fresh or dried:   | S | S | S |
| 0804   | Dates, figs, pineapples, avocados, guavas, mangoes and mangosteens, fresh or dried:   | S | S | S |
| 0805   | Citrus fruit, fresh or dried:   | S | S | S |
| 0807   | Melons (including watermelons) and papaws (papayas), fresh:   | S | S | S |
| 0808   | Apples, pears and quinces:  | S | S | S |
| 0809   | Apricots, cherries, peaches, (including nectarines), plums and sloes, fresh:  | S | S | S |
| 0810   | Other fruit, fresh:   | S | S | S |
| 0811   | Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added   | S | S | S |

|                       |  |                   |               |               |
|-----------------------|--|-------------------|---------------|---------------|
|                       | sugar or other sweetening matter:  |                   |               |               |
| 0812                  | Fruit and nuts, provisionally preserved (for example in sulphur dioxide, in salted water, in sulphur water or other preservative solutions), but unsuitable in that state for immediate consumption: | S                 | S             | S             |
| <b>Tariff CN Code</b> | <b>DESCRIPTION</b>   | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 0813                  | Fruit, dried, except for those from tariff numbers 0801 to 0806; mixtures of nuts or dried fruit of this chapter:  | S                 | S             | S             |
| 08140000              | Peel of citrus fruits and melons (including watermelons), fresh, chilled, dried or provisionally preserved in salted water, sulphur water or other preservative solutions.-                          | S                 | S             | S             |
| 0901                  | Coffee, whether or not roasted or decaffeinated; coffee husks and skins, coffee substitutes containing coffee in any proportion  | S                 | S             | S             |
| 0902                  | Tea, whether or not flavoured  | S                 | S             | S             |
| 09030000              | Maté   | S                 | S             | S             |
| 0904                  | Pepper of the genus <i>Piper</i> ; dried or crushed or ground fruits of the genus <i>Capsicum</i> or the genus <i>Pimenta</i> :  | S                 | S             | S             |

|                           |  |                   |               |               |
|---------------------------|--|-------------------|---------------|---------------|
| 09050000                  | Vanilla  | S                 | S             | S             |
| 0906                      | Cinnamon and cinnamon-tree flowers:  | S                 | S             | S             |
| 09070000                  | Cloves (whole fruit, cloves and stems):  | S                 | S             | S             |
| 0908                      | Nutmeg, mace and cardamoms:  | S                 | S             | S             |
| 0909                      | Seeds of anis, badian, fennel, coriander, cumin or caraway; juniper berries:   | S                 | S             | S             |
| 0910                      | Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices:  | S                 | S             | S             |
| 1006                      | Rice:  | S                 | S             | S             |
| 110100                    | Wheat or meslin flour:   | S                 | S             | S             |
| 1102                      | Cereal flours, other than wheat or meslin:   | S                 | S             | S             |
| 1103                      | Cereal groats, meal and pellets:   | S                 | S             | S             |
| 1104                      | Cereal grains otherwise worked (for example, hulled, rolled, flaked, pearled, sliced or kibbled), except rice of heading 1006; germ of cereals, whole, rolled, flaked or ground: | S                 | S             | S             |
| 1105                      | Flour, meal, powder, flakes, granules and pellets of potatoes:   | S                 | S             | S             |
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>   | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 1106                      | Flour, meal and powder of the dried leguminous vegetables of heading 0713, of sago, or of roots or tubers of heading 0714 or of the products of Chapter 8:                       | S                 | S             | S             |

|           |  |   |   |   |
|-----------|--|---|---|---|
| 1107      | Malt, whether or not roasted:  | S | S | S |
| 1108      | Starches; inulin:  | S | S | S |
| 11090000  | Wheat gluten, whether or not dried:  | S | S | S |
| 120100    | Soya beans, whether or not broken:   | S | S | S |
| 1202      | Groundnuts, not roasted or otherwise cooked, whether or not shelled or broken:   | S | S | S |
| 12030000  | Copra  | S | S | S |
| 120400    | Linseed, whether or not broken:  | S | S | S |
| 1205      | Rape or colza seeds, whether or not broken::   | S | S | S |
| 120600    | Sunflower seeds, whether or not broken:  | S | S | S |
| 1207      | Other oleaginous seeds and fruits, whether or not broken:  | S | S | S |
| 1208      | Flours and meals of oil seeds or oleaginous fruits, other than those of mustard:   | S | S | S |
| 1210      | Hop cones, fresh or dried, whether or not ground, powdered or in the form of pellets; lupulin:   | S | S | S |
| 1212      | Locust beans, seaweeds and other algae, sugar beet and sugar cane, fresh, chilled, frozen or dried, whether or not ground; fruit stones and kernels and other vegetable products (including unroasted chicory roots of the variety <i>Cichorium intybus sativum</i> ): | S | S | S |
| 12130000* | Cereal straw and husks, unprepared, whether or not chopped, ground, pressed or in the form   | S | S | V |

|                           |   |                   |               |               |
|---------------------------|---|-------------------|---------------|---------------|
|                           | of pellets:   |                   |               |               |
| 1214*                     | Swedes, mangolds, fodder roots, hay, lucerne (alfalfa), clover, sainfoin, forage kale, lupines, vetches and similar forage products, whether or not in the form of pellets: | S                 | V             | V             |
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>  | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 150100                    | Pig fat (including lard) and poultry fat, other than that of heading 0209 or 1503:  | V                 | S             | V             |
| 150200                    | Fats of bovine animals, sheep or goats, other than those of heading 1503:   | V                 | S             | V             |
| 150300                    | Lard stearin, lard oil, oleostearin, oleo-oil and tallow oil, not emulsified or mixed or otherwise prepared:  | V                 | S             | V             |
| 1504                      | Fats and oils and their fractions, of fish or marine mammals, whether or not refined, but not chemically modified:  | V                 | S             | V             |
| 15060000                  | Other animal fats and oils and their fractions, whether refined or not, but not chemically modified:  | V                 | S             | V             |
| 1507                      | Soya bean oil and its fractions, whether or not refined, but not chemically modified:   | S                 | S             | S             |

