## THE CROATIAN PARLIAMENT

**1554**

Pursuant to Article 88 of the Constitution of the Republic of Croatia, I hereby issue the

## *DECISION*

## PROMULGATING THE FOOD ACT

I hereby promulgate the Food Act passed by the Croatian Parliament at its session of 20 April 2007.

Class: 011-01/07-01/36
No.: 71-05-03/1-07-2
Zagreb, 25 April 2007

The President
of the Republic of Croatia
**Stjepan Mesić**, m.p.



# FOOD ACT

CHAPTER I
**SCOPE AND DEFINITIONS**

**Aim and scope**
Article 1

(1) This Act shall regulate the basis for ensuring a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the market. This Act shall determine the basic principles and responsibilities, scientific basis, efficient organizational arrangements and procedures to underpin decision-making in matters of food and feed safety.

(2) With the purpose of achieving the aim set forth in paragraph 1 hereof, this Act shall regulate:

- scope and definitions,
- general provisions of food law,
- the Croatian Food Agency,
- rapid alert system, emergencies and crisis management,
- hygiene of food,
- hygiene of feed,
- official control,
- novel food, genetically modified food and genetically modified feed,
- food and feed quality,
- indications “Traditional Speciality Guaranteed”, of food, origin and geographical origin of food
- authorities and responsibilities of the competent authority.

(3) This Act shall apply to all stages of production, processing and distribution of food and feed, except to primary production for private domestic use or to the domestic preparation, handling and storage of food for private domestic consumption .

**Definition of food**
Article 2

(1) For the purposes of this Act, food shall mean any substance or product, processed,

partially processed or unprocessed, intended to be or which can be expected to be ingested by humans.

(2) The term food shall also include drink, chewing gum, and any other substance, including water, that is intentionally incorporated into food during its production, preparation or treatment.

(3) The term food shall include water:

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

(4) The term food shall not include:

- feed,
- live animals unless they are prepared for placing on the market as food,
- plants prior to harvesting, picking, or collecting of fruits,
- medicines and medicinal products defined by a specific regulation,
- cosmetics defined by a specific regulation,
- tobacco and tobacco products defined by a specific regulation,
- narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971, and
- residues and contaminants.

**Other definitions**

Article 3

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

1. *"food law"* means this Act, the implementing regulations adopted on the basis of this Act and other special regulations (acts and subordinate regulations) relating to food, particularly the hygiene and safety of food, and including all stages of production, processing and distribution of food and feed produced for, or fed to, food-producing animals,

2. *"food business"* means any undertaking, whether for profit or not and whether public or private, carrying out any of activities related to any stage of production, processing or distribution of food,

3. *"food business operator"* means the natural or legal person responsible for ensuring that the requirements of food law are met within the food business under his control,

4. *"feed"* means any substance or product, including feed additives, processed, partially processed or unprocessed, intended for feeding of animals,

5. *"feed business"* means any undertaking, whether for profit or not and whether public or private, carrying out any of operation of production, manufacturing, processing, storage, transport or distribution of feed, including any producer producing, processing or storing feed for feeding to animals on his own holding,

6. *"feed business operator"* means the natural or legal person responsible for ensuring that the requirements of food law are met within the feed business under his control,

7. *"retail"* means handling of food and/or processing, preparation of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food supply operations, shops, supermarket distribution centres and wholesale outlets,

8. *"placing on the market"* means holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other form of transfer themselves,

9. *"risk"* means the function of probability of an adverse health effect and severity of that effect, consequential to a hazard,

10. *"risk analysis"* means a process consisting of three interconnected components: risk assessment, risk management and risk communication,

11. *"risk assessment"* means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation,

12. *"risk management"* means the process, distinct from risk assessment, of weighing policy alternatives of the competent authority relating to risk, in cooperation with interested parties, considering risk assessment and other legitimate factors, and, if necessary, the process of selecting appropriate prevention and control measures,

13. *"risk communication"* means the interactive exchange of information and opinions throughout the risk analysis process, as regards hazards and risks, risk-related factors and risk perceptions among risk assessors, competent authority, consumers, food and feed business operators, academic community and other interested parties, including the explanation of risk assessment findings and the basis for making decisions during risk management,

14. *"hazard"* means a biological, chemical or physical agent in food and feed or condition of food and feed, with the potential to cause an adverse health effect,

15. *"traceability"* means the ability to trace and follow a food, feed, food-producing animals, or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution,

16. *"stages of production, processing and distribution"* means any stage, including import, primary production, storage, transport, sale or supply to the final consumer with food, and, where relevant, importation, production, manufacture, storage, transport, distribution, sale and supply of feed,

17. *"primary production"* means the production and rearing or growing of primary agricultural products in plant farming, agriculture stock raising or fishery, including harvesting and picking of fruits, milking and farmed animal production prior to slaughter, hunting and fishing and collecting self-grown fruits and plants,

18. *"primary products"* means the products of primary production, including products of plant farming, agriculture stock raising, fishing and hunting,

19. *"final consumer"* means a physical person buying food for fulfilling his/her own needs, and not using it at any stage of food business,

20. *"food hygiene"* means the measures and conditions necessary to control hazards and to ensure fitness of food for human consumption, taking into account its intended use,

21. *"feed hygiene"* means the measures, procedures and conditions necessary to control hazards and to ensure fitness of feed, taking into account its intended use,

22. *"establishment"* means any unit of a food business operator,

23. *"contamination"* means the presence or introduction of a hazard,

24. "*processing*" means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes,

25. *"official control"* means any form of control that the competent authority or authorities responsible for inspection perform for the verification of compliance with food and feed law, animal health and animal welfare rules,

26. *"verification"* means checking, by examination and the consideration of objective evidence, whether specified requirements have been fulfilled,

27. *"feed law"* means the laws, regulations and administrative provisions governing feed in general and feed safety in particular; it covers all stages of production, processing and distribution of feed and the use of feed,

28. *"control body"* means an independent third party to which the competent authority has delegated certain control tasks,

29. *"audit"* means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives,

30. *"inspection"* means the control of food and feed, animal health and animal welfare, in order to verify compliance with the requirements of food and feed law, animal health and animal welfare rules,

31. "*monitoring"* means conducting systematically a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with food and feed law, animal health and animal welfare rules,

32. *"surveillance"* means a systematic observation of one or more food or feed business operators or their activities,

33. *"non-compliance"* means non-compliance with food and feed law, and with animal health and animal welfare rules,

34. *"sampling for analysis"* means taking food or feed or any other substance, including from the environment, relevant to the production, processing and distribution of food or feed or to the health of animals, in order to verify through analysis compliance with food and feed law, and animal health rules,

35. *"certification"* means the procedure by which the competent authority or the control body, authorized to act in such a capacity, provides written, electronic or equivalent assurance concerning compliance,

36. *"control plan (programme)"* means a plan established by the competent authority containing general information on the structure and organization of its official control systems,

37. *"novel food"* means foods and food ingredients which have not hitherto been used for human consumption to a significant degree, which are not a result of genetic modification, and which, with its composition, characteristics and effect, can have influence on the selection of food and/or on human health,

38. *"genetically modified organism"* (hereinafter: GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination,

39. *"genetically modified food"* (hereinafter: GM food) means food containing, consisting of or produced from GMOs,

40. *"genetically modified feed"* (hereinafter: GM feed) means feed containing, consisting of or produced from GMOs,

41. *"introduction"* means a physical introduction of consignments into the territory of the Republic of Croatia for the purpose of import, transfer or storage in duty free zones, free warehouses, customs warehouses or by registered ship chandlers,

42. *"competent authority"* means the Ministry of Agriculture, Forestry and Water Management which is the central state administrative authority responsible for the safety, hygiene and quality of food and feed and for the organization of official controls, and which is a contact point to the European Commission,

43. *"head of the competent authority"* means the Minister of Agriculture, Forestry and Water Management,

44. *"bodies competent for performing inspections"* means the Ministry of Agriculture, Forestry and Water Management, the ministry competent for health and the State Inspector's Office.

## CHAPTER II
## GENERAL PROVISIONS OF FOOD LAW

### Scope
Article 4

(1) This Chapter of this Act relates to all stages of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.

(2) The principles laid down in Articles 5 to 10 hereof shall form a general framework of a horizontal nature to be followed when measures are taken.

## SECTION 1
## GENERAL PRINCIPLES OF FOOD LAW

### General objectives
Article 5

(1) Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair

practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

(2) Food law shall aim to achieve the free movement of food and feed manufactured or marketed according to the general principles and requirements referred to in Chapter II hereof.

(3) Where international standards exist or their completion is imminent, they shall be taken into consideration in the development and implementation of food law, except where such standards or their relevant parts would be an ineffective or inappropriate means for the fulfilment of the objectives of food law, or where there is a scientific justification, or where they would result in a different level of protection from the one determined by food law.

**Risk analysis**

Article 6

(1) In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

(2) Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

(3) Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Croatian Food Agency (hereinafter: Agency), other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7, paragraph 1 hereof are relevant, in order to achieve the general objectives of food law established in Article 5 hereof.

**Precautionary principle**

Article 7

(1) In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the highest level of health protection shall be adopted, pending further scientific information for a more comprehensive risk assessment.

(2) Measures adopted pursuant to paragraph 1 of this Article shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures taken shall be reviewed within a reasonable period of time, depending on the nature of the risk to life and health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

**Protection of consumers' interests**

Article 8

(1) Food law shall aim at the protection of consumers' interests and shall provide a basis for consumers to be fully informed on the foods they consume thus enabling them to make choices in relation to the foods.

(2) Food law shall aim at the prevention of:

(a) fraudulent or deceptive practices,

(b) the adulteration of food; and

(c) any other practices which may mislead the consumer.

SECTION 2

**PRINCIPLES OF TRANSPARENCY**

**Public consultation**

Article 9

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

**Public information**

Article 10

(1) Without prejudice to the applicable provisions of special law on the right of access to information, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, the competent authority shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

(2) With a view of taking steps referred to in paragraph 1 of this Article, persons authorized to perform official controls, control bodies and the Agency shall, within their competence, inform the competent authority on the emergence of the risk.

SECTION 3

**GENERAL OBLIGATIONS OF FOOD TRADE**

**Import of food and feed**

Article 11

Food and feed imported into the Republic of Croatia for placing on the market shall comply with the relevant requirements of food law or conditions recognised by the Republic of Croatia to be at least equivalent thereto or, where a specific international agreement exists between the Republic of Croatia and the exporting country, with the requirements contained therein.

**Export of food and feed**

Article 12

(1) Food and feed exported or re-exported from the Republic of Croatia shall comply with the relevant requirements of food law, unless otherwise requested by the competent authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

(2) By way of derogation from paragraph 1 of this Article, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Republic of Croatia.

(3) By way of derogation from paragraph 1 of this Article, where the provisions of an international agreement concluded between the Republic of Croatia and an importing country are applicable, food and feed exported from the Republic of Croatia to that country shall comply with the provisions contained in the international agreement.

**International standards**

Article 13

Without prejudice to its rights and obligations, the Republic of Croatia shall:

(a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards,

(b) promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organisations,

(c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures,

(d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries,

(e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Republic of Croatia is not reduced.

SECTION 4

## GENERAL REQUIREMENTS OF FOOD LAW

### Food safety requirements

Article 14

(1) Food shall not be placed on the market if it is unsafe.

(2) Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health,

(b) unfit for human consumption.

(3) In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(b) to the information provided to the consumer, including information on the label and other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

(4) In determining whether any food is injurious to human health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations,

(b) to the probable cumulative toxic effects,

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

(5) In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

(6) Where any food which is unsafe is part of a batch, lot or consignment of food of the same class and description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

(7) Food that complies with specific provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific provisions are concerned.

(8) Conformity of a food with specific provisions applicable to that food shall not bar the competent authority from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

(9) Where there are no specific provisions, food shall be deemed to be safe when it conforms to the provisions of food law.

### Authority for the adoption of implementing food regulations

Article 15

(1) With implementing regulations, the head of the competent authority shall regulate the following:

- natural mineral, natural spring and table waters,
- types and quantities of residues of veterinary medicines and veterinary medicinal products and other harmful substances that can be present in foodstuffs,
- monitoring of residues of pesticides in food and feed.

