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Trade Policy Monitoring

English Text of Draft Croatian Food Law

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Report Highlights:

The Croatian government recently released a draft food law that covers, among other things, foods made from genetically modified organisms. The attached unofficial English translation was commissioned by the USDA/FAS office in Zagreb.

Includes PSD changes: No
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Vienna [AU1], HR

**MINISTRY OF AGRICULTURE AND FORESTRY OF THE REPUBLIC
OF CROATIA**

DRAFT

PROPOSED BILL ON FOOD

Zagreb, March 2003

[the following was not marked for translation and was omitted:

I THE CONSTITUTIONAL BASIS FOR THE PREPARATION OF THE BILL

**II THE EVALUATION OF THE SITUATION, THE MAIN ISSUES THE LAW SHOULD REGULATE,
AND THE CONSEQUENCES THAT WILL RESULT FROM THE PASSING OF THE BILL**

1. THE EVALUATION OF THE SITUATION

**The Normative Situation in the Sphere of Safety (Health Safety) and Quality
of Food and Cattle Feed**

**The Institutions in Charge of Legislation Regarding Food and Cattle Feed and
of Implementing Laws and Bylaws -- the Present System of Control of Food and Cattle Feed**

Border Inspections

Laboratory Analyses

The Reasons the Bill on Food Should Be Endorsed

European Union's Regulations and Guidelines]

2. THE MAIN ISSUES REGULATED BY THE BILL

The bill regulates the following issues:

- general principles and requirements concerning the safety of food and cattle feed;
- the responsibilities of the relevant persons in the food business and cattle feed business with regard to the safety of food and cattle feed;
- general requirements concerning the quality of food and cattle feed;
- general requirements for the protection of the marks of geographical origin, the marks of

- originality of food, and the marks of the food's traditional repute;
- general requirements concerning labeling or marking food and cattle feed;
 - general conditions for placing new food on the market;
 - general conditions for placing cattle feed that contains or consists of genetically modified organisms on the market;
 - the official control system;
 - the official research laboratories and reference laboratories;
 - crisis management and emergencies management;
 - the establishment of the Croatian Food Agency;
 - the authority and responsibilities of the relevant bodies with regard to the food and cattle feed that is produced in the Republic of Croatia and imported into the Republic of Croatia and placed on its market;
 - penalty clauses.

3. THE EFFECTS OF THE ENDORSEMENT OF THE BILL

The endorsement of the Bill on Food, that is, the new organization of inspection and control of food products, will secure the preconditions for the improvement of the strategic management of food safety. By founding the Food Agency, which will analyze the risks based on scientific foundations and which will take care of the food control problems by way of a distribution chain through all the production sectors, the Republic of Croatia will establish an institution or authority in charge of food safety.

Moreover, the new approach will result in a more efficient use of food control instruments, improve the level of information on food risks, and reduce the differences in the inspection standards, while the problem of food safety will be clearly separated from economic issues with regard to market standards for food (quality).

The establishment of the Food Agency with appropriate scientific leadership and taking into account the interest of the consumers and the industry will ensure the food safety policy being aimed at the key problems and facilitate speedy action with regard to appearance of new hazards in food or cattle feed.

The Food Agency will also be involved in the development of legislation on food and will advise the relevant ministries as to the adoption of the regulations aimed at harmonization with the EU, which will result in better coordination of the operation of the relevant bodies in charge of developing new legislation concerning food safety.

Generally speaking, the quality of food will not be a subject of regulations as is presently the case; instead, consumer protection will be ensured by way of regulations that relate to product labeling, presentation, and advertising. The cases in which the following actions are clearly justified will be the exceptions:

- protection of consumers from obvious fraud;
- regulation of the market of certain food products;
- promotion of the internal or external market for special products (organic food, geographical origin or originality of food, traditional repute);
- harmonization with the vertical regulations for food products that are in force in the EU and that set the food quality standards.

The existing regulations that regulate the basic quality requirements of nearly all food products will, in agreement with the food processing industry, gradually be annulled, depending on the adoption

of new regulations that will be harmonized with the EU's horizontal and vertical regulations. Food will no longer be subject to obligatory certification (issuing of quality certificates) before it is placed on the market; instead, food quality control will be taking place in retail trade by way of inspection of the label and other documentation and, if necessary, by taking samples that will be consequently sent for analysis in order to confirm the contents of the label. Certain types of food products will still be subject to control in the course of the production process, that is, before they are placed on the market (wine, spirits, milk, and other products that warrant this.) The Proposed Bill will facilitate the Republic of Croatia joining the European integration processes and its meeting the current and future obligations.