|                           |   |                   |               |               |
|---------------------------|---|-------------------|---------------|---------------|
| 1508                      | Groundnut oil and its fractions, whether or not refined, but not chemically modified:   | S                 | S             | S             |
| 1509                      | Olive oil and its fractions, whether or not refined, but not chemically modified:   | S                 | S             | S             |
| 151000                    | Other oils and their fractions, obtained solely from olives, whether or not refined, but not chemically modified, including blends of these oils or fractions with oils or fractions of heading 1509: | S                 | S             | S             |
| 1511                      | Palm oil and its fractions, whether or not refined, but not chemically modified:  | S                 | S             | S             |
| 1512                      | Sunflower, safflower or cotton-seed oil and fractions thereof, whether or not refined, but not chemically modified:   | S                 | S             | S             |
| 1513                      | Coconut(copra), palm kernel or babassu oil and fraction thereof, whether or not refined, but not chemically modified:   | S                 | S             | S             |
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>  | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 1514                      | Rape, colza or mustard oil and fractions thereof, whether or not refined, but not chemically modified:  | S                 | S             | S             |



|        |  |   |   |   |
|--------|--|---|---|---|
| 1515   | Other fixed vegetable fats and oils (including jojoba oil) and their fractions, whether or not refined, but not chemically modified:                                     | S | S | S |
| 1516*  | Animal or vegetable fats and oils and their fractions, partly or wholly hydrogenated, inter-esterified, re-esterified, whether or not refined, but not further prepared: | S | S | S |
| 1517*  | Margarine, edible mixtures or preparations of vegetable or animal fat or oil of this chapter, other than edible fat or oil or their fractions of heading 1516:           | S | S | S |
| 160100 | Sausages and similar products, of meat, meat offal or blood: food preparations based on these products:  | V | S | V |
| 1602   | Other prepared or preserved meat, meat offal or blood:   | V | S | V |
| 160300 | Extracts and juices of meat, fish, crustaceans, molluscs, or other aquatic invertebrates:  | V | S | V |
| 1604*  | Prepared or preserved fish, caviar or caviar substitutes prepared from fish eggs:  | V | S | V |
| 1605   | Crustaceans (crabs), molluscs and other aquatic invertebrates, prepared or preserved:  | V | S | V |

|      |   |   |   |   |
|------|---|---|---|---|
| 1701 | Cane or beet sugar, and chemically pure sucrose, in solid form: | S | S | S |
|------|---|---|---|---|

| Tariff<br>CN Code | DESCRIPTION  | PRODUCTION | RETAIL | IMPORT |
|-------------------|--|------------|--------|--------|
| 1702              | Other sugars, including chemically pure lactose, maltose, glucose and fructose, in solid form; sugar syrups not containing added flavouring or colouring matter; artificial honey, whether or not mixed with natural honey; caramel: | S          | S      | S      |
| 1703              | Molasses resulting from the extraction or refining of sugar:   | S          | S      | S      |
| 1704              | Sugar confectionery (including white chocolate), not containing cocoa:   | S          | S      | S      |
| 18010000          | Cocoa beans, whole or broken, raw or roasted:  | S          | S      | S      |
| 1803              | Cocoa paste, whether or not defatted:  | S          | S      | S      |
| 18040000          | Cocoa butter, fat and oil:   | S          | S      | S      |
| 18050000          | Cocoa powder, not containing added sugar or  | S          | S      | S      |

|          |   |   |   |   |
|----------|---|---|---|---|
|          | other sweetening matter:  |   |   |   |
| 1806     | Chocolate and other food preparations containing cocoa:   | S | S | S |
| 1901     | Malt extract; food preparations of flour, groats, meal, starch or malt extract, not containing cocoa or containing less than 40% by weight of coca calculated on a totally defatted basis, not elsewhere specified or included: | S | S | S |
| 1902*    | Pasta, whether or not cooked or stuffed (with meat or other substances) or otherwise prepared, such as spaghetti, macaroni, noodles, lasagne, gnocchi, ravioli, cannelloni; couscous, whether or not prepared:                  | S | S | S |
| 19030000 | Tapioca and substitutes therefor prepared from starch, in the form of flakes, grains, pearls, siftings or similar forms:  | S | S | S |

| Tariff<br>CN Code | DESCRIPTION   | PRODUCTION | RETAIL | IMPORT |
|-------------------|---|------------|--------|--------|
| 1904              | Prepared foods obtained by the swelling or roasting of cereals or cereal products (for example, corn flakes); cereals (other than maize) in grain form or in the form of flakes or other worked grains (except flour, groats and meal), pre-cooked or otherwise prepared: | S          | S      | S      |
| 1905              | Bread, pastry, cakes, biscuits and other bakers' wares, whether or not containing cocoa; communion wafers, empty cachets of a kind suitable for pharmaceutical use, sealing wafers, rice paper and similar products:  | S          | S      | S      |
| 2001              | Vegetables, fruit, nuts and other edible parts of plants, prepared or preserved by vinegar or acetic acid:  | S          | S      | S      |
| 2002              | Tomatoes prepared or preserved otherwise than by vinegar or acetic acid:  | S          | S      | S      |
| 2003              | Mushrooms and truffles, prepared or preserved otherwise than by vinegar or acetic acid:   | S          | S      | S      |

|                           |   |                   |               |               |
|---------------------------|---|-------------------|---------------|---------------|
| 2004                      | Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, frozen, other than products of heading 2006:   | S                 | S             | S             |
| 2005                      | Other vegetables prepared or preserved otherwise than by vinegar or acetic acid, not frozen, other than products of heading 2006:   | S                 | S             | S             |
| 200600                    | Vegetables, fruit, nuts, fruit-peel and other parts of plants, preserved by sugar (drained, glacé or crystallised):   | S                 | S             | S             |
| 2007                      | Jams, fruit jellies, marmalades, fruit or nut purée and fruit or nut pastes, obtained by cooking, whether or not containing added sugar or other sweetening matter:                             | S                 | S             | S             |
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>  | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 2008                      | Fruit, nuts and other edible parts of plants, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included: | S                 | S             | S             |