(2) With implementing regulations, the minister competent for health, with the consent of the head of the competent authority, shall regulate the following:

- safety of articles and materials coming into direct contact with foodstuffs,

- safety of potable water,
- contaminants in food, except pesticides,
- food additives,
- flavourings,
- processing aids (including solvents),
- enzymes,
- food supplement,
- food for particular nutritional needs,
- food for infants and small children,
- process cereal based food for infants and small children,
- food for weight reduction,
- food for special medicinal purposes,
- gluten-free food,
- food enriched with nutrients (addition of vitamins, minerals and other substances to food),
- quick-frozen foodstuffs,
- food treated with ionising radiation,
- food monitoring with a view to determining the level of nutrients, contaminants, except pesticides, additives and other food ingredients,
- nutrition and health claims indicated on food labels.

**Feed safety requirements**

Article 16

(1) Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

(2) Feed shall be deemed to be unsafe for its intended use if it is considered to:

- have an adverse effect on human or animal health;
- make the food derived from food-producing animals unsafe for human consumption.

(3) Where a feed which has been identified as not satisfying the feed safety requirements is part of a batch, lot or consignment of feed of the same class and description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirements.

(4) Feed that complies with specific provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific provisions are concerned.

(5) Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authority from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

(6) Where there are no specific provisions, feed shall be deemed to be safe when it conforms to the provisions of law governing feed safety.

**Presentation of food and feed**

Article 17

(1) Food and feed placed on the market of the Republic of Croatia shall be labelled, advertised and presented in accordance with the implementing regulations brought pursuant to this Act and other food law.

(2) The labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

(3) The head of the competent authority shall bring the implementing regulations stipulating the labelling, advertising and presentation of food and the nutritional labelling of food.

(4) The head of the competent authority shall bring the implementing regulations

stipulating the labelling, advertising and presentation of feed.

**Advertising alcoholic beverages**

Article 18

(1) It shall be prohibited to advertise alcoholic beverages through the press, the public media, the internet and 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 alcoholic beverages.

(2) By way of derogation from paragraph 1 of this Article, advertising of wine and fruit wine shall be permitted in accordance with specific regulations.

(3) By way of derogation from paragraph 1 of this Article, advertising of beer shall be permitted in accordance with an implementing regulation brought by the minister responsible for health with the consent of the head of the competent authority.

(4) 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 a producer of alcoholic beverages for advertising purposes and the distribution of alcoholic beverages for advertising purposes.

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

(6) 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 the facilities in which they are sold.

(7) The minister responsible for health, with the consent of the head of the competent authority, shall establish an implementing regulation specifying the conditions of and manner for informing consumers about the characteristics of alcoholic beverages, which is not considered to be advertising in the sense specified in paragraph 1 of this Article.

**Responsibilities**

Article 19

(1) Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

(2) The competent authority, the ministry responsible for health and the State Inspector's Office shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, a system of official controls shall be established and other activities as appropriate to the circumstances, including public communication on food and feed safety and risks, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Food law shall also lay down the rules on measures and penalties applicable to infringements of its provisions which shall be effective, proportionate and dissuasive.

**Traceability**

Article 20

(1) The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

(2) Food and feed business operators shall be able to identify any physical or legal person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authority on demand.

(3) Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authority on demand.

(4) Food or feed which is placed on the market or is likely to be placed on the market shall be adequately labelled or otherwise identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of food law or other specific provisions.

(5) The head of the competent authority shall regulate the requirements for ensuring the traceability as referred to in this Article with an implementing regulation.

**Responsibilities for food: food business operators**

Article 21

(1) If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and shall inform the competent authority thereof. Where the food may have reached the consumer, the food business operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers foods already supplied to them when other measures are not sufficient to achieve a high level of health protection.

(2) A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authority.

(3) A food business operator shall immediately inform the competent authority if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Food business operators shall inform the competent authority of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with food law and legal practice, with the competent authority, where this may prevent, reduce or eliminate a risk arising from a food.

(4) Food business operators shall collaborate with the competent authority on action taken to avoid or reduce risks posed by a food which they supply or have supplied to the market.

**Responsibilities for feed: feed business operators**

Article 22

(1) If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authority thereof. In these circumstances or, in the case of Article 16, paragraph 3 hereof, where the batch, lot or consignment does not satisfy the feed safety requirements, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The feed business operator shall effectively and accurately inform owners and/or possessors of animals using the feed, or other feed business operators of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

(2) A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in

the action taken by producers, processors, manufacturers of feed and/or the competent authority.

(3) A feed business operator shall immediately inform the competent authority if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. A feed business operator shall inform the competent authority of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with food law and legal practice, with the competent authority, where this may prevent, reduce or eliminate a risk arising from a feed.

(4) Feed business operators shall collaborate with the competent authority on action taken in order to avoid or reduce risks posed by a feed which they supply or have supplied to the market.

**Liability**

Article 23

The provisions of Chapter II shall be without prejudice to the provisions of special regulations concerning liability for defective products.

## CHAPTER III
## THE CROATIAN FOOD AGENCY

### SECTION 1
### GENERAL PROVISIONS

**Legal status**

Article 24

(1) The Agency shall conduct scientific and professional activities of risk assessment and communication on the results of risk assessment, in the sense of this Act, regarding the safety and hygiene of food and feed.

(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 Osijek.

(4) The Agency shall be entered into the judicial records.

(5) The Management Board of the Agency shall adopt a Statute in accordance with the Government of the Republic of Croatia.

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

(7) The Agency may, with previous consent of the competent authority, entrust legal persons with public authorities to perform particular professional activities from its scope of activity.

(8) The Agency is a budget beneficiary of the State Budget, and the funds for performing the activities of the Agency shall be provided from the State Budget of the Republic of Croatia within the competent authority.

(9) The Agency may, in addition to the proceeds provided for in paragraph 8 of this Article, have its own proceeds from other activities which it organises and implements within the its scope of activities.

(10) The Institutions Act and the Budget Act shall be applied to those issues which are not regulated by this Act.

### SECTION 2
### MISSION AND TASKS

**Mission of the Agency**

Article 25

(1) The Agency's mission shall include providing scientific advice and scientific and technical support for the legislation and issues in all fields which have a direct or indirect impact on food and feed safety. The Agency shall provide independent information on all matters within these fields and communicate on risks.

(2) With its mission, the Agency shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health, the environment, and the operation of the market.

(3) The Agency shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.

(4) The mission of the Agency shall also include the provision of:

(a) scientific advice and scientific and technical support on human nutrition, including food quality, in relation to the legislation of the Republic of Croatia and, at the request of the competent authority, assistance concerning communication on nutritional issues within the framework of the health programme of the Republic of Croatia,

(b) scientific opinions on other matters relating to animal health and welfare and plant health,

(c) scientific opinions on products other than food and feed relating to genetically modified organisms and without prejudice to the procedures established by special regulations.

(5) The Agency shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of measures of the Republic of Croatia pursuant to the provisions of this Act in the fields falling within its mission.

(6) The Agency shall carry out its tasks in an independent, transparent and diligent way, ensuring the scientific and technical quality of the opinions it issues and the information it disseminates in conditions which enable it to serve as a point of reference in risk assessment and communication on the results of risk assessment. The Agency shall act in close cooperation with institutes, institutions, academic community, laboratories and other legal persons engaged in the food and feed safety system in the Republic of Croatia, carrying out similar tasks to these of the Agency.

(7) The Agency and the competent authority shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.

(8) The institutions referred to in paragraph 6 of this Article shall cooperate with the Agency to ensure the accomplishment of its mission.

(9) The Agency shall cooperate with international institutions and organizations within the scope of its mission.

**Tasks of the Agency**

Article 26

The tasks of the Agency shall be the following:

(a) to provide the competent authority with the best possible scientific opinions in all cases provided for by this Act,

(b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission,

(c) to provide scientific and technical support to the competent authority in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions,

(d) to commission scientific studies necessary for the accomplishment of its mission,

(e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission,

(f) to undertake action to identify and characterise risks, in the fields within its mission,

(g) to establish a system of networks of institutions referred to in Article 25, paragraph 6 hereof and be responsible for the operation of the networks,

(h) to provide scientific and technical assistance, when requested to do so by the competent authority, in the crisis management procedures implemented by the competent authority with regard to the safety of food and feed,

(i) to provide scientific and technical assistance in the fields within its mission, when requested to do so by the competent authority, with a view to improving cooperation between the Republic of Croatia and the European Union, international organisations and other countries,

(j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission,

(k) to express independently its own conclusions and orientations on matters within its mission,

(l) to undertake any other task assigned to it by the competent authority within its mission.

SECTION 3
**ORGANISATION**

**Bodies of the Agency**
Article 27

The bodies of the Agency shall be:

(a) a Management Board,

(b) an Executive Director,

(c) an Advisory Forum,

(d) a Scientific Committee and Scientific Panels.

**Management Board**
Article 28

(1) The Management Board of the Agency shall be composed of nine members appointed by the Government of the Republic of Croatia at the proposal of the head of the competent authority.

(2) The Management Board shall be composed of two representatives of the competent authority, two representatives of the ministry responsible for health, two representatives of the institutions referred to in Article 25, paragraph 6 hereof, and three representatives of consumers' associations and other interested parties in the food chain.

(3) The members of the Management Board shall be appointed in such a way as to secure the highest standards of competence and the relevant experience, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution.

(4) The term of office of the Management Board members shall be four years, and may be renewed once.

(5) The Management Board shall elect one of its members as its Chair for a two-year period, which may be renewed once.

**Tasks and way of work of the Management Board**
Article 29

(1) The Management Board of the Agency shall approve and adopt the Agency's internal rules at the proposal of the Executive Director which shall be made public.

(2) The Management Board shall adopt its rules of procedure. Unless otherwise provided by the rules of procedure, the Management Board shall act by a majority of its members.

(3) The Management Board shall meet at the invitation of the Chair or at the request of at least four of its members.

(4) The Management Board shall ensure that the Agency carries out its mission and performs the tasks assigned to it under the conditions laid down in this Act.

(5) Before 31 January each year, the Management Board shall adopt the Agency's programme of work for the coming year. The Management Board shall also adopt a revisable multi-annual programme of work for the maximum of four years. The Management Board shall ensure that these programmes are consistent with the legislative and policy priorities of the Republic of Croatia in the area of food safety. Before 30 March each year, the

Management Board shall adopt the general report on the Agency's activities for the previous year.

(6) The Management Board shall adopt the Agency's financial regulation which specifies in particular the procedure for drawing up and implementing the Agency's financial budget from the State Budget, in accordance with the Act on Execution of the State Budget of the Republic of Croatia.

(7) The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the technical and professional support to its work. The Management Board shall invite the Chair of the Scientific Committee to attend its meetings without voting rights.

**Executive Director**

Article 30

(1) The Executive Director and the Deputy Director of the Agency shall be appointed by the Management Board of the Agency on the basis of a list of candidates proposed by the head of the competent authority after an open competition.

(2) The term of office of the Executive Director and the Deputy Director shall be five years, and may be renewed.

(3) The Executive 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 internal rules to the Management Board with a view of their adoption, fulfil the decisions of the Management Board, and perform other activities within the competence thereof, pursuant to the law, Statute and other Agency's internal rules.

**Advisory Forum**

Article 31

(1) The Advisory Forum shall advise the Executive Director in the performance of the Agency's duties under this Act, in particular in drawing up a proposal for the Agency's work programme.

(2) The Advisory Forum shall be composed of thirteen members: two representatives of the competent authority, two representatives of the ministry responsible for health, one representative of the ministry responsible for environmental protection and one representative of the ministry responsible for nature protection, and six representatives of the institutions referred to in Article 25, paragraph 6 hereof, and one representative of consumers' associations.

(3) The members of the Advisory Forum from the competent authority and the ministries referred to in paragraph 2 of this Article shall be appointed by the Management Board at the proposal of the head of the competent authority, and other members on the basis of a public invitation.

(4) Members of the Advisory Forum may not be members of the Management Board, Scientific Committee and Scientific Panels.

(5) The Advisory Forum shall be chaired by the Executive Director of the Agency, who shall ensure technical and professional support to its work.

(6) Tasks and method of work of the Advisory Forum shall be regulated by the Statute and other internal rules of the Agency.

**Scientific Committee and Scientific Panels**

Article 32

(1) The Agency shall have the Scientific Committee and permanent Scientific Panels as expert bodies for providing the scientific opinions within the mission of the Agency.

(2) The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. The Scientific Committee shall provide opinions on interdisciplinary issues falling within the competence of

more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels. Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up a working group.

(3) The Scientific Committee shall be composed of the Chairs of the Scientific Panels and four independent experts who do not belong to any of the Scientific Panels.