III EVALUATION AND THE SOURCES OF THE FUNDS NECESSARY FOR THE IMPLEMENTATION OF THE LAW

At the moment the Republic of Croatia does not have a separate budget item intended for food safety. However, funds for this purpose are secured within the framework of the budget items of the Ministry of Health and the Ministry of Agriculture and Forestry, both for inspection activity (inspectors within the ministries) and for certain professional and analytical activity that institutes carry out for the ministries and inspectorates.

According to a rough estimate (taking into account the employed inspectors and the funds of the Ministry of Health and the Ministry of Agriculture and Forestry), the amount that is spent on food control is 37 million [kuna] from the budgetary funds. Of this amount nearly 33 million kuna is spent on the official control inspection system. It is important to note that the budget expenditure of 37 million kuna does not represent the real expenditure for food control. The food processing industry makes a considerable contribution to the real amount of the expenses by paying for the inspection fees for certificates. It has been estimated that the industry pays at least 133 million kuna per year for food safety control.

The establishment of the Food Agency will, through the next three years, require securing funds from the state budget. After this period the Food Agency will also take over the relevant food control inspections and begin to derive the necessary funds from its own sources (fees for the approval of facilities and additional fees for import and export certificates). However, it is important to note that the establishment of the Food Agency does not envisage employing new personnel unless necessary. The civil servants and inspectors from some of the state administration bodies (Ministry of Agriculture and Forestry and the Ministry of Health) and from other relevant state institutions are to be transferred to the Food Agency. Moreover, the existing laboratories of the Croatian Public Health Institute and the Croatian Veterinary Institute will carry out research into official food control and risk assessment and monitor food safety, for which some funds have already been secured in the state budget.

It will therefore be possible to re-channel certain funds for the operation of the Food Agency from the budget of the Ministry of Agriculture and Forestry and the Ministry of Health, since the ministries cover the current costs of food safety control. Moreover, in addition to the fact that after the period of three years the new system envisages the industry's payment directly to the Food Agency, the industry would thus contribute two thirds of the funds necessary for the operation of the Food Agency.

Therefore, it is possible to organize the operation of the Food Agency without increasing the state budget and with decreasing the inspection fees that are paid by the food processing industry.

However, it is necessary to plan the amount of the funds for the so-called restructuring costs and for the income deficit that will be present until the new system is fully installed, that is, in the initial stages of the operation of the Food Agency.

The funds in the amount of 9,000,000.00 kuna have therefore been secured in the 2003 state budget of the Republic of Croatia for the implementation of the law, that is, for the establishment of the Food Agency.

IV TEXT OF THE DRAFT PROPOSED BILL WITH THE EXPLANATION

The text of the Draft Proposed Bill on Food is provided in the form of a draft proposed bill with an explanation.

THE DRAFT PROPOSED BILL ON FOOD

I GENERAL PROVISIONS

Article 1

This Law regulates the following:

- general principles and requirements concerning the safety of food and cattle feed;
- the responsibilities of the relevant persons in the food business and cattle feed business with regard to the safety of food and cattle feed;
- general requirements concerning the quality of food and cattle feed;
- general requirements for protecting the marks of geographical origin, the marks of originality of food, and the marks of the food's traditional repute;
- general requirements concerning labeling or marking food and cattle feed;
- general conditions for placing new food on the market;
- general conditions for placing cattle feed on the market that contains or consists of genetically modified organisms;
- the official control system;
- the official research laboratories and reference laboratories;
- crisis management and emergencies management;
- the establishment of the Croatian Food Agency;
- the authority and responsibilities of the relevant bodies with regard to food and cattle feed that is produced in the Republic of Croatia and imported into the Republic of Croatia and placed on its market;

with the aim to protect human health and consumer interests, taking into account the diversity in food supply, including traditional products, and ensuring efficient functioning of the market of the Republic of Croatia.