|         |  |   |   |   |
|---------|--|---|---|---|
| 2009    | Fruit juices (including grape must) and vegetable juices, unfermented and not containing added spirit, whether or not containing added sugar or other sweetening matter:   | S | S | S |
| 2101    | Extracts, essences and concentrates, of coffee, tea or maté and preparations with a basis of these products or with a basis of coffee, tea or maté; roasted chicory and other roasted coffee substitutes, and extracts, essences and concentrates thereof: | S | S | S |
| 2102    | Yeasts (active of inactive); other single-cell micro-organisms, dead (but not including vaccines of heading 3002);   | S | S | S |
| 2103    | Sauces and preparations therefor; mixed condiments and mixed seasonings; mustard flour and meal and prepared mustard; mayonnaise:  | S | S | S |
| 2104*   | Soups and broths and preparations therefor; homogenised composite food preparations:   | S | S | S |
| 210500* | Ice cream and other edible ice whether or not containing   | V | S | S |

|                           |  |                   |               |               |
|---------------------------|--|-------------------|---------------|---------------|
|                           | cocoa:   |                   |               |               |
| 2106*                     | Food preparations not elsewhere specified or included:   | S                 | S             | S             |
| 2201                      | Waters, including natural or artificial mineral waters and aerated waters, not containing added sugar or other sweetening matter nor flavoured; ice and snow:  | S                 | S             | S             |
| 2202                      | Waters, including mineral waters and aerated waters, containing added sugar or other sweetening matter or flavoured, and other non-alcoholic beverages, not including fruit or vegetable juices of heading 2009: i | S                 | S             | S             |
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>   | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 220300                    | Beer made from malt:   | S                 | S             | S             |
| 2204                      | Wine of fresh grapes, including fortified wines; grape must other than that of heading 2009:   | S                 | S             | S             |
| 2205                      | Vermouth and other wine of fresh grapes flavoured with plants or aromatic substances:  | S                 | S             | S             |
| 220600                    | Other fermented beverages (for example, cider, perry, mead); mixtures of fermented beverages and   | S                 | S             | S             |

|        |  |   |   |   |
|--------|--|---|---|---|
|        | beverages and mixtures of fermented beverages and non-alcoholic beverages, not elsewhere specified or included:  |   |   |   |
| 2207   | Undenaturated ethyl alcohol of an alcoholic strength by volume of 80 % vol or higher; ethyl alcohol and other spirits, denaturated, of any strength:           | S | S | S |
| 2208   | Undenaturated ethyl alcohol of an alcoholic strength by volume of less than 80% vol; spirits, liqueurs and other spirituous beverages:                         | S | S | S |
| 220900 | Vinegar and substitutes for vinegar obtained from acetic acid:   | S | S | S |
| 2301   | Flours, meals and pellets of meat or meat offal, of fish or of crustaceans, molluscs or other aquatic invertebrates, unfit for human consumption; greaves:     | V | V | V |
| 2302   | Bran, sharps and other residues, whether or not in the form of pellets, derived from the sifting, milling or other working of cereals or of leguminous plants: | V | V | V |



|                           |   |                   |               |               |
|---------------------------|---|-------------------|---------------|---------------|
| 2303                      | Residues of starch manufacture and similar residues, beet-pulp, bagasse and other waste of sugar manufacture, brewing or distilling dregs and waste, whether or not in the form of pellets: | V                 | V             | V             |
| <b>Tariff<br/>CN Code</b> | <b>DESCRIPTION</b>  | <b>PRODUCTION</b> | <b>RETAIL</b> | <b>IMPORT</b> |
| 23040000                  | Oilcake and other solid residues whether or not ground or in the form of pellets, resulting from the extraction of soya-bean oil:   | V                 | V             | V             |
| 23050000                  | Oilcake and other solid residues whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil:   | V                 | V             | V             |
| 2306                      | Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of vegetable fats or oils, other than those of heading 2304 or 2305:       | V                 | V             | V             |
| 230700                    | Wine lees; argol:   | V                 | V             | V             |
| 230800                    | Vegetable materials and vegetable waste, vegetable residues and by-products, whether or not in the form of pellets, of a kind   | V                 | V             | V             |

|      |  |   |   |   |
|------|--|---|---|---|
|      | used in animal feeding, not elsewhere specified or included: |   |   |   |
| 2309 | Preparations of a kind used in animal feeding:               | V | V | V |
| 3501 | Casein, caseinates and other casein derivatives:             | V | S | V |
| 3502 | Egg and milk albumins:                                       | S | S | V |
| 3503 | Gelatin  | V | S | V |
| 3504 | Peptones and their derivatives:                              | V | S | V |

**NOTE:**

1. By the way of derogation from the distribution of the control competence of the sanitary and veterinary inspection shown in the table, in one part of retail the inspectoral control of all food in catering facilities, stationary and ambulant food kiosks and food surveillance during supplying with prepared food (catering) is carried out by the sanitary inspection.
2. Pursuant to the Article 19, paragraph 2 of this Act, the Agency shall, in cooperation with the Minister of Agriculture and Forestry and the Minister of Health, within the tariff CN Codes marked by an asterisk (\*), determine the products for which the derogations from the inspections shown in the table shall be defined.

## EXPLANATIONS EXPLAINING CERTAIN PROVISIONS OF THE FOOD ACT

### ***I. GENERAL PROVISIONS***

#### With Article 1

The provisions of the Article 1 of the Food Act provide the basis for ensuring the high level of human health and consumer interest protection in relation to food. It establishes the

common principles and efficient organizational solutions by shall mean of foundation of Croatian Food Agency. It establishes the procedures by shall mean of which it supports making decisions about the sanitary safety of food and feed.