(4) The members of the Scientific Committee and the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Agency's Executive Director, for a three-year term of office, which may be renewable.

(5) The procedures and way for the operation of the Scientific Committee and the Scientific Panels, their scope of activity, a number of Scientific Panels with the corresponding number of members and the procedure for providing scientific opinions shall be laid down in the Agency's Statute and other internal rules of the Agency.

SECTION 4
**OPERATION**

**Scientific opinions**
Article 33

(1) The Agency shall issue a scientific opinion:

(a) at the request of the competent authority, in respect of any matter within its mission, and in all cases where provided for by this Act,

(b) on its own initiative, on matters falling within its mission.

(2) Requests referred to in paragraph 1 of this Article shall be accompanied by background information explaining the scientific issue to be addressed.

(3) The head of the competent authority shall lay down the procedure and time limits for the delivery of a scientific opinion referred to in paragraph 1 of this Article by means of an implementing regulation, and in cases when time limits are not specified, the Agency shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

(4) Where the request is not in accordance with paragraph 2 of this Article, or is unclear, the Agency may either refuse, or propose amendments to a request for an opinion in consultation with the institution that made the request. Justifications for the refusal of the request for an opinion shall be given.

(5) Where the Agency has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications for the refusal of the request for an opinion shall be given.

(6) The Agency's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

**Diverging scientific opinions**
Article 34

(1) The Agency shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by the institutions referred to in Article 25, paragraph 6 hereof.

(2) Where the Agency identifies a potential source of divergence, it shall contact the competent institution in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.

**Scientific and technical assistance**
Article 35

(1) The Agency may be requested by the competent authority to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and

technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which do not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the competent authority for the establishment or evaluation of technical criteria and in the development of technical guidelines.

(2) Where the competent authority refers a request for scientific or technical assistance to the Agency, it shall specify, in agreement with the Agency, the time limit within which the task must be completed.

**Scientific studies**

Article 36

(1) Using the best independent scientific resources available, the Agency shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in accordance with special regulations on public procurement. The Agency shall seek to avoid duplication of research programmes with the programmes of the institutions referred to in Article 25, paragraph 6 hereof, and shall foster cooperation through appropriate coordination.

(2) The Agency shall inform the competent authority, the ministry responsible for health and the institutions referred to in Article 25, paragraph 6 hereof of the results of its scientific studies.

**Collection of data**

Article 37

(1) The Agency shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve in particular the collection of data relating to:

(a) food consumption and the exposure of individuals to risks related to the consumption of food,

(b) incidence and prevalence of biological risk,

(c) contaminants in food and feed,

(d) residues.

(2) For the purposes of paragraph 1 of this Article, the Agency shall work in close cooperation with the institutions referred to in Article 25, paragraph 6 hereof operating in the field of data collection.

(3) The institutions referred to in Article 25, paragraph 6 hereof shall transmit the data they collect in the fields referred to in paragraph 1 of this Article to the Agency.

(4) The Agency shall forward to the competent authority, the ministry responsible for health and the institutions referred to in Article 25, paragraph 6 hereof appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at the national and international level, in a way to facilitate their efficiency.

(5) The competent authority shall publish a report containing an inventory of data collection systems existing in the Republic of Croatia in the fields within the mission of the Agency. The report may be accompanied, where appropriate, by proposals relating to:

(a) for each system, the role which should be assigned to the Agency, and any modifications or improvements which might be required to enable the Agency to carry out its mission, in cooperation with the institutions referred to in Article 25, paragraph 6 hereof,

(b) the shortcomings which should be remedied to enable the Agency to collect and summarise relevant scientific and technical data in the fields within its mission.

(6) The Agency shall forward the results of its work in the field of data collection to the competent authority, the ministry responsible for health and the institutions referred to in Article 25, paragraph 6 hereof.

**Identification of emerging risks**

Article 38

(1) The Agency shall establish monitoring procedures for systematic searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.

(2) Where the Agency has information leading it to suspect an emerging serious risk, it shall request additional information from the competent authority, the ministry responsible for health and the institutions referred to in Article 25, paragraph 6 hereof, international institutions, agencies and competent authorities of the Member States of the European Union.

(3) The Agency shall use all the information it receives in the performance of its mission to identify an emerging risk.

(4) The Agency shall forward the evaluation and information collected on emerging risks to the competent authority, the ministry responsible for health and the institutions referred to in Article 25. paragraph 6 hereof.

**Rapid alert system**

Article 39

To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Agency shall be the recipient of any messages forwarded via the rapid alert system and analyse the content of such messages with a view to providing the competent authority with any information required for the purposes of risk analysis.

**National network of institutions**

Article 40

(1) The Agency shall establish and coordinate the national network of institutions referred to in Article 25, paragraph 6 hereof. The aim of such networking is to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Agency's mission.

(2) The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of the institutions referred to in Article 25, paragraph 6 hereof which may assist the Agency, either individually or in networks, with its mission. The Agency may entrust to these institutions certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. The Agency shall plan financial funds for this purpose.

(3) The rules for the establishment of the national network, the conditions and criteria for inclusion of an institution on the list of competent institutions, and the financial rules referred to in paragraphs 1 and 2 hereof shall be laid down by the head of the competent authority in an implementing regulation.

SECTION 5

**INDEPENDENCE, TRANSPARENCY, CONFIDENTIALITY AND COMMUNICATION**

**Independence**

Article 41

(1) The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest. For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests. Those declarations shall be made annually in writing.

(2) The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence. For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests

which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

(3) The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their work shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

**Transparency**

Article 42

(1) The Agency shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:

(a) agendas and minutes of the Scientific Committee and the Scientific Panels,

(b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included,

(c) without prejudice to Articles 43 and 45 of this Act, the information on which its opinions are based,

(d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings,

(e) the results of its scientific studies,

(f) the general annual report of its activities,

(g) requests from the competent authority for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

(2) The Management Board shall hold its meetings in public unless it decides otherwise for certain specific points of its agenda.

(3) The Agency shall lay down in its internal rules the arrangements for implementing the transparency rules referred to in paragraphs 1 and 2 of this Article.

**Confidentiality**

Article 43

(1) By way of derogation from Article 42 of this Act, the Agency shall not divulge confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.

(2) Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Agency, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to the internal rules of the Agency.

(3) The conclusions of the scientific opinions delivered by the Agency relating to foreseeable health effects shall on no account be kept confidential.

(4) The Agency shall lay down in its internal rules the arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2 of this Article.

**Communicating risk assessment results**

Article 44

(1) The Agency shall communicate on its own initiative the issues in the fields within its mission without prejudice to the competent authority's competence to communicate its risk management decisions.

(2) The Agency shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Agency shall develop and disseminate information material for the general public.

(3) The Agency shall act in close collaboration with the competent authority to promote the necessary coherence in the risk communication process. The Agency shall publish all opinions issued by it in accordance with Article 42 of this Act.

(4) The Agency shall ensure appropriate cooperation with the institutions referred to in Article 25, paragraph 6 hereof and other interested parties with regard to public information campaigns.

**Access to documents**

Article 45

(1) The Agency shall ensure access to the documents which it possesses.

(2) The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1 of this Article, pursuant to the provisions of a special regulation governing the right of access to information.

**Consumers, producers and other interested parties**

Article 46

The Agency shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.

CHAPTER IV

**RAPID ALERT SYSTEM, EMERGENCIES AND CRISIS MANAGEMENT**

**Rapid alert system**

Article 47

(1) A rapid alert system is hereby established as a network for the notification of a direct or indirect risk to human health deriving from food or feed. It shall involve the competent authority, persons authorized to perform official controls, control bodies and the Agency. Each body shall designate a contact point, which shall be a part of the network.

(2) The competent authority shall be responsible for managing the network and shall be a contact point to the European Commission.

(3) The head of the competent authority shall regulate the methods for the establishment and organization of the rapid alert system for food and feed with an implementing regulation.

**Emergencies**

Article 48

(1) Where the competent authority determines that food or feed of domestic origin or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken, the head of the competent authority may order one or more of the measures referred to in paragraphs 3 and 4 of this Article, depending on the gravity of the situation.

(2) The persons authorized to perform official controls and the control bodies shall undertake within their competence to inform the competent authority on the emergence of the risk.

(3) In the case of food and feed of domestic origin, measures referred to in paragraph 1 may include the following:

- suspension of the placing on the market or use of the food or feed in question,
- laying down special conditions for the food or feed in question,
- any other appropriate interim measure.

(4) In the case of food and feed imported from a third country, measures referred to in paragraph 1 may include the following:

- suspension of imports of the food or feed in question from all or part of the exporting country concerned or from the country of transit,

- laying down special conditions for the food or feed in question from all or part of the exporting country concerned or from the country of transit,

- any other appropriate interim measure.

(5) Where, on the basis of risk analysis the gravity of a risk referred to in paragraph 1 of this Article is confirmed, the head of the competent authority shall order a permanent prohibition of the placing on the market of the food or feed in question.

**Crisis management**

Article 49

(1) The competent authority, in close cooperation with the ministry responsible for health and the Agency, shall draw up a general crisis management plan in the field of the safety of food and feed.

(2) The plan referred to in paragraph 1 of this Article shall be brought by the head of the competent authority, and they shall envisage measures to be taken without delay when it is establish that foods or feeds pose a serious threat to the people or animals either directly or through the environment.

(3) The competent authority shall revise the general crisis management plan as required, in particular as a consequence of changes of organisation of the competent authority and on the basis of acquired experience, including the experience acquired during the implementing simulation exercises.

(4) The competent authority shall establish a crisis unit for the implementation of the plan referred to in paragraph 1 of this Article.

CHAPTER V

**FOOD HYGIENE**

**Obligations of food business operators**

Article 50

(1) Food business operators shall ensure that all stages of production, processing and distribution of food under their control satisfy the hygiene requirements laid down in chapter V of this Act and in implementing regulations made under this Act.

(2) By way of derogation from paragraph 1 of this Article, the provisions of chapter V of this Act shall not apply to:

(a) primary production for private domestic use,

(b) the domestic preparation, handling or storage of food for private domestic consumption,

(c) the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer,

(d) collection centres and tanneries which fall within the definition of food business only because they handle raw material for the production of gelatine or collagen.

(3) The head of the competent authority shall establish, by an implementing regulation, rules governing the activities referred to in item (c) of paragraph 2 of this Article.

(4) Food business operators carrying out primary production and associated operations must comply with the general hygiene provisions and specific hygiene requirements for food of animal origin laid down in implementing regulations referred to in Article 56 of this Act.

(5) Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 4 of this Article applies shall comply with the general hygiene requirements and specific hygiene requirements for food of animal origin laid down in implementing regulations referred to in Article 56 of this Act.

(6) Food business operators shall, as appropriate, apply the following specific hygiene measures:

– compliance with microbiological criteria for foodstuffs;

– procedures necessary to achieve the objectives of this Act;

– compliance with temperature control requirements for foodstuffs;

– maintenance of the cold chain;

– sampling and analysis.

Article 51

(1) Food business operators shall establish and implement regular checks on hygiene conditions at all stages of production, processing and distribution of food, except at the level of primary production and associated operations, in each establishment under their control, by implementing a preventive own-control programme developed in accordance with the HACCP principles.

(2) Detailed rules for the implementation of the own-control system developed in accordance with the HACCP principles shall be laid down by the head of the competent authority by means of an implementing regulation.

**Registration or approval of establishments**

Article 52

(1) A food business operator shall submit an application to the competent authority or the ministry responsible for health, in accordance with the distribution of powers referred to in Article 86, paragraph 1, items (a), (b) and (c) of this Act, in the required manner, for each establishment under its control that carries out any of the stages of production, processing and distribution of food, with a view to the registration or approval of the establishment.

(2) Food business operators shall provide to the competent authority or the ministry responsible for health up-to-date information on establishments, including information on any significant change in activities and any closure of a registered or approved establishment.

(3) Establishments subject to approval shall be determined in an implementing regulation issued by the head of the competent authority.

(4) Food business operators shall ensure that establishments referred to in paragraph 3 of this Article are approved by the competent authority or the ministry responsible for health, following at least one on-site visit, and that they shall not commence their activities unless the competent authority has:

– granted the establishment approval to operate following an inspection; or

– provided the establishment with conditional approval to operate.

**Register of registered establishments**

Article 53

(1) Establishments which are not subject to approval shall, on the basis of a decision on the registration of an establishment, which is made by the competent authority or the ministry responsible for health, be entered in the Register of registered establishments, maintained by the competent authority or the ministry responsible for health.