Article 2

- 1) The provisions of this Law shall be applied to all the stages of production, processing, and distribution of food and cattle feed.
- 2) The provisions of this Law shall not be applied to primary production, preparation, handling, or storing food in households and intended for personal consumption in the household.

Article 3

The Definition of Food

- 1) For the purposes of this Law, "food" (or "foodstuffs") is any substance or product -- processed, partially processed, or not processed -- that is intended or that can be expected to be intended for human consumption.
- 2) The term, food, includes beverages, chewing gum, additives, and any other substances that

are intentionally incorporated in food in the course of production, preparation, or processing.

- 3) The term, food, also includes water, as follows:
 - the water that is used for public supply of the population as drinking water;
 - the water that is used and/or incorporated in food during production, preparation, or processing;
 - the water packed in original packaging as table water, mineral water, and spring water.
- 4) The term, food, does not include the following:
 - cattle feed;
 - live animals, unless they are to be placed on the market as food;
 - plants before they are harvested or picked;
 - medicine and medicinal products in line with a special regulation;
 - objects for general use in line with a special regulation;
 - tobacco and tobacco products in line with a special regulation;
 - narcotics or psychotropic substances within the framework of the meaning taken from the UN Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971;
 - residues and contaminants.

Article 4

Other Definitions

For the purposes of this Law the terms listed below have the following meanings:

- 1) "food business" -- a business operation regardless of whether it was conducted with the aim to make profit, public or private, within the framework of which activities regarding any stage of production, processing, and distribution of food are carried out;
- 2) "person in charge of the food business" -- physical person or the designated person within the legal person registered for carrying out activities connected to the food business, who is in charge of securing unobstructed implementation of the Law in the business section they manage;
- 3) "cattle feed" -- any substance or product, including additives, that is processed, partially processed, or not processed, and that is intended for feeding animals that produce food or are used for food production;
- 4) "cattle feed business" -- a business operation regardless of whether it was conducted with the aim to make profit, public or private, within the framework of which activities regarding any stage of production, processing, storage, transport, and distribution of cattle feed are carried out, which includes production, processing, and storage of cattle feed intended to feed animals on one's estate;
- 5) "person in charge of the cattle feed business" -- physical person or the designated person within the legal person registered for carrying out activities connected to the cattle feed business, who is in charge of securing unobstructed implementation of the Law in the business section they manage;
- 6) "relevant bodies" -- the Croatian Food Agency, the Ministry of Agriculture and Forestry, and the Ministry of Health;
- 7) "retail trade" -- handling food and/or its preparation and storage at the selling point or the

point of delivery to the end consumer. It includes supply of prepared food (catering), institutional food supply, catering facilities in which food is served, stationary and mobile food kiosks, stores, and wholesale points;

8) "market placement" -- keeping food or cattle feed for the purpose of sale, which includes supply and sale or any other form of transfer -- regardless of whether it is free -- distribution, and other forms of transfer, on the territory of the Republic of Croatia;

9) "risk" -- the probability and degree of harmful effects on human health;

10) "risk analysis" -- a process that comprises three mutually connected components: risk assessment, risk management, and risk notification;

11) "risk assessment" -- a scientifically based process involving four stages: hazard identification, hazard characterization, assessment of exposure, and risk characterization;

12) "risk management" -- a process of reexamining alternative positions in cooperation with the interested parties, taking into account risk assessment and legal options, and, if necessary, the process of selecting appropriate preventive measures and control measures;

13) "risk notification" -- an interactive exchange of information and opinions -- among the risk assessors, the persons responsible for risk management, consumers, producers of food and cattle feed, the academic community, and other interested parties -- in the course of the entire risk analysis process, concerning hazards and risks, risk-related factors and the concepts of risk, which includes explanations of the findings following risk assessment and the basis for making decisions in risk management;

14) "hazard" -- biological, chemical, or physical substance in food or cattle feed or the condition of food and cattle feed that may potentially have a harmful effect on human health;

15) "traceability" -- the possibility of tracing food, cattle feed, an animal that produce food or serve for the production of food, a primary good, or a substance that is intended to be incorporated or is expected to be incorporated in food or cattle feed, through all the stages of production, processing, and distribution;

16) "the stage of production, processing, and distribution" -- any stage, including import and primary production, processing, storage, transport, sale, or supply of the end consumer with food, and, where relevant, import, production, manufacture, storage, transport, distribution, and sale of cattle feed and cattle feed supply;