For this reason, the present Act lays down:

- general principles and requirements concerning the hygiene and sanitary safety of food and feed,
- the obligations of the food business and feed business operators concerning the hygiene and sanitary safety of food and feed,
- general requirements relating to food quality,
- general requirements for acquiring the registration of the geographical indication and designations of origin and traditional reputation of the food,
- general requirements relating to the declaration or labelling of food and feed,
- general requirements for the marketing of food and feed,
- general provisions for the placing on the market of novel foods,
- general provisions for the placing on the market of food and feed which contains genetically modified organisms or consists of them,
- the system of official food and feed control,
- the system of authorized testing and reference laboratories,
- crisis and emergency management,
- the founding of the Croatian Food Agency.
- Authority and responsibilities of competent authorities relating to food and feed produced in the Republic of Croatia, and those imported and placed on the market in the Republic of Croatia.

#### With Article 2.

This Article lays down the scope of validity of this Act. This Act is valid for all phases of production, processing and distribution of food and feed. The provisions of this Act are not valid for the primary production, processing and storage of food on family agricultural farms intended for independent farming.

#### With Article 3.

Article 3 lays down the definition of the term foodstuff and all which is understood by it, as well as what is not included in this term. Foodstuff is, therefore, every stuff, ingredient, raw material or additive which is taken through the gastrointestinal tract, including chewing gum, beverages and all water intended for human consumption or integrated in it during its production. The animals which produce food or which are used for the production of food are considered foodstuffs, but not live animals. Besides live animals, the term foodstuff does not include animal feed, plants before harvesting or picking, medicines and medicinal products, cosmetics, tobacco and tobacco products, narcotics and psychotrope stuffs, residues and contaminants.

The definition includes every stuff which is intended to, or which can be expected to be consumed by humans. This reference to «can be expected» is given because of those stuffs which can be used not only in food industry, but also in other industries, since such stuffs are treated with equal care as foodstuffs until it becomes clear that it is not to become foodstuff (e.g. palm oil).

#### With Article 4.

The provisions of Article 4 lay down and define the terms which are used in this Act and establish their meaning.

## II GENERAL PRINCIPLES

### With Articles 5 – 7

The provisions of Articles 5 – 7 regulate the principles of the hazard analysis and lay down the foundations for the structure and mechanism relating to scientific and technical risk assessment. The hazard analysis is a process which consists of three interconnected components – risk assessment, risk management and risk notification. Risk analysis is conducted with the objective of achieving a high level of human health and life protection.

The term risk assessment includes all activities (scientific and technical) relating to the identification and characterisation of the risk and the assessment and characterisation of harmfulness and risk for human health.

This Act requires the scientific risk assessment to be conducted in an independent, objective and transparent way.

The risk management is a process by which different possibilities of acting of competent authorities concerning risk are compared, in light of the risk assessment findings, and, if necessary, the taking of preventive and control measures required for diminishing, removing and avoiding the human health risk. The measures taken must be effective, impartial and adequate.

The risk notification is the third component of the risk analysis process, in which all the phases are included. The Croatian Food Agency (hereinafter: the Agency) notifies the Ministry of Agriculture and Forestry and the Ministry of Health, state authorities which participate in risk management, food business operators and feed business operators, consumers and other competent institutions and concerned parties about the hazards or risks relating to food or animal feed respectively, as well as about the decisions made during risk management and the reasons underlying those decisions.

### With Article 8.

This Article defines the principle of precaution (carefulness) as a shall mean necessary for the competent authorities that manage risks when they must take decisions for the protection of people's health, and when there are scientific doubts after the conducted risk assessment. The principle of precaution is relevant in those special circumstances in which there are justified reasons for being concerned that there is a risk for human health, but the underlying information and data may not be sufficiently complete to enable the decision of the overall risk assessment. When they face such special circumstances, the competent authorities that manage risks may take temporary measures mandatory for people's health protection, based on the principle of precaution until they look for the clarification of scientific doubts. Such measures must be adequate and may not restrict trade more than it is necessary in order to achieve high level of human health protection. During the implementation of such measures, the care should be taken about their technical and economic feasibility.

### With Article 9

The provisions of this Article constitute the framework for greater involvement of all concerned parties and the establishment of the mechanism for increasing consumer trust. The consumer trust and the increasing of the public acceptance of the level of the health protection is achieved by the active involvement of the consumer in the process of preparation, assessment and revision of the measures for risk management and by the transparency of the

legislative. Therefore, the Agency conducts open and transparent public consultations with the objective of informing the public, directly or by shall mean of other concerned groups, unless the urgency of the matter renders it impossible. The principle of transparency represents the foundation for the inclusion of the public concerning the seriousness and extent of the risk, as well as for notifying the public about the measures taken so far or the measures to be taken for the prevention, reduction or removal of that risk.

#### With Article 10

In this Act, the consumer, besides the right to sanitary safe food, has the right to the protection of other interests. In this Article, the other rights and interests of the consumer relating to the prevention of frauds in food business, including food forgery and the right of the consumer not to be misled by specifying erroneous information on the declaration and the right to access correct information which shall enable them to choose food, are established.

### **III. GENERAL REQUIREMENTS RELATING TO THE SANITARY SAFETY OF THE FOOD**

#### With Articles 11 and 12

The provisions of these Articles define the requirements relating to food safety, and all that must be taken into consideration when deciding whether a foodstuff is unsafe.

The defined requirements relating to food safety consist of two elements: foodstuff must not be harmful for human health or unfit for consumption. In order for a foodstuff to be unsafe, only one of those elements is needed.

When considering whether a foodstuff is unsafe, the conditions in every phase of production, processing and distribution, as well as the use of the foodstuff by the consumer, and the information given to the consumer on the declaration, were taken into consideration. Moreover, the direct or indirect, short-term or long-term effects of that foodstuff on human health were also taken into consideration, as well as the effects upon future generations. Relative to the term harmfulness for human health, cumulative effects were also taken into consideration. Certain foodstuff is placed on the market for specific categories of consumers, so the concept of harmfulness for the health of those consumers is taken into consideration when making decisions whether such foodstuff is harmful for their health.

In all provisions, the foodstuff which is unfit for human consumption is defined. Such foodstuff is, for example: putrefied foodstuff, polluted by insect parts or some other exterior agent, whether or not it is harmful for human health, but nonetheless unacceptable for human consumption. It may be almost impossible to prove the harm for human health concerning such foodstuffs.