(2) The central registry of registered establishments referred to in paragraph 1 of this Article shall be maintained by the competent authority. The ministry responsible for health shall submit to the competent authority information concerning the registered establishments which, according to this Act, fall under its jurisdiction.

(3) An establishment referred to in paragraph 1 of this Article shall, by means of a decision, be removed from the Register of registered establishments if:

– a request has been submitted by a person authorised by the food business operator,

– deficiencies have been identified during inspectional control of the establishment.

(4) The form and contents of, and the manner of keeping, the Register of registered establishments referred to in paragraph 1 of this Article, and of the central registry referred to in paragraph 2 of this Article, as well as the procedure for the registration of establishments shall be laid down by the head of the competent authority by means of an implementing regulation, with a prior opinion of the minister responsible for health.

**Register of approved establishments**

Article 54

(1) Establishments which are subject to approval shall, on the basis of a decision on approval, which is made by the competent authority, be entered in the Register of approved establishments which is maintained by the competent authority.

(2) The establishments referred to in paragraph 1 of this Article shall, by means of a decision, be removed from the Register of approved establishments if:

– a request has been submitted by a person authorised by the food business operator,

– approval has been withdrawn due to deficiencies identified during inspectional control of the establishment,

– the approval period has expired,

– conditional approval has been withdrawn.

(3) The form and contents of, and the manner of keeping, the Register of approved establishments and the procedure for the approval of establishments shall be laid down by the head of the competent authority by means of an implementing regulation.

**Guides**

Article 55

Food business operators shall use guides to good practice for hygiene and for the application of HACCP principles, which are developed, evaluated and disseminated in accordance with the provisions of food law.

**Powers to issue implementing regulations**

Article 56

(1) The head of the competent authority shall, by means of implementing regulations and with a prior opinion of the minister responsible for health, lay down:

– general rules for food business operators on the hygiene of food,

– specific food hygiene requirements relating to staff, records, premises and equipment at any of the stages of production, processing and distribution,

– microbiological and other criteria for the placing of food on the market,

(2) The head of the competent authority shall, by means of implementing regulations, lay down:

– specific rules on the hygiene of food of animal origin for food business operators,

– specific rules on the hygiene of food of animal origin for certain types of products,

– specific animal and public health rules relating to the movement of food of animal origin,

– specific animal health rules governing the production, processing, distribution and introduction of food of animal origin,

– specific rules for the placing on the market of food of animal origin,

– specific rules for handling animal by-products.

**National measures**

Article 57

(1) The competent authority may grant derogations from the regulations referred to in Article 56 of this Act in order to facilitate the implementation of regulations by small food business operators, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of food law.

(2) The competent authority may, without compromising achievement of the objectives of this Act and regulations referred to in paragraph 1 of this Article, adopt national measures adapting the general hygiene requirements for food business operators carrying out any stage of production, processing and distribution of food after primary production and associated operations.

(3) The national measures referred to in paragraph 2 of this Article shall have the aim of:

– enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food, or

– enabling the work of food business operators situated in regions suffering from special geographical constraints.

(4) In cases other than those specified in paragraph 3 of this Article, the national measures shall apply only to the construction, layout and equipment of food business establishments.

(5) The competent authority shall notify the Commission and other Member States of the adopted national measures referred to in this Article.

## CHAPTER VI
## FEED HYGIENE

### Obligations of feed business operators

Article 58

(1) Feed business operators shall ensure that all stages of production, processing and distribution of feed under their control satisfy the hygiene requirements laid down in Chapter VI. of this Act and in implementing regulations made under this Act as well as in other special rules and regulations concerning animal feed.

(2) The head of the competent authority may provide for possible exemptions from paragraph 1 of this Article, by means of an implementing regulation.

(3) When feeding food-producing animals, feed business operators must take measures and adopt procedures to keep the risk of biological, chemical and physical contamination of feed, animals and animal products as low as possible.

Article 59

(1) Feed business operators carrying out primary production and associated operations must comply with the hygiene provisions laid down in implementing regulations referred to in Article 65 of this Act.

(2) Feed business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 of this Article applies must comply with the feed hygiene requirements laid down in implementing regulations referred to in Article 65 of this Act.

(3) Feed business operators shall:

– comply with specific microbiological criteria,

– take measures and adopt procedures necessary to achieve the objectives of this Act.

Article 60

(1) Feed business operators other than at the level of primary production and associated operations shall put in place, implement and maintain regular own-control procedures in accordance with the HACCP principles.

(2) The competent authority may grant derogations from paragraph 1 of this Article, in particular in order to facilitate the implementation of regulations by small food business operators or operators situated in regions suffering from special geographical constraints, taking into account the relevant risk factors, provided that such derogations do not affect the achievement of the objectives of feed law.

(3) Detailed rules for the implementation of the own-control system developed in accordance with the HACCP principles shall be laid down by the head of the competent authority by means of an implementing regulation.

### Registration or approval of establishments

Article 61

(1) A feed business operator shall submit an application to the competent authority, in the required manner, for each establishment under its control that carries out any of the stages of production, processing and distribution of feed, with a view to the registration or approval of the establishment.

(2) Feed business operators shall provide to the competent authority up-to-date information on establishments, including information on any significant change in activities and any closure of a registered or approved establishment.

(3) Establishments subject to approval shall be determined in an implementing regulation issued by the head of the competent authority.

(4) Feed business operators shall ensure that establishments referred to in paragraph 3 of this Article are approved by the competent authority, following at least one on-site visit, and that they shall not commence their activities unless the competent authority has:

– granted the establishment approval to operate following an inspection; or

– provided the establishment with conditional approval to operate.

**Register of registered establishments**

Article 62

(1) Establishments which are not subject to approval shall, on the basis of a decision on the registration of an establishment, which is made by the competent authority, be entered in the Register of registered establishments, maintained by the competent authority.

(2) An establishment referred to in paragraph 1 of this Article shall, by means of a decision, be removed from the Register of registered establishments if:

– a request has been submitted by a person authorised by the feed business operator,

– deficiencies have been identified during inspectional control of the establishment.

(3) The form and contents of, and the manner of keeping, the Register of registered establishments and the procedure for the registration of establishments shall be laid down by the head of the competent authority by means of an implementing regulation.

**Register of approved establishments**

Article 63

(1) Establishments which are subject to approval shall, on the basis of a decision on approval, which is made by the competent authority, be entered in the Register of approved establishments which is maintained by the competent authority.

(2) The establishments referred to in paragraph 1 of this Article shall, by means of a decision, be removed from the Register of approved establishments if:

– a request has been submitted by a person authorised by the feed business operator,

– approval has been withdrawn due to deficiencies identified during inspectional control of the establishment,

– the approval period has expired,

– conditional approval has been withdrawn.

(3) The form and contents of, and the manner of keeping, the Register of approved establishments and the procedure for the approval of establishments shall be laid down by the head of the competent authority by means of an implementing regulation.

**Guides**

Article 64

Feed business operators shall use guides to good practice for hygiene and for the application of HACCP principles, which are developed, evaluated and disseminated in accordance with the provisions of feed law.

**Powers to issue implementing regulations**

Article 65

The head of the competent authority shall, by means of implementing regulations, lay down:

– feed hygiene rules for feed business operators,

– specific rules concerning the packaging, wrapping, placing on the market and terminology of feed,

– specific feed hygiene rules for feed business operators that use products of animal origin, products originating from a specific source or products intended to meet particular nutritional needs of animals,

– specific feed hygiene requirements relating to staff, records, premises and equipment at any of the stages of production, processing and distribution,

– specific feed hygiene requirements and rules for certain types of products,
– microbiological and other criteria for feed intended to be placed on the market or fed to food-producing animals,
– additional requirements concerning the labelling of feed
– methods of sampling and methods of analysis of feed.

## CHAPTER VII
## OFFICIAL CONTROLS

### General obligations
Article 66

(1) The competent authority shall ensure that official controls are carried out regularly, on a risk basis and with appropriate frequency, so as to achieve the objectives of this Act.

(2) The purpose of official controls is to verify compliance with food and feed rules and regulations aiming, in particular, at:

(a) preventing, eliminating or reducing to acceptable levels risks which may arise, either directly or through the environment, for human and animal health,

(b) guaranteeing fair practices in food and feed trade and protecting consumer interests, including food and feed labelling and other forms of consumer information.

(3) When performing official controls, the competent authority shall take into account:

(a) identified risks associated with animals, food or feed, animal or feed or food business operators, the use of food or feed or any process, material, substance, activity or operation that may influence food or feed safety, animal health or animal welfare,

(b) food or feed business operators' past record as regards the implementation of food or feed law or of animal health and animal welfare rules,

(c) the reliability of own controls / self-checks that have already been carried out, and

(d) any information that might indicate non-compliance with law.

(4) Official controls shall be carried out without prior warning, except in the case of an audit.

(5) Official controls shall be carried out at any of the stages of production, processing and distribution of food or feed and on animals and animal products. In order to achieve the objectives of this Act, official controls shall include controls on food and feed business operators, on the use of food and feed, on the storage of food and feed, on any process, material, substance, activity or operation including transport applied to food or feed and on live animals.

### Obligations of the competent authority
Article 67

(1) The competent authority shall ensure:

(a) the effectiveness and purposefulness of official controls on live animals, food and feed at all stages of production, processing and distribution, and on the use of feed,

(b) that staff carrying out official controls are free from any conflict of interest,

(c) adequate laboratories for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively,

(d) appropriate and properly maintained facilities and equipment to ensure that staff can perform official controls efficiently and effectively;

(e) that official controls are carried out and measures taken in accordance with legal powers,

(f) that contingency plans are in place and operated in the event of an emergency,

(g) that the food and feed business operators undergoing an inspection in accordance with this Act cooperate with authorised staff of the competent authority carrying out the inspection.

(2) Bodies responsible for carrying out inspections pursuant to this Act shall provide conditions referred to in paragraph 1, item (d) of this Article.

(3) The competent authority shall ensure efficient and effective coordination between all the bodies involved in the performance of official controls, in particular at regional or local level, including where appropriate in the field of environmental and health protection.

(4) When, within one body, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation must be ensured between the different units.

(5) The competent authority and the bodies referred to in paragraph 3 of this Article must ensure the impartiality, quality and consistency of official controls at all levels.

(6) The competent authority shall carry out internal audits or may have external audits carried out, and shall take appropriate measures in the light of their results, to ensure that they are achieving the objectives of this Act. The audits must be carried out in an impartial and transparent manner.

**Control and verification procedure**

Article 68

(1) Official controls shall be carried out according to the instructions established by the competent authority.

(2) The competent authority shall:

(a) verify the effectiveness of official controls that it carries out, and

(b) take corrective action when needed and update the instructions referred to in paragraph 1 of this Article as appropriate.

**Control activities, methods and techniques**

Article 69

(1) Official controls shall be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

(2) Official controls on food and feed shall include, inter alia, the following activities:

(a) examination of control systems that food and feed business operators have put in place and the results obtained;

(b) inspection of:

– establishments of primary products producers, food and feed business operators, including their surroundings, premises, equipment, installations and machinery, transport, as well as of food and feed,

– raw materials, ingredients, processing aids and other products used for the preparation and production of food and feed,

– semi-finished products,

– materials and articles intended to come into direct contact with food,

– cleaning and maintenance products and processes, and pesticides,

– labelling, presentation and advertising,

(c) check on the hygiene conditions in food and feed businesses,

(d) assessment of procedures on good manufacturing practices, good hygiene practices, good farming practices and HACCP, taking into account the guides established in accordance with food law,

(e) examination of documents and other records which may be relevant to the assessment of compliance with food or feed law;

(f) an interview with food and feed business operators and with their staff,

(g) the reading of values recorded by food or feed business measuring instruments,

(h) control carried out with the competent authority's own instruments to verify measurements taken by food and feed business operators,

(i) control carried out to verify the compliance of food and feed with the required quality standards,

(j) control carried out to verify the compliance of food with the required standards for food bearing an indication “Traditional Speciality Guaranteed”, a designation of origin or a geographical indication,

(k) control carried out to verify the compliance of novel food, GM food and GM feed with the prescribed requirements,

(l) any other activity required to ensure that the objectives of this Act are met.

**General principles for official controls on food of animal origin**

Article 70

(1) Official controls shall be carried out without prior warning, except in the case of an audit where prior notification of the food or feed business operator is necessary.