17) "primary production" -- production and breeding, raising, and growing primary agricultural products resulting from growing plants, breeding cattle, and fishing -- including harvesting and picking the produce, milking and breeding animals prior to slaughter, hunting and fishing, and collection of wild fruits and plants;

18) "end consumer" -- a physical person who procures food to meet their own needs and does not use it in any of the stages of the food business;

19) "official control" -- the control of the safety and quality of food and cattle feed the aim of which is to establish whether the provisions of this Law are observed;

20) "safety" -- the harmlessness of food and cattle feed to human health and the health of animals with regard to the presence of biological, chemical, or physical substances in food and cattle feed;

21) "quality" -- the overall characteristics of food that contribute to its ability to meet the needs of the end consumers and the overall characteristics of cattle feed;

22) "labeling" (or "marking") -- written marks, manufacturers' brands, trademarks, brand names, images, or symbols that relate to food and cattle feed and are put on the packaging, sticker, or tag;

23) "new food" -- the food and food ingredients that have not yet been used for nutrition by the

people in the Republic of Croatia.

II GENERAL PRINCIPLES

1. The Principles of Risk Analysis

Article 5

Risk Assessment

- 1) In order to achieve the main aim, which is a high level of protection of human health and life, the measures that are applied in line with this Law are based on risk assessment except when this is not appropriate with regard to circumstances or the nature of the measure.
- 2) Risk assessment is based on available scientific evidence and is carried out in an independent, objective, and transparent way.
- 3) Risk assessment is carried out by the Croatian Food Agency.

Article 6

Risk Notification

Risk notification is carried out by the Food Agency in order for the subjects listed below to receive prompt, reliable, objective, and intelligible information on the hazards, that is, the risks related to food or cattle feed:

- the Ministry of Agriculture and Forestry or the Ministry of Health, depending on whose jurisdiction the issue is within;
- authorized persons in charge of official control of the safety of food and cattle feed;
- relevant persons in the food business and cattle feed business;
- consumers.

Article 7

Risk Management

- 1) Risk management facilitates the preventive measures and the control measures, which are taken with the aim to reduce, eliminate, or avoid risks to human health that are present in the process of food consumption, being based on the results of risk assessment and being efficient, impartial, and appropriate.
- 2) Risk management is carried out by the relevant bodies.

Article 8

2. The Principle of Precaution

- 1) Under special circumstances in which, following an assessment of the available information,

the possibility of harmful effects of food on human health is identified but scientific dilemmas are present, the relevant bodies may take temporary risk management measures that are necessary to secure a high level of protection of human health until further scientifically based information necessary for a comprehensive risk assessment is available.

- 2) The measures taken on the basis of Paragraph 1 of this Article must be appropriate and must not limit trade any more than is necessary to achieve a high level of protection of human health, taking into account the established facts and the technical and economic feasibility of the measures.
- 3) The measures that are taken must be reconsidered within a period set depending on the nature of the identified risk to human lives and health and on the type of scientifically based information that is necessary to clarify scientific dilemmas and to carry out a comprehensive risk assessment.

Article 9

3. The Principle of Transparency

- 1) In the course of preparing, evaluating, and revising the risk management measures, the Food Agency must -- directly or through authorized representatives of consumers or other interest groups -- carry out open and transparent public consultations, except in the cases when urgency precludes this.
- 2) In case a reasonable doubt is present that food, that is, cattle feed, may present a risk to the health of people or animals, the Food Agency -- depending on the nature, seriousness, and scope of the risk -- shall take measures to inform the public of the nature of the health risk.
- 3) In the case presented in Paragraph 2 of this Article it is necessary to identify, to the maximum extent possible, the food or cattle feed, the risk it represents, and the measures that have been taken or will be taken to prevent, reduce, or eliminate the risk.

Article 10

4. Protection of Consumer Interests

- 1) The interests of the consumer must be protected to the maximum extent possible.
- 2) The Law on Food and the implementation regulations are aimed toward protecting the consumer and shall provide the basis for the consumers to be fully informed about the food they are to consume, that is, they shall facilitate the consumer's selecting the food.
- 3) The aim of the regulation stated in Paragraph 2 of this Article is to prevent the following:
 - fraud or misleading actions in the food business;
 - adulteration of food;
 - any other action that may mislead the consumer.