#### With Article 13

In this Article, all that is understood as foodstuff that is harmful for human health and what is meant by the foodstuff being unfit for human consumption.

#### With Article 14

In the Article 14, the competence and measures that may be taken by a competent authority if there are reasons for suspecting that the food is unsafe. The measures that a

competent authority may take are the restriction of placing such food on the market or its withdrawal from the market if other shall mean of consumer protection are not sufficient.

#### With Article 15

This Article lays down the exact way of treating the food whose validity date has expired, and was established not to be unsafe by laboratory testing. Also, the competence for the issuing of permits for further treatment of such food is established. Such food may be reused in production, sold or given away for charity. If such food is marketed, the outlet must have the note informing that it is the food whose validity date has expired and, but which is still safe. The reason for the aforementioned note is the informing of the consumer.

The provisions of this Article establish the competence for the adoption of the list concerning such food and the shall mean of submitting a request.

#### Uz clanak 16.

The provisions of Article 16 give the authority to the competent minister for the adoption of the implementing regulations relating to food safety. If the implementing regulations are adopted by the Minister of Agriculture and Forestry, the approval of the Minister of Health is mandatory and vice versa. Besides that, during the adoption of the implementing regulations, it is always mandatory to acquire the approval of the Agency.

### ***IV. IMPORTING AND EXPORTING OF FOOD***

#### Uz clanke 17. – 18.

The provisions of Articles 17 and 18 regulate general issues concerning the importing and exporting of food.

#### With Articles 19 – 21

The provisions of these Articles establish the competences of the safety control inspections as well as their authorizations and the procedure while importing food in the Republic of Croatia.

The competence is established in the Annex 1, and it gives the authority to the Food Agency to determine, jointly with the Minister of Agriculture and Forestry, the products from the marked tariff CN Code from the aforementioned Annex, and to determine the competences of the inspections which are different from those specified in the Annex 1.

### ***V. REGISTER BOOK AND THE APPROVAL OF THE FACILITIES***

#### With Article 22

The provisions of this Article establish the obligation of the entering in the Register book (registration) of the facilities which are in food business and the competences concerning the registration of the facilities. Each facility is issued a decision and assigned a registration number with the purpose of registration. Food business operators, except for those in retail trade, must ensure in an adequate way that the food they produce, process or distribute be identified by their register number. For the operators on the retail level, the obligation of keeping the records of facilities approved by the decision of the competent offices for economy in districts is established.

Moreover, the competence regarding the contents, shape and keeping the register book of the registered facilities is also established.

The objective of the provisions of this Article is to enable the improvement of traceability of the foodstuffs, and to enable the competent inspection the tracing the foodstuffs for which it is established that they do not meet the requirement of the regulations about food.

Prior to the commencement of their business activities, the food business facilities dealing with the food of animal origin are subject to approval by the competent inspection pursuant to the veterinary regulations.

#### With Articles 23 – 24

The competent authorities are given the option of provisional prohibition of running the business when they determine that the facility was used contrary to the provisions of food regulations, or when it is considered to be of paramount concern for the reason of protecting the food safety.

Furthermore, the authorization is given to the competent Ministers to determine the amount and the shall mean of payment of the fee for covering the costs of work of the expert commission that they may found with the objective of approving the facilities.

## **VI. THE OBLIGATIONS OF FOOD BUSINESS OPERATORS**

#### With Articles 25. –28.

In these Articles, the obligations of food business operators are established. The primary responsibility for the food hygiene and safety is contingent upon food business operators in all the stages from production, sale and distribution, including primary production up to and including the supply of foodstuffs to the final consumer. If the food which is placed on the market does not meet the requirements established by the food regulations, and if it causes harm to human health, the concerned food business operator is held responsible for all the material and immaterial damage done.

Furthermore, by the provisions of these Articles, the competence for adopting the implementing regulations is defined:

- about the general and specific requirements of food hygiene on all levels of production, processing, storage and distribution,
- about the specific hygienic requirements in retail trade,
- about the specific hygienic requirements in catering facilities.

The responsibility for meeting the specified requirements is contingent upon the food business operator.

Moreover, the responsibilities of the food business operators relative to the food that does not meet the provisions of this Act are also defined. The general obligation of food business operators is to ensure within its operating area that the food that is placed on the market be compliant with the safety principles. Furthermore, the general requirements of the food business operators to inform the competent authorities in order to achieve a high level of human health protection are also laid down. Besides that, food business operators are required to provide assistance and must not prevent other persons to cooperate with the competent authorities in order to achieve a high level of human health protection. When a sufficient risk for human health of some foodstuff is identified, food business operators are

required to withdraw that foodstuff from the market and to inform the final consumer about the reasons for the withdrawal.

Food business operators are required to develop a database which shall enable them to identify the producers of a foodstuff or food producing animal or which is used for food production, and to whom they have delivered their products. Such a system must enable them to identify the food origin, including every stuff that is intended for integration or may be expected to be integrated into foodstuffs. The said informations should be provided to the competent authorities, if they should require them.

#### With Article 29.

The provisions of this article define the requirements in the system of self-control, where the exemption for primary production was made. A food business operator is obliged to establish a system of self-control in the objects for food production, compliant with the principles of hazard analysis and critical control points (HACCP) These principles lay down a certain number of logical steps which should be followed, and the result of correct acting and implementing of these principles shall be a hygienic and safe food.

With the objective of better understanding and easier implementation of the self-control system, the development of the guide to good production practices and the guide to the application of the HACCP system for food business operators is to be provided for by the Food Agency.

Furthermore, in this Article the authority and competence in adopting the implementing regulations about the requirements for implementing the self-control system measures is defined, as well as the competence for the verification of the compatibility of HACCP plans.