(2) Audits of good hygiene practices shall verify that food business operators apply procedures continuously and in accordance with law, concerning at least:

(a) checks on food-chain information,

(b) the construction, design and maintenance of premises and equipment,

(c) pre-operational, operational and post-operational hygiene,

(d) staff personal hygiene,

(e) training in hygiene and in work procedures,

(f) pest control,

(g) water quality,

(h) temperature control, and

(i) controls on food entering and leaving the establishment and accompanying documentation.

(3) Audits of hazard analysis and critical control point (HACCP)-based procedures shall verify that food business operators apply such procedures regularly and in accordance with law, and in particular that products of animal origin:

(a) comply with microbiological criteria laid down in accordance with food law,

(b) comply with legislation on residues, contaminants and prohibited substances, and

(c) do not contain physical hazards, such as foreign bodies.

(4) When a food business operator uses procedures set out in guides to the application of HACCP principles, the audit shall verify the correct use of these guides.

**Transparency and confidentiality**

Article 71

(1) The competent authority must ensure that official controls are carried out with a high level of transparency.

(2) No information relating to the activities of a food or feed business operator, and acquired during official controls by persons performing such controls, or information relating to risk analysis, shall be disclosed without a written consent from the food or feed business operator, except:

– when disclosure is necessary for the implementation of the provisions of this Act and permitted by the head of the competent authority,

– when disclosure is necessary for a proceeding conducted based on criminal charges or on a request to initiate minor offence proceedings, following inspectional supervision.

**Methods of sampling and analysis**

Article 72

(1) Sampling and analysis methods used in the context of official controls must comply with the provisions of an implementing regulation issued by the head of the competent authority.

(2) The regulation referred to in paragraph 1 of this Article must guarantee the right of a food or feed business operator whose products are subject to sampling and analysis to apply for a supplementary expert opinion, without prejudice to the obligation of the competent authority to take prompt action in case of emergency.

(3) In the case referred to in paragraph 2 of this Article, it must be ensured that that food or feed business operators can obtain sufficient numbers of samples for a supplementary expert opinion, unless impossible in case of highly perishable products or very low quantity of available substances.

(4) Samples must be handled and labelled in the prescribed manner so as to ensure their integrity and adequacy for the planned analyses.

(5) The costs of sampling and analyses referred to in this Article shall be borne by the competent authority, except in the case referred to in paragraph 2 of this Article and when the result of the analysis is unfavourable.

(6) Funds for the costs referred to in paragraph 5 of this Article shall be secured from the State Budget.

**Delegation of specific tasks related to official controls**

Article 73

(1) The competent authority may delegate specific tasks related to official controls to one or more control bodies in accordance with the provisions of implementing regulations made under this Act and other special regulations, with the exception of the tasks referred to in Article 74 of this Act.

(2) The control bodies referred to in paragraph 1 of this Article must be accredited in accordance with Croatian standards.

(3) The competent authority delegating specific tasks to control bodies shall organise audits or inspections of control bodies as necessary. If, as a result of an audit or an inspection, it is established that such bodies are failing to carry out the delegated tasks in accordance with relevant regulations, the competent authority may withdraw the delegation. The delegation shall be withdrawn without delay if the control body fails to take appropriate and timely action.

(4) The head of the competent authority shall, by means of an implementing regulation, prescribe the conditions that control bodies must meet, the list of tasks that can be delegated to them as well as the procedure for delegating those tasks.

**Action in case of non-compliance**

Article 74

(1) When the competent authority or the person authorised to perform official control identifies non-compliance with the provisions of food law, it must take measures to ensure that deficiencies are corrected. When deciding which measures to take, the competent authority or the person authorised to perform official control shall take account of the nature of the offence and the food or feed business operator's past record as regards compliance with law.

(2) The measures referred to in paragraph 1 of this Article shall include, where appropriate:

(a) the imposition of sanitary or other procedures deemed necessary to ensure the safety of food or feed, or compliance with food or feed law or animal health and animal welfare rules,

(b) the restriction or prohibition of the placing on the market, import or export of food, feed or animals,

(c) monitoring and, if necessary, ordering the withdrawal, recall and/or destruction of food or feed,

(d) the authorisation to use food or feed for purposes other than those for which they were originally intended,

(e) the suspension of operation or closure of all or part of the food or feed establishment for an appropriate period of time,

(f) the suspension or withdrawal of the food or feed establishment's approval to operate,

(g) the measures laid down in special regulations governing consignments from third countries,

(h) other measures the competent authority deems appropriate.

(3) Where appropriate, the competent authority shall also notify the competent authority of the country of origin of its decision.

(4) All costs incurred in relation to the implementation of this Article shall be borne by the responsible food or feed business operator.

**Staff authorised to perform official controls**

Article 75

(1) The competent authority must ensure that staff authorised to perform official controls:

(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner,

(b) systematically receive additional training,

(c) cooperate multidisciplinary.

**Multi-annual national control plan**

Article 76

The competent authority shall prepare a single multi-annual national control plan.

**Annual reports**

Article 77

The competent authority shall prepare an annual report on the implementation of the control plan referred to in Article 76 of this Act, which it shall submit to the European Commission.

**Financing of official controls**

Article 78

(1) Funds shall be secured in the State Budget to provide for the necessary number of staff performing official controls and to cover all the costs for the implementation of such controls.

(2) Fees and charges shall be levied and collected to cover the costs occasioned by official controls.

(3) The head of the competent authority shall, by means of an implementing regulation, determine the criteria for setting the level of fees, the level of charges and the method of their calculation and payment.

**Food business operators' obligations concerning official controls**

Article 79

Food business operators must enable the competent authority, or the person authorised to carry out official control, to effectively perform official controls, and they must in particular:

– give access to buildings, premises, installations or other infrastructures, and enable the taking of sufficient number of samples,

– make available any documentation and record required under the provisions of food law or considered necessary by the competent authority or the person authorised to carry out official control.

**Mutual cooperation between national competent authorities**

Article 80

Where the outcome of official controls on food and feed, whether in the territory of the Republic of Croatia or in the territory of another country, requires action in more than one country, the competent authority shall cooperate with competent authorities of other countries.

**Official laboratories**

Article 81

(1) The head of the competent authority shall authorise official laboratories to carry out the analysis of samples taken during official controls.

(2) Official laboratories referred to in paragraph 1 of this Article in which the analysis of samples taken by the sanitary inspection during official controls are carried out shall be authorized by the head of the competent authority at the proposal of the minister responsible for health.

(3) Official laboratories must be accredited in accordance with Croatian norms.

(4) The head of the competent authority shall, by means of an implementing regulation, prescribe the authorisation procedure and method, the conditions that must be met by the laboratories referred to in paragraph 1 of this Article as well as the obligations of those laboratories.

(5) The head of the competent authority shall, by means of an implementing regulation and with the consent of the minister responsible for health, prescribe the authorisation procedure and method, the conditions that must be met by the laboratories referred to in paragraph 2 of this Article as well as the obligations of those laboratories.

(6) The list of the laboratories referred to in paragraph 1 of this Article shall be published in the Official Gazette.

**Reference laboratories**

Article 82

(1) The head of the competent authority shall authorise reference laboratories for food, feed and animal health dedicated to the areas determined in the implementing regulation referred to in paragraph 4 of this Article.

(2) Reference laboratories must meet the conditions referred to in Article 81, paragraph 3, of this Act.

(3) If for certain area, no reference laboratory meeting the conditions referred to in paragraph 2 of this Article exists in the Republic of Croatia, the head of the competent authority may designate a laboratory outside the Republic of Croatia to be a reference laboratory.

(4) The head of the competent authority shall, by means of an implementing regulation and with the consent of the minister responsible for health, prescribe the areas for which reference laboratories are to be authorised, the authorisation method and the obligations of reference laboratories.

(5) The list of reference laboratories referred to in paragraph 1 of this Article shall be published in the Official Gazette.

**Persons authorised to perform official controls on food and feed**

Article 83

(1) Official controls on food of animal origin and feed shall be carried out by persons authorised to perform official control in accordance with the provisions of this Act and a special veterinary regulation.

(2) Official controls on food of non-animal origin shall be carried out by persons authorised to perform official control in accordance with the provisions of this Act and a special regulation.

(3) Official control on food bearing a geographical indication, a designation of origin or an indication "Traditional Speciality Guaranteed" shall be carried out by the food quality inspection of the competent authority.

(4) The operations of a food quality inspector may be carried out by a graduate engineer of food technology or a graduate engineer of agronomy who, in addition to general requirements for public service employment, passed state vocational examination and has at least five years of working experience in the profession.

(5) While carrying out official control on food bearing a geographical indication, a designation of origin or an indication "Traditional Speciality Guaranteed" , a competent inspector referred to in paragraph 4 of this Article may:

- bring a decision on the prohibition of the placing on the market of food bearing a geographical indication, a designation of origin or an indication "Traditional Speciality Guaranteed" which does not comply with the requirements indicated in the specification of that food,
- propose deleting from the Register Book referred to in Article 102, paragraph 1 and Article 113, paragraph 1 hereof.

(6) The provisions of the regulations referred to in paragraphs 1 and 2 of this Article and the Act on General Administrative Procedure shall apply to the work of persons authorised to perform official controls.

**Official controls on imported food and feed**

Article 84

(1) Official controls on imported food of animal origin and feed shall be carried out by persons authorised to perform official control in accordance with the provisions of this Act and a special veterinary regulation.

(2) Official controls on imported food of non-animal origin shall be carried out by persons authorised to perform official control in accordance with the provisions of this Act and a special regulation.

(3) Food referred to in paragraph 2 of this Article that constitutes a known or imminent risk and is being imported shall be subjected to pre-clearance control at the customs office which is nearest to the point of entry into the Republic of Croatia.

(4) The list of food referred to in paragraph 3 of this Article shall be adopted by the head of the competent authority. The list shall be published in the Official Gazette.

(5) The head of the competent authority shall, by means of a special regulation, prescribe the manner of carrying out the checks and the places at which the checks are to be carried out.

(6) Food intended for importation, which is subjected to food safety laboratory analysis, shall remain under customs control until the analysis is completed and its results known.

**Powers to issue implementing regulations**

Article 85

The head of the competent authority shall, by means of implementing regulations, lay down:

– general rules for the organisation and performance of official controls for the verification of compliance with food and feed law, animal health and animal welfare rules,

– special rules for the organisation and performance of official controls on food of animal origin.

**Organisation of official controls on food and feed**

Article 86

(1) The official control of food safety and hygiene shall be carried out:

(a) at the level of primary production and associated operations:

– on food of animal origin, by the veterinary inspection,

– on food of plant origin, by the agricultural inspection,

(b) at the levels of production and processing:

– on food of animal origin, by the veterinary inspection,

– on food of non-animal origin, by the sanitary inspection,

– on food containing ingredients of animal and non-animal origin, by the veterinary or sanitary inspection, as laid down in an implementing regulation made by the head of the competent authority,

(c) at the level of retail, by the sanitary inspection, except in establishments approved by the competent authority where official controls shall be carried out by the veterinary inspection,

(d) at the import:

– on food of animal origin, by the border veterinary inspection,

– on food of non-animal origin, by the border sanitary inspection,

– on food containing ingredients of animal and non-animal origin, by the border veterinary inspection or the border sanitary inspection, as laid down in an implementing regulation made by the head of the competent authority.