III THE GENERAL REQUIREMENTS CONCERNING THE SAFETY OF FOOD AND CATTLE FEED

1. The Requirements Concerning Food Safety

Article 11

- 1) Placing unsafe food on the market is not permitted.
- 2) Food shall be considered unsafe, that is, harmful to human health, and unsuitable for human consumption in the following cases:
 - if it contains biological, chemical, or physical substances of various origins that are potentially harmful to human health;
 - if it contains food additives that are not allowed or are not allowed for that particular type of food, or if the quantity of the additives exceed the maximum quantity allowed;
 - if its nutritive composition is changed, that is, if it does not contain the set quantities of nutrients and is intended for persons with special dietary needs, or if it may have a negative effect on human health for some other reason.

Article 12

- 1) In deciding whether food is unsafe, the following shall be taken into account:
 - the conditions in each stage of production, processing, and distribution of food and the conditions of its use by the end consumer;
 - the information provided to the end consumer, including the data on the label and the information that is generally available to the end consumer about avoiding specific harmful effects of certain food or a food category on human health.
- 2) In deciding whether food is harmful to human health the following shall be taken into account:
 - possible direct or indirect, short-term or long-term effects of the food on the health of the person who consumes it and its effect on the future generations;
 - possible cumulative toxic effect;
 - special health sensitivity of a specific category of consumers for whom the food is intended.
- 3) In deciding whether food is not fit for human consumption, the fact whether the food is not fit for its intended use because it is contaminated by either an external factor or in some other way -- because rotting, spoiling, or decomposition is involved -- shall be taken into account.
- 4) When unsafe food is part of a production batch or shipment, it shall be assumed that all the food from the batch is unsafe unless the contrary is established following a laboratory analysis and superanalysis.

Article 13

The Ministry of Health and the Ministry of Agriculture and Forestry shall, in keeping with Appendix 1 to this Law, take the measures of limiting the placement of the food on the market, that is, they will demand that the food be recalled from the market when a suspicion about the safety of the food is present.

Article 14

- 1) Semi-perishable food may, after its best-before date, be sold or donated based on the approval issued by the Ministry of Agriculture and Forestry and the Ministry of Health, depending

on whose jurisdiction the issue is within.

- 2) The food mentioned in Paragraph 1 of this Article must be accompanied by a prominent notice saying that its best-before date has expired but that it is still safe for consumption.
- 3) The list of the food, the terms of submitting applications, and the conditions for receiving approval for sale or donation of the food mentioned in Paragraph 1 of this Article shall be prescribed by the minister of health in collaboration with the minister of agriculture and forestry.

2. The Requirements Concerning the Safety of Cattle Feed

Article 15

- 1) Placing unsafe cattle feed on the market is not permitted.
- 2) Cattle feed shall be considered unsafe if it has a harmful effect on the health of animals that produce food or are used to produce food and if it makes the food that the animals produce or that is produced from them unsafe for human consumption.
- 3) When the cattle feed that does not meet safety requirements is part of a production batch or shipment, it shall be assumed that all the cattle feed from the batch is unsafe unless the contrary is established following a laboratory analysis.

Article 16

- 1) The Ministry of Agriculture and Forestry shall, in line with Appendix 1 to this Law, take the measures of limiting the placement of the food on the market, that is, they shall demand that the food be recalled from the market when suspicion about the safety of the food is present.
- 2) The minister of agriculture and forestry shall prescribe the implementation regulations that shall determine the following:
 - the requirements concerning the safety of cattle feed;
 - the sanitary conditions and actions in cattle feed business;
 - the introduction of internal control systems and their implementation on the part of a person in charge of the cattle feed business with the aim to ensure the safety of cattle feed that is placed on the market;
 - prescribing the conditions concerning expert personnel, rooms, and equipment that the laboratories for conducting analyses and superanalyses of cattle feed must meet;
 - introducing a ban or limited use of certain primary goods in the production of cattle feed that originate from sources specific for the type of animal, place of origin, its nature, the subsequent processing, or other characteristics;
 - prescribing other conditions concerning cattle feed that are established to be necessary in order to ensure that cattle feed meets the safety requirements.