### **VII. NOVEL FOODS**

#### With Articles 30 -34

The provisions of these Articles define what is understood under the term novel food and what it must not be. The authority of the competent bodies has been laid down, with respect to:

- conditions and process of placing novel foods on the market,
- conditions and procedures of placing foodstuffs and foodstuff ingredients, whether or not they contain GMO, on the market, as well as foodstuffs and foodstuff ingredients which have been made of GMO, but do not contain them; uvjeta i postupka izdavanja dopuštenja za stavljanje takve hrane na tržište,
- keeping the Register Book concerning issued permits
- contents, form and the way of keeping the Register Book,
- taking measures if the harmfulness of such foodstuffs to human health is established, or if there are scientific doubts concerning its harmful effect.

In the provisions of these Articles, the way of treating such foodstuffs if it is established that it does not meet the requirements for sanitary safety is laid down.

### **VIII. FOOD QUALITY**

#### With Article 35.



In this Article, a possibility is given to the responsible food business operators to produce, apart from the foodstuffs for which the quality requirements are laid down, such foodstuffs for which the quality requirements are not specific; the only condition is the sanitary safety of that food, and that it corresponds to the information given on the declaration. Furthermore, the authority is given to the Minister of Agriculture and Forestry to adopt implementing regulations about the quality of foodstuffs when it is indispensable in order to:

- protect the interests of the consumer,
- enable the consumers to choose the food they consume,
- **make order on the food market.**

Furthermore, the provisions of this Article lay down the obligation of possessing the specification for the categories of foodstuffs or specific products for which the quality requirements are not specified, do give the authority to the Minister of Agriculture and Forestry to lay down the contents of the specification in greater detail.

### ***IX. THE INDICATION OF THE TRADITIONAL REPUTATION OF THE FOOD***

With Articles 36. – 38.

The provisions of these Articles define what is meant by the food with traditional reputation and what food can bear this indication. Such food has special characteristics which set it apart from similar products, and therefore this Act provides the possibility of evaluating domestic traditional products and the ways of their production. The authority is given to the Minister of Agriculture and Forestry to lay down by implementing regulations the categories and types of food products for which it is possible to obtain the indication of traditional reputation. The right to submitting the request and acquiring the indication are granted to the associations of producers or processors that produce or process the same food product. The advertising of those products can contribute considerably to the rural economy, particularly in distant regions. In order to protect the consumer and achieve fair competition, the competent body (Ministry of Agriculture and Forestry) keeps the Register Book of all agrifood products which bear the indication of traditional reputation. Moreover, the other authorities of the competent body, with respect to the requirements and proceedings of the acceptance of special characteristics of the food and the authority with respect to the contents, form and the way of keeping the Register Book, have been laid down.

### ***X. DESIGNATIONS OF ORIGIN AND GEOGRAPHICAL INDICATION***

With Articles 39. – 40.

The provisions of these Articles, encourage the production of foodstuffs with recognizable geographical and authentic origin, in order to achieve better offer on the market. Moreover, such an approach will enable the producers of such foodstuffs to make greater profit in exchange for the honest efforts made to improve the quality, and the final consumer will be able to buy high quality products with the guarantee concerning their way of production and origin. The aim of these provisions is to protect all food that by its characteristics, way or conditions of production or processing differs from similar foodstuffs. Therefore, the provisions of these Articles define what is meant by the foodstuff that bears the geographical indication and designation of origin and what food may receive such indications. Furthermore, the authority of the competent body (Ministry of Agriculture and Forestry) with respect to such foodstuffs is also defined.

With Articles 41. – 46.

The procedure for the registration of the designation of origin and geographical indication is described in the provisions of these Articles, and the regulations for the registration of traditional names, whether geographical or not, are laid down, and the and the names which may not be registered as the designation of origin and geographical indication are also established. It is furthermore laid down that the application for registration may be submitted only by a group of producers or processors of a specific foodstuff, and the derogations from this provision. The contents of the application for registration and the authority of the Minister of Agriculture and Forestry to establish more closely by shall mean of implementing regulations the information that must be contained in the application for registration and the contents of the specification of a foodstuff. The Registrar of geographical indication and designation of origin is kept by the Ministry of Agriculture and Forestry.

With Articles 47. – 51.

The provisions of these Articles define the right to use the registered geographical indications and designations of origin and the entering of authorised users in the Register books kept by the Ministry of Agriculture and Forestry. Furthermore, with the objective of customer protection, it is forbidden to specify any information in relation to geographical indication and designation of origin which could be misleading. Therefore, these provisions define what is meant by the information that could mislead the final consumer. The relation of the registered geographical indications or designations of origin to the marks is defined, as well as the international registration of indications. It is, furthermore, laid down that the provisions of the regulation about the geographical indication of products and services are applicable to the protection of the registered geographical indications and designations of origin under civil law.

## ***XI. DECLARING OR LABELLING OF FOOD***

With Articles 52 – 55

In this part of the Act, it is defined what is meant by a declaration, what it must be like and what the obligatory information that it must contain is. These provisions are laid down with the objective of protecting the final consumer. The information that are provided to them may not be fraudulent or misleading.

Furthermore, the authority of the competent authorities for the adoption of the implementing regulations about the declaring and labelling of foodstuffs are laid down.

With Article 56

The provisions of this Article concern the prohibition of advertising alcoholic beverages, except for beer, wines and fruit wines, advertising of which is regulated by special regulations. The authority is given to the Minister of Health to adopt an implementing regulation which regulates the requirements and the way of informing the consumer about the characteristics of alcoholic beverages which are not considered advertising

With Article 57

Article 57 establishes the requirements for declaring novel foodstuffs, foodstuffs and foodstuff ingredients which contain GMO and foodstuffs and foodstuff ingredients derived from GMO, but which do not contain them. The aforementioned foodstuffs, besides general requirements for declaring and labelling, must contain other specific information, so that the consumers may be completely informed. Moreover, the provisions of these Articles require obligatory marking of such foodstuffs, and in that way provide an additional protection to consumers, giving them the possibility of choosing their food.

The authority of the Minister of Health to lay down further requirements for declaring and marking of such foodstuffs is also established.