(2) The official control feed safety and hygiene shall be carried out:

(a) at the level of primary production and associated operations:

– on feed of animal origin, by the veterinary inspection,
– on feed of plant origin, by the agricultural inspection,
(b) at the levels of production and processing, regardless of feed origin, by the veterinary inspection,
(c) at the level of retail of feed, regardless of feed origin, by the veterinary inspection,
(d) at the import of feed, regardless of feed origin, by the border veterinary inspection or the veterinary inspection.
(3) The official control of food quality shall be carried out:
(a) at the levels of primary production and associated operations, production and processing, regardless of food origin, by the competent inspection of the Department of Agricultural Inspection of the competent authority,
(b) at the level of retail of food, regardless of food origin, by economic inspectors,
(c) at the import:
– on food of animal origin, by the border veterinary inspection,
– on food of non-animal origin, by the border sanitary inspection,
– on food containing ingredients of animal and non-animal origin, by the border veterinary inspection or the border sanitary inspection, as laid down in an implementing regulation made by the head of the competent authority.
(4) The official control of feed quality shall be carried out:
(a) at the levels of primary production and associated operations, production and processing of feed, regardless of its origin, by the competent inspection of the Department of Agricultural Inspection of the competent authority,
(b) at the level of retail of feed, regardless of feed origin, by economic inspectors,
(c) at the import of feed, regardless of feed origin, by the border veterinary inspection or the veterinary inspection.
(5) The official control on food bearing a geographical indication, a designation of origin or an indication "Traditional Speciality Guaranteed" shall be carried out, at the levels of primary production and associated operations, production and processing, by the food quality inspection, at the level of retail, by economic inspectors, and at the import, by the inspection referred to in item (c) of paragraph 3 of this Article.
(6) The official control on novel food at the levels of production, processing and retail shall be carried out by the sanitary inspection, and at the time of importation, by the border sanitary inspection.
(7) The official control on GM food and GM feed shall be carried out:
(a) at the level of primary production and associated operations, by the competent inspection service of the Department of Agricultural Inspection of the competent authority,
(b) at the levels of production and processing:
– on GM food of animal origin, by the veterinary inspection, on GM food of non-animal origin, by the sanitary inspection service, on GM food containing ingredients of animal and non-animal origin, by the veterinary or sanitary inspection in accordance with an implementing regulation made by the head of the competent authority,
– on GM feed, regardless of its origin, by the veterinary inspection,
(c) at the level of retail:
– on GM food, regardless of its origin, by the sanitary inspection,
– on GM feed, regardless of its origin, by the veterinary inspection,
(d) at the import:
– on GM food of animal origin, by the border veterinary inspection,
– on GM food of non-animal origin, by the border sanitary inspection,
– on GM food containing ingredients of animal and non-animal origin, by the border veterinary inspection or the border sanitary inspection in accordance with an implementing regulation made by the head of the competent authority,
– on GM feed, regardless of its origin, by the border veterinary inspection or the veterinary inspection.
(8) The competent inspection shall carry out official controls in accordance with the provisions of Chapter VII of this Act and special regulations.

(9) Inspections which are not organised within the competent authority shall, when performing official controls, cooperate with the competent authority, participate in the preparation of a multi-annual national control plan, participate in the preparation of annual reports on official controls and provide for the financing of official controls falling within their competence.

(10) The head of the competent authority shall, by means of an implementing regulation, prescribe the methods and procedures for cooperation between the competent authority and inspection services which are not organised within the competent authority, as well as the time period within which the plans and reports referred to in paragraph 9 of this Article must be prepared and submitted to the competent authority.

## CHAPTER VIII
## NOVEL FOODS, GENETICALLY MODIFIED FOOD AND GENETICALLY MODIFIED FEED

### Novel food categories
Article 87

(1) Novel foods shall include the following categories of foods:

a) foods and food ingredients with a new or intentionally modified primary molecular structure,

b) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae,

c) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use,

d) foods and food ingredients to which has been applied a technological production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, the metabolism of man or the level of substances undesirable for human consumption.

(2) Novel foods referred to 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 to such an extent that their consumption would be nutritionally disadvantageous for the consumer.

(3) Novel foods do not include food additives authorised for use in foodstuffs, and flavourings and extraction solvents used in the production of foodstuffs in accordance with specific regulations.

### Genetically modified food
Article 88

(1) GM food includes:

a) genetically modified organisms (GMOs) for food use,

b) food containing or consisting of GMOs,

c) food produced from or containing ingredients produced from GMOs.

(2) Food referred to in paragraph 1 of this Article must not:

– have adverse effects on human health, animal health or the environment,

– mislead the consumer,

– differ from the food which it is intended to replace to such an extent that its consumption would be nutritionally disadvantageous for the consumer.

(3) The provisions of this Act and of specific regulations shall apply to GM food referred to in paragraph 1 of this Article.

### Genetically modified feed
Article 89

(1) GM feed shall include:

a) genetically modified organisms (GMOs) for feed use,

b) feed containing or consisting of GMOs,
c) feed produced from or containing ingredients produced from GMOs.
(2) Feed referred to in paragraph 1 of this Article must not:
– have adverse effects on human health, animal health or the environment
– mislead the user
– harm or mislead the consumer by impairing the distinctive features of the animal products
– differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.
(3) The provisions of this Act and of specific regulations shall apply to GM feed categories referred to in paragraph 1 of this Article.

**The placing on the market of novel foods, GM food and GM feed**

Article 90

(1) For the first placing on the market in the Republic of Croatia of novel foods, GM food or GM feed, a food business operator must obtain an authorisation in accordance with the provisions of this Act and of specific regulations.
(2) An authorisation to place novel foods on the market shall be issued by the minister responsible for health, with the consent of the head of the competent authority, on the basis of a prior scientific opinion of the Agency, in accordance with an implementing regulation laying down the conditions and procedures for the first placing on the market in the Republic of Croatia of novel foods and the specific requirements for the labelling of novel foods.
(3) An authorisation to place on the market GM food and GM feed shall be issued by the minister responsible for health, with the consent of the head of the competent authority, on the basis of a prior scientific opinion of the Agency, in accordance with an implementing regulation made under this Act and with a specific regulation.
(4) The minister responsible for health shall, with the consent of the head of the competent authority, prescribe the conditions and procedure for issuing authorisations referred to in paragraph 1 of this Article.

**Register of authorisations granted for the placing on the market of novel foods, GM food and GM feed**

Article 91

(1) The ministry responsible for health shall keep a register of authorisations granted for the placing on the market of novel foods, GM food and GM feed.
(2) The minister responsible for health shall, with the consent of the head of the competent authority, prescribe the contents and form of, and the manner of keeping, the register referred to in paragraph 1 of this Article.

**Risk management measures associated with the placing on the market of novel foods, GM food and Gm feed**

Article 92

(1) If there are scientific uncertainties about adverse effects of novel foods, GM food or GM feed on health, the minister responsible for health shall, with the consent of the head of the competent authority, order measures to prohibit temporarily the placing on the market of such food or feed in accordance with the precautionary principle referred to in Article 7 of this Act.
(2) The minister responsible for health may, with the consent of the head of the competent authority, order other appropriate measures and prescribe the conditions for and the manner of implementing those measures.
(3) The minister responsible for health shall, with the consent of the head of the competent authority, order a measure to permanently prohibit the placing on the market of novel foods, GM food or GM feed, when it is established on the basis of a scientific risk assessment that such food or feed is harmful to human and animal health.

**The traceability and labelling of GM food and GM feed and the labelling of novel foods**

Article 93

(1) At the first stage of the placing on the market of food or feed consisting of or containing GMOs, including bulk quantities, operators dealing with such food or feed shall ensure that the following information is transmitted in writing to the operator receiving such food or feed:

– that the food or feed contains or consists of GMOs,

– the unique identifier in accordance with an implementing regulation.

(2) The requirements relating to the placing on the market of food or feed consisting of or containing GMOs, including bulk quantities, for the case referred to in paragraph 1 of this Article and for all other stages, shall be prescribed by means of an implementing regulation by the minister responsible for health, with the consent of the head of the competent authority.

(3) In addition to the general labelling requirements referred to in Article 17 of this Act, the labelling of GM food, GM feed and novel foods placed on the market must contain additional specific information in order to ensure that the final consumer is informed of all the characteristics and properties of such food or feed.

(4) The requirements relating to the traceability, the special labelling requirements for GM food and GM feed and the special labelling requirements for novel foods shall be prescribed by means of an implementing regulation by the minister responsible for health, with the consent of the head of the competent authority.

## CHAPTER IX
## FOOD AND FEED QUALITY

### SECTION 1
### FOOD QUALITY

**Basic food quality requirements**

Article 94

(1) Food business operators shall be allowed to produce and place on the market food of the required quality as well as food for which quality requirements have not been prescribed, provided such food meets the prescribed food safety and labelling requirements.

(2) The head of the competent authority shall issue implementing regulations laying down food quality requirements relating to:

– the classification, categorisation and terminology of food,

– physical, chemical, physico-chemical and organoleptic properties and composition of food

– physico-chemical and organoleptic properties of raw materials and the type and quantity of raw materials, added and other substances used in the production and processing of food,

– sampling methods and analytical methods used for food quality control,

– the designation of panels of selected and trained sensory assessors for certain food,

– technological processes used in the production and processing of food,

– minimum technical requirements to be met by establishments producing certain food,

– food wrapping and packaging,

– additional food labelling requirements.

(3) In addition to the requirements referred to in paragraph 2 of this Article, the head of the competent authority may, by means of an implementing regulation, prescribe a procedure that must be undertaken in respect of certain food before such food is placed on the market.

(4) Food business operators shall not place on the market food of the required quality which does not comply with the implementing regulations referred to in paragraph 2 of this Article and food for which the procedure referred to in paragraph 3 is prescribed, unless this procedure is undertaken.

Article 95

(1) Establishments producing, processing and/or packing certain food must, for the purposes of the organisation of the market, be approved and entered in the registers of establishments, which are kept by the competent authority.

(2) In addition to meeting the requirements referred to in paragraph 1 of this Article, the producers of certain food must also be entered in the registers of producers, which are kept by the competent authority.

(3) The head of the competent authority shall, by means of an implementing regulation, prescribe the requirements for approval of establishments referred to in paragraph 1 of this Article, the requirements for and the manner of entering in and removal from the registers, the form and contents of the registers referred to in paragraphs 1 and 2 of this Article, as well as the costs of the approval and registration.

SECTION 2

**FEED QUALITY**

Article 96

(1) Feed business operators shall be allowed to produce and place on the market feed of the required quality, whether packed or in bulk, provided such feed meets the prescribed feed safety and labelling requirements.

(2) Only feed that meets the prescribed quality requirements is allowed to be fed to animals.

(3) Feed quality includes its physico-chemical and nutritional properties.

(4) The head of the competent authority shall issue implementing regulations laying down the quality requirements for feed, relating to:

– the categorisation, physico-chemical and nutritional properties,

– physico-chemical and nutritional properties of raw material and the type and quantity of raw materials,

– technological processes used in the production and processing.

CHAPTER X

Indications “Traditional Speciality Guaranteed“**, designations of origin and geographical indications for foodstuffs**

SECTION 1

**Indication “Traditional Speciality Guaranteed“**

**Specific character**

Article 97

(1) A food may be granted an indication “Traditional Speciality Guaranteed“ if its specific character has been recognized.

(2) A food shall be considered to have specific character if it is produced using traditional raw materials or has a traditional composition or is produced and/or processed in a traditional way, and it has specific characteristics which distinguish it from other similar food or foods of the same category.

(3) The term "traditional" as used in the paragraph 2 of this Article means proven usage on the market for a time period showing transmission from one generation to another and lasting at least 25 years.

(4) A food shall not be granted an indication “Traditional Speciality Guaranteed“ if its specific character is due to its geographic origin.

**Requirements relating to food names**

Article 98

(1) To be registered with an indication “Traditional Speciality Guaranteed“, a food name shall:

– be specific in itself, or

– express the specific character of the food.

(2) A food name as referred to in the first indent of paragraph 1 of this Article must be traditional or be established by custom.

(3) A food name as referred to in the second indent of paragraph 1 of this Article may not be registered if:

– it refers only to claims of a general nature used for similar foods or if it is prescribed by specific regulations,

– it misleads the consumer as to the obvious characteristics of the food, or if it does not correspond to the specification of the food or does not meet the expectations of the consumer as regards the characteristics of the food.

(4) The name of a plant variety or breed of animal may form part of the name of the food referred to in paragraph 1 of this Article, provided that it is not misleading as regards the nature of the food.

**Procedure for granting the designation**

Article 99

(1) The procedure for the recognition of the specific character of a food, the name registration and the granting of the indication “Traditional Speciality Guaranteed“ shall be carried out by the competent authority.

(2) The procedure referred to in paragraph 1 of this Article shall be initiated by an application for recognition of the specific character of the food, the name registration and the granting of the indication “Traditional Speciality Guaranteed“.

(3) The head of the competent authority shall, by means of an implementing regulation, prescribe the manner of and the conditions for initiating and carrying out the procedure for the recognition of the specific character of a food, the name registration and the granting of the indication “Traditional Speciality Guaranteed“, as well as the level of the costs of the procedure and the publication of the documents in the Official Gazette.

**Persons entitled to submit an application**

Article 100

(1) A group of producers and/or processors is entitled to submit the application referred to in Article 99, paragraph 2, of this Act, but only for the food which it produces or processes.

(2) The term "group" as used in paragraph 1 of this Article means any association, irrespective of its legal form or composition, of producers or processors of certain food. Other interested parties may participate in the group.