3. Regulations Concerning Food Safety

Article 17

The minister of agriculture and forestry and the minister of health shall prescribe the implementation regulations that may:

- order, ban, or regulate the presence of any toxic or other specific substance in food

that may be harmful to human health;

- ensure that the food is fit for human consumption and that it meets the microbiological and other conditions set by the regulations;
- prescribe the types and the permitted quantities of additives in the food;
- prescribe the safety conditions of the water that is used for public supply of the population as drinking water or as water that is used in the production of food that is to be placed on the market;
- prescribe the conditions concerning the safety and composition of nutrients intended for persons with special dietary needs;
- prescribe specific requirements concerning labeling, presentation, or advertising food, as well as descriptions that may be put on food;
- prescribe the sanitary conditions and the conditions of the activities in the food business;
- prescribe the health and sanitary conditions that the persons who come into direct contact with the food must meet, as well as the requirements regarding the clothing and footwear necessary to protect the food safety;
- prescribe the introduction of internal control systems and their implementation on the part of a person in charge of the food business with the aim to ensure the safety of the food that is placed on the market;
- prescribe the conditions concerning expert personnel, rooms, and equipment that the laboratories for conducting analyses and superanalyses of food must meet;
- prescribe the health conditions and actions concerning objects that come into direct contact with the food (dishes, accessories, equipment, machinery, and packaging) and that may influence the safety of the food;
- prescribe the implementation of any procedure in the production and preparation of food;
- under certain conditions, introduce a ban or limit on sale of the food intended for human consumption;
- introduce a ban or limited use of certain primary goods in the production of food that originate from sources specific for the type of animal, place of origin, its nature, the subsequent processing, or other characteristics;
- order the processing and recall of any food that is not fit for human consumption or does not meet the prescribed conditions;
- prescribe other food-related conditions that are established to be necessary to ensure that the food meets the safety requirements or to be in the interest of human health.

IV IMPORT AND EXPORT OF FOOD AND CATTLE FEED

1. Import and Export of Food and Cattle Feed Into and From the Republic of Croatia

Article 18

Import

- 1) The food and cattle feed that is imported into the Republic of Croatia to be placed on the

market must be in line with the provisions of this Law or special regulations unless otherwise stipulated by this Law or a regulation adopted on the basis of this Law.

2) As an exception to Paragraph 1 of this Article, if a special international agreement is concluded by the Republic of Croatia and the country of export, the food and cattle feed imported into the Republic of Croatia to be placed on the market must meet the conditions contained in the agreement.

3) The imported food and cattle feed shall be placed on the market of the Republic of Croatia upon the completion of the customs procedure.

Article 19

Export

1) The food and cattle feed exported from the Republic of Croatia to be placed on a market of another country must be in line with the provisions of this Law or special regulations unless otherwise stipulated by this Law or a regulation adopted on the basis of this Law.

2) As an exception to Paragraph 1 of this Article, the food and cattle feed exported from the Republic of Croatia must meet the conditions set by the laws that are in force in the country of import or the conditions set by the relevant bodies of the country of import.

2. The Control of the Safety of Food and Cattle Feed During Import

Article 20

1) The importer of food and cattle feed must submit, to the border veterinary inspector of the Ministry of Agriculture and Forestry, that is, the border sanitary inspector of the Ministry of Health, a request for the inspection of the shipment of food, that is, cattle feed that they are importing in order for its safety to be determined, in line with the jurisdiction established in Appendix 1.

2) The inspection of the safety of food and cattle feed shall be carried out at the border crossings and other places established by the minister of agriculture and forestry and the minister of health, depending on their jurisdiction.

Article 21

1) The customs service bodies cannot carry out the procedure of charging customs on the food or cattle feed before they receive, from the relevant state administration body or a relevant border inspector from Article 20, Paragraph 1 of this Law, a decision confirming the safety of the shipment of food or cattle feed that is being imported.

2) The bodies of the customs service shall, within the framework of their rights and obligations, provide the relevant border inspector from Article 20, Paragraph 1 of this Law with the documentation and facilitate unobstructed control of the safety of food and cattle feed.

3) Before the beginning of the customs procedure and the completion of the procedure of establishing the safety of food and cattle feed the shipments may be stored in the customs storehouses.