## ***XII. OFFICIAL CONTROL OF FOOD SAFETY AND FOOD HYGIENE***

### With Articles 58 – 62

The official control is an integral part of the system of food safety and its regular implementation will contribute to the prevention of the violation of the provisions of this Act and other food regulations. Therefore, in this part of the Food Act, the activities and the authority of the competent bodies and inspections (sanitary and veterinary inspector, border sanitary and veterinary inspector and other state officials authorised by the competent Minister), which are implemented which the objective of official control of the food safety and food hygiene.

Furthermore, these provisions lay down the principles and the contents of the inspectoral control which is carried out with the objective of official control of food safety and food hygiene, and the authority of the authorised inspectors to take samples for laboratory analysis within the scope of inspectoral control.

## ***XIII. OFFICIAL CONTROL OF FOOD QUALITY***

### Uz clanke 63. – 67.

The official quality control is conducted in order to verify whether the requirements of the provisions of this Act are met, since this Act contains the provisions concerning food quality whose objective is the protection of consumers' interests. Therefore, the provisions of these Articles define the activities that are conducted with the objective of the official food quality control. Furthermore, the authority for the competence for carrying out the official control of food quality, as well as where it is carried out, is laid down.

In order to avoid double sampling by competent inspections (sanitary inspections, veterinary inspections when competent for retail trade in order to test the safety and economic inspectors of the State inspectorate in order to test the quality), which represents the costs to the food business operators, the competence of the sanitary and veterinary inspections has been laid down for the quality control in retail trade as well. Namely, by taking samples for determining the sanitary safety and by laboratory testing for the same purpose, the composition, value of the stuff and its quantity in a foodstuff are determined simultaneously, which shall mean that the quality of the foodstuff is determined and the specifications on the declaration verified. The competence of economic inspectors of the State Inspectorate for the official control of production and retailing of foodstuffs with the registered designation of origin and geographical indication, and the traditional reputation of food is laid down, and, exceptionally, for the official control of the quality of food in retail trade for which it is suspected that it does not meet the laid down quality requirements.

Furthermore, general principles and contents of the inspectoral control conducted with the objective of official food quality control are also laid down.

#### ***XIV. GENERAL PROVISIONS WHICH REGULATE THE OFFICIAL CONTROL OF FOOD***

##### With Articles 68 – 72

The protection of consumers' health and interests being the chief priority in this Food Act, it is necessary to increase the efficiency of the official control of foodstuffs. In order to achieve a more efficient official control, these provisions lay down the measures, authority and obligations of competent authorities in official control. In order to achieve an unobstructed official control, these provisions define the obligations of the food business operators with respect to official control. The provisions define the obligation of the competent authorities to communicate the annual programmes of inspections and the reports about the conducted inspections to the Food Agency which approves them and notifies the Government of the Republic of Croatia.

#### ***XV. AUTHORISED TESTING LABORATORIES AND REFERENCE LABORATORIES***

##### With Articles 73 - 75

Since taking and analysis of samples is done in order to conduct official control, it is necessary to ensure the quality of the testing results. Therefore, it is necessary to set up such a system of quality standards for laboratories in which official control is conducted. In all provisions, the requirements which must be met by testing laboratories and reference laboratories are laid down. Furthermore, in these provisions, the way of funding the costs of analysis is defined.

In addition to this, the provisions of these Articles give the authority to the Minister of Agriculture and Forestry and the Minister of Health, depending on their respective

- authorise and evaluate testing laboratories,
- determine the reference laboratory for every analysis which is conducted with the reason of official control.

These provisions also establish the tasks of reference laboratories and the way of funding thereof.

#### ***XVI. CRISIS AND EMERGENCY MANAGEMENT***

##### With Articles 76 – 77

For the domestic or imported foodstuffs that present a serious or immediate risk for human health, it is of paramount concern to act quickly and effectively in order to eliminate the said risk. Therefore, the provisions of these Articles lay down the measures, commensurate to the severity of the hazard, which may be taken in order to prevent or eliminate the risk for human health. The provisions of these Articles define the competence for the drawing up of a general plan which is drawn up for the purpose of crisis management on the area of sanitary safety of the food. The general plan lays down the types of the situations which present a risk for human health and establish the operative procedures to enable the efficient crisis management.

#### ***XVII. ANIMAL FEED***

##### With Articles 78 -90

The provisions of this Article define the requirements with respect to animal feed safety, intended for feeding food producing animals or animals that serve for food production. It is necessary to define the said requirements, due to the fact that the animal feed that serves for feeding food producing animals or that are used for food production may indirectly affect the sanitary safety of the food, intended for human consumption. The animal feed, therefore, must be sanitary safe and must not have harmful effects on animal health and in that way make the food produced from those animals unfit for human consumption.

The provisions lay down the competences and measures that can be taken by the competent authority if there are reasons for suspecting that the animal feed is unsafe.

The competent authority may take the measures of restricting or placing such animal feed on the market or its withdrawal from the market. The provisions of the Article 79 give the authority to the Minister of Agriculture and Forestry to lay down special requirements concerning safety of animal feed.

A special procedure during importing, registration and approval of facilities for production and storing of animal feed and the obligations and necessary agreements of feed business operators.

The chapter lays down the authority of the competent authority with respect to conditions and procedure of placing on the market of feed that contains genetically modified organisms or which consists of them. The competent authority keeps a Record book about the issued permits and lays down the contents, form and way of keeping the Record book. The declaring and marking of feed which contains GMO or which consists of GMO is laid down.

The competences with respect to official control of animal feed are laid down, and the general principles of inspectoral control and the contents of the inspectoral control are established pursuant to the principles and contents which relate to the official control of the food. Furthermore, the provisions lay down the system and requirements which must be met by the authorised testing laboratories and reference laboratories.

## ***XVIII. CROATIAN FOOD AGENCY***

### With Articles 91 – 95

The provisions of these articles regulate the establishment, activity and role of the Croatian Food Agency (the Agency). By the establishment of the Agency, the realisation of the basic provisions of this Act will be accomplished, which will contribute to the realisation of the high level of consumer health protection and the increase of consumers' trust. The competence thereof extends to all issues that indirectly or directly affect the safety and the health of the consumer, and are contingent upon the consumption of food. Therefore, it covers all stages from the primary food and feed production when the feed is related to the safety of the food intended for human consumption, processing and up to the distribution to the final consumer. It will secure independent scientific and technical advice which is of paramount necessity for politics and legislative in the area of food and feed safety.