**Contents of the application**

Article 101

(1) The application referred to in Article 99, paragraph 2, of this Act shall include:

– the name and address of the applicant, including information about each individual member of the group who is a producer or processor of the food in respect of which the application is submitted, and evidence proving that the requirements of the food law are satisfied,

– the specification of the food in respect of which the application is submitted,

– documents proving that the food has specific and traditional character,

– the name and address of the certification body verifying compliance.

(2) The head of the competent authority shall, by means of an implementing regulation, prescribe additional information to be included in the application, as well as the contents of the food specification referred to in paragraph 1 of this Article.

**Register and Register Book**

Article 102

(1) A food name registered as an indication “Traditional Speciality Guaranteed“shall, as of the date on which a decision on registration of the food name becomes final, be entered in

the Register of foods bearing indications “Traditional Speciality Guaranteed“, and the applicant or the members of the group who are listed in the application and who satisfy all the requirements of the food law shall, as of the date on which a decision on the right to use the registered name becomes final, be included in the Register Book of users of the registered name of the food bearing an indication “Traditional Speciality Guaranteed“.

(2) The Register and the Register Book referred to in paragraph 1 of this Article shall be maintained by the competent authority.

(3) The Register referred to in paragraph 1 of this Article shall have two lists of foods bearing an indication “Traditional Speciality Guaranteed“, according to whether or not use of the name of the food is reserved. The food name may be reserved by the applicant exclusively for the food which is produced and/or processed in accordance with the specification requirements.

(4) The head of the competent authority shall, by means of an implementing regulation, prescribe the contents and form of, and the manner of keeping, the Register and the Register Book referred to in paragraph 1 of this Article, as well as the requirements for removal from the Register or the Register Book and the requirements for reservation of the names referred to in paragraph 3 of this Article.

(5) The list of registered names shall be published in the Official Gazette.

**Cancellation of the registered name of food**

Article 103

(1) A decision on registration of a food name, referred to in Article 102, paragraph 1, of this Act, shall be cancelled if it is established that compliance with the specification requirements has not been ensured.

(2) The procedure for the cancellation of the registration, as referred to in paragraph 1 of this Article, may be initiated by the competent authority ex officio, and by any natural or legal person having legal interest and furnishing reasons in support of such a request.

(3) The head of the competent authority shall, by means of an implementing regulation, prescribe the manner of and the requirements for initiating the procedure for the cancellation of the registration, as referred to in paragraph 1 of this Article.

(4) The decision by which a decision on registration, referred to in paragraph 1 of this Article, is cancelled shall be published in the Official Gazette.

**The right to use the registered names**

Article 104

(1) A producer or processor intending to produce or process a food the specific character of which has been recognized, the name of which has been registered and to which an indication “Traditional Speciality Guaranteed“ has been granted, must submit to the competent authority an application for the right to use the registered name.

(2) The provisions of paragraph 1 of this Article shall also apply to a producer or processor who, at the time of submitting an application referred to in Article 99, paragraph 2, of this Act, was a member of a group but was not eligible to be directly included in the Register Book of users of the registered name of the food bearing an indication “Traditional Speciality Guaranteed“.

(3) On the basis of the application submitted, the head of the competent authority shall issue a decision on the right to use the registered name of the food bearing an indication “Traditional Speciality Guaranteed“.

(4) As of the date on which the decision referred to in paragraph 3 of this Article becomes final, the applicant referred to in paragraph 1 of this Article shall be included in the Register Book referred to in Article 103, paragraph 1, of this Act.

(5) The head of the competent authority shall, by means of an implementing regulation, prescribe the information that an application must contain, as well as the requirements for and the manner of acquiring the right referred to in paragraph 1 of this Article.

**Food labelling**

Article 105

(1) A food with an indication “Traditional Speciality Guaranteed“must have on its label the visible indication " Traditional Speciality Guaranteed " and must bear a symbol of traditional speciality.

(2) The head of the competent authority shall, by means of an implementing regulation, prescribe the form, size and contents of the symbol of traditional speciality.

**Amending the food specification**

Article 106

(1) The procedure for amending the specification of the food bearing an indication “Traditional Speciality Guaranteed“ is initiated by submission of an application to the competent authority.

(2) The procedure referred to in paragraph 1 of this Article may be initiated by a group of food producers and/or processors referred to in Article 100 of this Act.

(3) The application referred to in paragraph 1 of this Article must describe the amendments sought and must state the reasons for them and demonstrate legitimate economic interest.

(4) The head of the competent authority shall, by means of an implementing regulation, determine the requirements for and the manner of carrying out the procedure referred to in paragraph 1 of this Article.

**Scope of protection**

Article 107

The registered name of the food bearing an indication “Traditional Speciality Guaranteed“ shall be protected from any:

– misuse or practice liable to mislead the public and consumers, including, inter alia, practices suggesting that some other food has the same characteristics as the food bearing an indication “Traditional Speciality Guaranteed“,

– use or imitation of names registered and reserved by an applicant.

SECTION 2

**DESIGNATION OF ORIGIN AND GEOGRAPHICAL INDICATION OF FOOD**

**Designation of origin and Geographical indication**

Article 108

(1) A designation of origin is the name of a region, a specific place or, in exceptional cases, a country, used to describe a food:

– originating in that region, specific place or country,

– the quality or characteristics of which are essentially or exclusively due to particular natural and human factors of the defined geographical environment, and

– the production, processing and preparation of which entirely take place in the defined geographical area.

(2) A geographical indication is the name of a region, a specific place or, in exceptional cases, a country, used to describe a food:

– originating in that region, specific place or country, and

– which possesses a specific quality, reputation or other characteristics attributable to that geographical origin, and

– the production and/or processing and/or preparation of which take place in that geographical area.

(3) Traditional geographical or non-geographical names designating a food which originates in a specific region or a specific place may be registered as designations of origin or geographical indications, provided that such food fulfils the conditions referred to in paragraphs 1 and 2 of this Article.

(4) By way of derogation from the provisions of paragraph 1, certain geographical designations shall be registered as designations of origin where the raw materials for the

food concerned come from an area larger than, or different from, the processing area, provided that:

– the production area of the raw materials is defined,

– special conditions for the production of the raw materials exist, and

– there are inspection arrangements to ensure that the conditions referred to in the second subparagraph of this paragraph are fulfilled.

(5) The head of the competent authority shall determine raw materials referred to in paragraph 4 of this Article.

**Generic names, conflicts with names of plant varieties and animal breeds, homonyms and trademarks**

Article 109

(1) The following names may not be registered as a designation of origin or a geographical indication:

– a name which does not meet the requirements of this Act,

– a name the registration of which is liable to mislead the public and the consumers as to the true identity of the food, due to a trademark's reputation and renown and the length of time it has been used,

– a name which conflicts with the name of a plant variety or an animal breed and as a result is likely to mislead the consumer as to the true origin of the food,

– a name which, although it relates to the place or the region where the food was originally produced or marketed, has become the common name for such food (generic name).

(2) To establish whether or not a name has become generic within the meaning of the fourth indent of paragraph 1 of this Article, account shall be taken of all factors, in particular the existing situation in the geographical area in which the name originates and in areas of consumption.

(3) A name wholly or partially homonymous with a name already registered in accordance with this Act shall be registered with due regard for local and traditional usage and the actual risk of misleading the public and consumers. In particular:

– a homonymous name which misleads the public and consumers into believing that the food comes from another territory shall not be registered even if the name is accurate as far as the actual territory, region or place of origin of the food is concerned;

– when using of a registered homonymous name, care must be taken that there is a sufficient distinction in practice between the homonym registered subsequently and the name already on the register, having regard to the need to treat the producers concerned in an equitable manner and not to mislead the public and consumers.

(4) Registered names may not become generic during the period of protection.

**Procedure for the registration of a food name**

Article 110

(1) The procedure for the registration of a food name as a designation of origin or a geographical indication shall be carried out by the competent authority.

(2) The procedure referred to in paragraph 1 of this Article shall be initiated by submission of an application for the registration of a food name as a designation of origin or a geographical indication.

(3) The head of the competent authority shall, by means of an implementing regulation, prescribe the manner of and the conditions for initiating and carrying out the procedure referred to in paragraph 1 of this Article, as well as the level of the costs of the procedure and the publication of the documents in the Official Gazette.

**Persons entitled to submit an application**

Article 111

(1) A group of producers and/or processors is entitled to submit the application referred to in Article 110, paragraph 2, of this Act, but only for the food which it produces or processes.

(2) The term "group" as used in paragraph 1 of this Article means any association, irrespective of its legal form or composition, of producers and/or processors of certain food. Other interested parties may participate in the group.

(3) The head of the competent authority shall, by means of an implementing regulation, determine the conditions under which natural or legal persons can be considered as a group referred to in paragraph 2 of this Article.

**Contents of the application**

Article 112

(1) The application referred to in Article 110, paragraph 2, of this Act shall include:

– the name and address of the applicant, including information about each individual member of the group who is a producer or processor of the food in respect of which the application is submitted, and evidence proving that the requirements of the food law are satisfied,

– the specification of the food in respect of which the application is submitted,

– a single document setting the main points of the specification.

(2) The head of the competent authority shall, by means of an implementing regulation, prescribe additional information to be included in the application, as well as the contents of the food specification and single document referred to in paragraph 1 of this Article.

**Registers and Register Books**

Article 113

(1) A food name registered as a designation of origin or a geographical indication shall, as of the date on which a decision on registration becomes final, be entered in the Register of designations of origin or the Register of geographical indications, and the applicant or the members of the group who are listed in the application and who satisfy all the requirements of the food law shall, as of the date on which a decision on the right to use the registered name becomes final, be included in the Register Book of users of the registered designations of origin or the Register Book of users of the registered geographical indications, which are kept by the competent authority

(2) The head of the competent authority shall, by means of an implementing regulation, prescribe the contents and form of, and the manner of keeping, the Registers and the Register Books referred to in paragraph 1 of this Article, as well as the requirements for removal from the Registers or the Register Books.

(3) The list of food names registered as designations of origin or food names registered as geographical indications shall be published in the Official Gazette.

**Cancellation of the registered name of food**

Article 114

(1) A decision on registration of a food name as a designation of origin or a geographical indication shall be cancelled if it is established that compliance with the specification requirements has not been ensured.

(2) The procedure for the cancellation of the registration, as referred to in paragraph 1 of this Article, may be initiated by the competent authority ex officio, and by any natural or legal person having legal interest and furnishing reasons in support of such a request.

(3) The head of the competent authority shall, by means of an implementing regulation, prescribe the manner of and the requirements for initiating the procedure for the cancellation of the registration as provided for in paragraph 1 of this Article.

(4) The decision by which a decision on registration, referred to in paragraph 1 of this Article, is cancelled shall be published in the Official Gazette.

**The right to use the registered names**

Article 115

(1) The procedure for acquiring the right to use a food name registered as a designation of origin or a geographical indication shall be initiated by submission an application to the competent body.

(2) The application referred to in paragraph 1 of this Article may be submitted by any producer and/or processor who satisfy the requirements stated in the specification for the food concerned.

(3) On the basis of the application submitted, the head of the competent authority shall issue a decision on the right to use the food name registered as a designation of origin or a geographical indication.

(4) As of the date on which the decision referred to in paragraph 3 of this Article becomes final, the applicant referred to in paragraph 2 of this Article shall be included in the Register Books referred to in Article 113, paragraph 1, of this Act.

(5) The head of the competent authority shall, by means of an implementing regulation, prescribe the information that an application must contain, as well as the requirements for and the manner of acquiring the right referred to in paragraph 1 of this Article.

**Food labelling**

Article 116

(1) A food the name of which is registered as a designation of origin or a geographical indication must have on its label the visible indication " DESIGNATION OF ORIGIN" or " GEOGRAPHICAL INDICATION" and must bear a symbol.

(2) The head of the competent authority shall, by means of an implementing regulation, prescribe the form, size and contents of the symbol referred to in paragraph 1 of this Article.

**Amending the food specification**

Article 117

(1) A group satisfying the conditions of Article 111 of this Act and having a legitimate interest may initiate the procedure for amending a specification, in particular to:

– take account of developments in scientific and technical knowledge, or

– redefine the geographical area stated in the specification.

(2) The procedure referred to in paragraph 1 of this Article shall be initiated by submission of an application for amendments to the specification. The application must contain information on the applicant and must describe and give reasons for the amendments requested.

(3) The head of the competent authority shall, by means of an implementing regulation, determine the requirements for and the manner of carrying out the procedure referred to in paragraph 2 of this Article, as well as the procedure to be followed when the amendment application affects the single document.

**Scope of protection**

Article 118

(1) Food names registered as designations of origin or geographical indications shall be protected against:

– any direct or indirect commercial use of a registered name in respect of food not covered by the registration in so far as that food is comparable to the food registered under that name or in so far as using the name exploits the reputation of the protected name,

– any misuse, imitation or evocation, even if the true origin of the food is indicated, or if the protected name is translated or accompanied by an expression such as "style", "type", "method", "as produced in", "imitation" or similar,

– any other false or misleading indication as to the provenance, origin, nature or essential properties of the food, on the inner or outer packaging, advertising material or documents relating to the food concerned, and the packing of the food in a container liable to convey a false impression as to its origin,

– any other practice liable to mislead the consumer as to the true origin of the food.

(2) Where a registered name contains within it the name which is considered generic, the use of that generic name for the appropriate food shall not be considered to be contrary to paragraphs 1 and 2 of paragraph 1 of this Article.

**Relations to trademarks**

Article 119

(1) Where a food name is registered as a designation of origin or a geographical indication in accordance with this Act, the application for registration of a trademark corresponding to one of the situations referred to in Article 118 of this Act and relating to the same type of food shall be refused if the application for registration of the trademark is submitted after the date of submission of the application for the registration of the food name.

(2) A trademark the use of which corresponds to one of the situations referred to in Article 118 of this Act which has been registered in good faith in accordance with a specific regulation, before the date of submission of an application for registration of a food name as a designation of origin or a geographical indication, may continue to be used provided that no grounds for its invalidity or revocation exist.

SECTION 3

**OTHER PROVISIONS**

**International registration**

Article 120

(1) International registration of food names registered as indications “Traditional Speciality Guaranteed”, designations of origin or geographical indications shall be carried out on the basis of an international agreement on mutual protection of food names registered as indications “Traditional Speciality Guaranteed”,, designations of origin or geographical indications, which are binding on the Republic of Croatia.

(2) A name that is not registered or no longer used in the country of origin, may not be registered as an indication “Traditional Speciality Guaranteed”,, a designation of origin or a geographical indication in the Republic of Croatia.

**Civil protection**

Article 121

The provisions of specific regulations governing geographical indications and designations of origin of products and services shall apply to civil protection of food names registered as indications “Traditional Speciality Guaranteed”,, designations of origin or geographical indications.

**Verification of compliance with food specifications**

Article 122

(1) Verification of compliance of a food with its specification shall be carried out before the application referred to in Article 99, paragraph 2 and Article 110, paragraph 2, of this Act is submitted and during the registration of the food name.

(2) Verification of compliance referred to in paragraph 1 of this Article shall be carried out by legal persons (hereinafter: certification bodies) authorised by the head of the competent authority.

(3) Certification bodies referred to in paragraph 2 of this Article must be accredited in accordance with the requirements of the relevant Croatian standard.

(4) The costs of verification of compliance shall be determined by certification bodies, with the consent of the competent authority, and shall be borne by the applicant or users of designations or indications.

(5) The head of the competent authority shall, by means of an implementing regulation, determine the conditions that certification bodies must meet, the time period within which the requirements of paragraph 3 must be satisfied, the procedure for verifying compliance as

well as the obligations of certification bodies in the procedure referred to in paragraph 1 of this Article.

(6) The list of certification bodies shall be published in the Official Gazette.

(7) The competent authority shall supervise the work of certification bodies.

**Protection of designations and indications for spirit drinks and aromatised spirit drinks**

Article 123

(1) The provisions of this Act governing indications “Traditional Speciality Guaranteed”,, designations of origin and geographical indications shall not apply to spirit drinks and aromatised spirit drinks.

(2) Protection of geographical indications and indications “Traditional Speciality Guaranteed”, of spirit drinks and aromatised spirit drinks shall be regulated by an implementing regulation issued by the head of the competent authority.

(3) Spirit drinks and aromatised spirit drinks having a protected designation or indication in accordance with the regulation referred to in paragraph 2 shall be included in the list of spirit drinks and aromatised spirit drinks, which is published in the Official Gazette.

CHAPTER XI
PENAL PROVISIONS

Article 124

(1) A legal person shall be guilty of a misdemeanour and fined from HRK 100 000.00 to HRK 500 000.00 for:

– placing on the market novel foods, GM food or GM feed in contravention of Article 90, paragraph 1, of this Act,

– failing to ensure traceability and labelling of GM food and GM feed and traceability of novel foods as required by Article 93 of this Act.

(2) The responsible person of the legal person shall be fined from HRK 5 000.00 to HRK 10 000.00 for committing a misdemeanour from paragraph 1 of this Article.

(3) A natural person shall be also fined from HRK 5 000.00 to HRK 10 000.00 for committing a misdemeanour from paragraph 1 of this Article.

Article 125

(1) A legal person shall be guilty of a misdemeanour and fined from HRK 50 000.00 to HRK 100 000.00 for:

– importing food contrary to Article 11 of this Act,

– placing food on the market contrary to Article 14, paragraph 1 of this Act,

– acting in contravention of the provisions of Article 15 of this Act,

– placing feed on the market contrary to Article 16, paragraph 1 of this Act,

– labelling, advertising, and presenting food and feed contrary to Article 17, paragraphs 1 and 2, of this Act,

– advertising alcoholic drinks contrary to Article 18 of this Act,

– failing to ensure food and feed traceability as required by Article 20 of this Act,

– failing to act in accordance with Article 21 of this Act,

– failing to act in accordance with Article 22 of this Act,

– failing to act in accordance with Article 50, paragraphs 1, 4, 5 and 6, of this Act,

– failing to establish and implement regular checks on hygiene conditions of production in accordance with Article 51 of this Act,

– failing to act in accordance with Article 52 of this Act,

– carrying out its activities in contravention of Article 54 of this Act,

– acting contrary to the provisions of the regulations referred to in Article 56 of this Act,

– failing to act in accordance with Article 58 of this Act,

– acting contrary to Article 59 of this Act,

– acting contrary to Article 60 of this Act,

– failing to act in accordance with Article 61 of this Act,
– carrying out its activities in contravention of Article 63 of this Act,
– acting contrary to the provisions of the regulations referred to in Article 65 of this Act,
– failing to enable official control to be performed effectively in accordance with Article 79 of this Act.

(2) The responsible person of the legal person shall be fined from HRK 5 000.00 to HRK 10 000.00 for committing a misdemeanour from paragraph 1 of this Article.

(3) A natural person shall be also fined from HRK 5 000.00 to HRK 10 000.00 for committing a misdemeanour from paragraph 1 of this Article.

Article 126

(1) A legal person shall be guilty of a misdemeanour and fined from HRK 30 000.00 to HRK 70 000.00 for:
– placing food on the market contrary to Article 94, paragraphs 1 and 4, of this Act,
– carrying out its activities in the establishment contrary to Article 95 of this Act,
– acting contrary to Article 96, paragraphs 1 and 2, of this Act,
– using the registered name of a food bearing an indication “Traditional Speciality Guaranteed”,, contrary to Article 102, paragraph 1, of this Act,
– using the registered name of a food bearing an indication “Traditional Speciality Guaranteed”,, in respect of which a decision referred to in Article 103, paragraph 1, of this Act has been made,
– using the registered name of a food bearing an indication “Traditional Speciality Guaranteed”,, contrary to Article 104, paragraph 4, of this Act,
– labelling food contrary to Article 105, paragraph 1, of this Act,
– using the name of a food bearing an indication “Traditional Speciality Guaranteed”,, contrary to Article 107 of this Act,
– using a food name registered as a designation of origin or a geographical indication, contrary to Article 113, paragraph 1, of this Act,
– using a food name registered as a designation of origin or a geographical indication, in respect of which a decision referred to in Article 114, paragraph 1, of this Act has been made,
– using a food name registered as a designation of origin or a geographical indication, contrary to Article 115, paragraph 4, of this Act
– labelling food contrary to Article 116, paragraph 1, of this Act,
– using the registered food name contrary to Article 118, paragraph 1, of this Act,
– using a trademark contrary to the provision of Article 119, paragraph 1, of this Act,
– using geographical indications or indications “Traditional Speciality Guaranteed”, for spirit drinks and aromatised spirits drinks contrary to the regulation referred to in Article 123, paragraph 2, of this Act.

(2) The responsible person of the legal person shall be fined from HRK 5 000.00 to HRK 10 000.00 for committing a misdemeanour from paragraph 1 of this Article.

(3) A natural person shall be also fined from HRK 5 000.00 to HRK 10 000.00 for committing an offence from paragraph 1 of this Article.

CHAPTERXII

## TRANSITIONAL AND FINAL PROVISIONS

Article 127

(1) The head of the competent authority and the minister responsible for health shall, within two years from the date of entry into force of this Act, issue regulations pursuant to authority granted to them by this Act.

(2) For the purposes of alignment with European Union legislation, the head of the competent authority, or the minister responsible for health following the consent of the head of the competent authority, may issue other regulations necessary for the implementation of this Act, in addition to those specified in particular Articles of this Act.

Article 128

Pending the issuance of regulations referred to in Article 127 of this Act, the regulations issued or taken over in accordance with the Food Act (Official Gazette 117/03, 130/03, 48/04 and 85/06), the Veterinary Act (Official Gazette 70/97, 105/01 and 172/03), the Livestock Act (Official Gazette 70/97, 36/98, 151/03 and 132/06), the Act on the technical requirements and conformity assessment (Official Gazette 158/03) shall remain in force.

Article 129

(1) The Government of the Republic of Croatia shall appoint the members of the Management Board of the Agency within thirty days from the date of entry into force of this Act.

(2) The Management Board of the Agency shall appoint the Director and the Deputy Director of the Agency within thirty days from the date of entry into force of this Act.

Article 130

(1) The Agency shall bring its activities and legislation into compliance with the provisions of this Act within ninety days from the date of entry into force of this Act.

(2) The Management Board of the Agency shall appoint the members of the Advisory Forum within ninety days from the date of entry into force of this Act.

Article 131

No authorisation for the placing on the market of novel foods, GM food and GM feed, referred to in Article 90 of this Act, shall be granted until implementing regulations referred to in Article 90, paragraph 4, of this Act are issued.

Article 132

Food names registered as designations of origin or geographical indications prior to the entry into force of this Act shall be valid and recognized until a decision referred to in Article 113, paragraph 1, of this Act is issued, but not later than 31 December 2008.

Article 133

(1) No appeal can be lodged against a decision issued under this Act, but an administrative dispute may be initiated.

(2) The lodging of a claim against the decision referred to in paragraph 1 of this Act shall not involve suspension of the execution of the decision.

Article 134

(1) Food business operators and feed business operators shall bring their activities into compliance with the provisions of Article 51, paragraph 1, Article 52, paragraph 1, Article 60, paragraph 1, Article 61, paragraph 1 and Article 95, paragraphs 1 and 2, of this Act by 1 January 2009, unless otherwise provided for by a special regulation.

(2) Official laboratories and reference laboratories must satisfy the requirements of Article 81, paragraph 2, of this Act by 1 January 2009 at the latest.

Article 135

Pending the establishment of the food quality inspection service referred to in Article 86, paragraph 5, of this Act, official controls on food bearing a protected geographical indication, designation of origin and indication “Traditional Speciality Guaranteed”, shall be carried out by trade inspectors, at the level of production, processing and retail sale, in accordance with the provisions of the Food Act (Official Gazette 117/03, 130/03, 48/04 and 85/06).

Article 136

(1) The Food Act (Official Gazette 117/03, 130/03, 48/04 and 85/06) shall cease to have effect by virtue of the entry into force of this Act.

(2) The provisions of the Act on Genetically Modified Organisms (Official Gazette 70/05), the provisions of the Consumer Protection Act (Official Gazette 90/03) and the provisions of the Act on Sanitary Inspection (Official Gazette 27/99) which are in conflict with the provisions of this Act shall cease to have effect by virtue of the entry into force of this Act.

Article 137

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette, with the exception of the provision of Article 57, paragraph 5 and Article 77 of this Act, which shall enter into force on the date of the accession of the Republic of Croatia to the European Union.

Class: 310-26/07-01/01
Zagreb, 20 April 2007.

THE CROATIAN PARLIAMENT
The President
of the Croatian Parliament
**Vladimir Šeks**, m.p.