Besides its central role in risk assessment, risk notification and risk management, the Agency maintains some other additional activities related to risk analysis. One of these activities is the interactive exchange of information and opinions about risk between the risk assessor (Agency) and the competent authorities which, together with the Agency, manage risks, in order to establish a unified risk assessment. The Agency is given the authority to coordinate the activities conducted by the Ministry of Agriculture and Forestry, as well as the Ministry of Health, particularly the activities related to the inspectoral control of food and feed safety. Furthermore, it is put in charge of drawing up scientific studies, which are of paramount necessity for the upgrading of risk assessment and taking the necessary steps for the

identification and characterisation of new risks. Moreover, its task is to establish the network system of all institutions that are involved in the jobs connected to food and feed safety, in order to conduct risk analysis more efficiently. Therefore, the provisions of these Articles provide for the possibility of including the existing expert knowledge and resources like the laboratories of the Croatian Institute of Public Health and Croatian Veterinary Institute, and other authorised laboratories. The Agency is given the competence for the system of quick alerting, relative to monitoring the food hazards. The Agency receives all the information forwarded through this system and analyses them, and, if necessary, provides this information to the competent authorities in the Republic of Croatia and the relevant institutions in other countries. This system will enable the competent authorities which are involved in risk management to manage crisis situations. The Agency establishes databases within its scope which act on the area of food and feed information retrieval and can delegate specific tasks to those authorities and institutions concerning the preparation of scientific opinions, scientific and technical aid, information retrieval and identification of the possibility of risk emergence.

#### With Article 96

Article 96 defines the bodies of the Agency.

#### With Articles 97 – 99

The provisions of these Articles lay down the system and the term of the Management Board and its obligations. The Management Board is a management body that will make decisions and that will be appointed by the Government. Bearing in mind that when the management personnel and the members of the Management Board are being selected, it is necessary to ensure that all institutions and groups involved in food and feed safety are included in an equal proportion, these provisions lay down the criteria which must be taken into account during the selection of those members.

#### With Article 100

The Director is the legal representative of the Agency and the provisions of this Article define the responsibility and obligations thereof. The selection of the Director and the Deputy Director is made by the Management Board.

Their term is also laid down by the provisions of this Article.

#### With Article 101

This Article lays down the way of selecting and the composition of the Advisory Committee and its role. The Advisory Council is an advisory body, composed of the representatives of the organisations and groups that have an interest on the area of food and feed safety. The Advisory Council is presided by the Director of the Agency. The function of the Advisory Council is, besides its advisory role, is to establish interactive communication and exchange of knowledge and opinions concerning risks between the Agency and all organisations or groups that have an interest on the area of food and feed safety, respectively. Furthermore, the task of the Advisory Council is to inform about any risks.

#### With Article 102

The provisions of this Article define the way and requirements of the establishment of the Scientific Council and scientific committees and to lay down their respective authorities and responsibilities in adopting and proposing scientific opinions of the Agency. Moreover, in this

Article, the authority of the Scientific council in adopting its proper regulations concerning the procedure for the preparation of scientific opinions for the area of food and feed safety, respectively.

Furthermore, the establishment of scientific committees is planned, in order to secure greater scientific coherence in related areas, as, for example, GM foodstuffs, additives, biological hazards, etc. However, when it is necessary to give an opinion about an area which is not within the competence of any scientific committee, the Scientific Council has the authority to appoint an ad hoc working group.

#### With Article 103

This Article lays down the obligations of the Scientific Council in the procedure of giving scientific opinions. Moreover, this Article lays down the conditions under which the Scientific Council may refuse the request for giving an opinion.

#### With Article 104

The provisions of this Article stipulate the obligations of the Scientific Council in case of disagreements between the scientific opinion of the Scientific Council and scientific opinions given by other bodies working on similar tasks in the Republic of Croatia or in another country. The Scientific Council is required to identify the differences in their respective opinions and reach an agreement.

#### With Article 105

This Article defines the remunerations and costs of the Management Board, Advisory Council, Scientific Council and scientific committees.

### ***XIX. PENAL PROVISIONS***

#### With Articles 106 – 109

The provisions of these articles lay down the fines for the violation of the provisions of this Act.

### ***XX. TRANSITIONAL AND FINAL PROVISIONS***

#### With Articles 110 – 113

The provisions of those articles establish the competences and terms for the adoption of implementing regulations on the basis of this Act and the obligation that the regulations concerning food safety and food hygiene be adopted following the approval of the Food Agency.

#### With Article 114

The provision of the Article establishes the term in which the government of the Republic of Croatia is to appoint the members of the Management Board and the provisional Director of the Agency, as well as the terms in which the the Management Board shall adopt the Statute and other general acts of the Agency. It also establishes the term in which the provisional

Director shall make the preparations for the commencement of the work and submit the request for the entering of the Agency into the court registrar.

With Article 115

This Article establishes the term in which the food business and feed business operators are obliged to establish the self-control systems with the objective of ensuring health and food safety.

With Article 116

This Article establishes the term from which the requirements established by this Act shall become applicable, and which must be met by testing and reference laboratories in relation to the internationally accepted norms.

With Article 117.

This Article establishes that the permits for placing on the market of novel foods and fodder, whether it contains or consists of GMO, shall not be issued until the adoption of implementing regulations pursuant to this Act.

With Article 118

This Article establishes the term until which the implementing regulations adopted pursuant to other Acts, relating to the contents of the provisions of this Act, shall remain valid.

With Article 119

This Article establishes the rules and provisions which are repealed in relation to food and feed with the entering in force of this Act.

With Article 120

This Article establishes the term of entering in force of this Act.

**With Annex 1**

Annex 1 lays down the competences of the inspections conducting safety control in production, retail and import of food and feed.