4) The importer shall cover the costs of the issuing of the decision from Paragraph 1 of this Article.

Article 22

- 1) In the course of import of the food and cattle feed that require, in line with special regulations, an international safety certificate, the shipments must be accompanied by a prescribed international product safety certificate unless otherwise specified by an international agreement.
- 2) International certificates on the safety of the shipment issued by the relevant body of the country of export may be acknowledged for food and cattle feed that is being imported on the basis of bilateral or multilateral agreements.
- 3) If the agreements specified in Paragraph 2 of this Article do not exist, the acknowledgement of international certificates and other documents, analytical reports on safety issued abroad, is done on the basis of implementation regulations prescribed by the minister of agriculture and forestry, that is, the minister of health.
- 4) International certificates and other safety documents must be written in the Croatian language and the language of the country of origin.

Article 23

- 1) For the purposes of inspecting the safety of food and cattle feed that is being imported, the relevant border veterinary inspector and the relevant border sanitary inspector are entitled to take samples and forward them for laboratory testing.
- 2) The expenses of the laboratory testing of the safety of food, that is, cattle feed, shall be covered by the importer in the case the food, that is, the cattle feed, does not meet the prescribed requirements, while if the food, that is, cattle feed, is safe, the expenses shall be covered by the relevant state administration body.

Article 24

The Register of the Importers of Food and Cattle Feed

- 1) In order to introduce order on the food market, that is, the cattle feed market, and following the proposal by the minister of agriculture and forestry, the Government of the Republic of Croatia shall prescribe the regulation that shall establish the types of food, that is, cattle feed, for which it is necessary to keep a register of importers.
- 2) The Ministry of Agriculture and Forestry shall keep the following registers for the food and cattle feed from Paragraph 1 of this Article:
 - the register of food importers;
 - the register of cattle feed importers.
- 3) The minister of agriculture and forestry shall set the conditions that the legal and physical persons must meet to be entered in the registers from Paragraph 2 of this Article, as well as the contents, form, and mode of keeping the registers.

Article 25

- 1) The Ministry of Agriculture and Forestry shall adopt the decision on the entries in the registers specified in Article 24 of this Law at the request of legal and physical persons if the legal

and physical persons meet the conditions set by this Law and the regulations adopted on the basis of this Law.

2) The Ministry of Agriculture and Forestry shall adopt decisions by which they will strike out the legal persons or physical persons from Article 24 of this Law from the registers at their request, that is, when it establishes that the legal person or physical person ceased to meet the conditions set by this Law and the regulations adopted on the basis of this Law.

V THE APPROVAL OF FACILITIES

Article 26

The Approval of Facilities

1) The facilities that are used in the food business and the cattle feed business must have permits issued by the Ministry of Health and the Ministry of Agriculture and Forestry in line with the jurisdictions defined in Appendix 1 to this Law.

2) To approve the facilities, the relevant bodies from Paragraph 1 of this Article shall issue a decision on the meeting of the sanitary and technical and hygienic conditions, that is, veterinary and health conditions.

3) The conditions specified in Paragraph 2 of this Article are set by the minister of health, that is, the minister of agriculture and forestry, which also includes the conditions concerning the following:

- the design, construction, and layout of all the rooms;
- the design and layout of the equipment that is used;
- the actions of any person that enters the rooms in which food, that is, cattle feed, is handled;
- the implementation of internal control systems that ensure the safety of the food, that is, cattle feed, that is placed on the market.

4) The state administration bodies in charge of issuing location permits and building inspection certificates cannot issue a location permit or a building inspection certificate unless the decision from Paragraph 2 of this Article has already been obtained.

5) The decision from Paragraph 2 of this Article is issued for the period of four years.

6) Before the deadline from Paragraph 5 of this Article expires, the relevant bodies described in Paragraph 1 of this Article shall, at the request of the legal person or physical person, adopt a decision on further meeting of the prescribed conditions or the failure to meet them.

7) Only the activity stated in the decision specified in Paragraph 2 of this Article may be carried out in the approved facility.

8) The Ministry of Health, that is, the Ministry of Agriculture and Forestry, shall keep a Register of Approved Facilities and, once a year, publish the list of the approved facilities in Narodne Novine [Official Gazette of the Republic of Croatia].

9) The Ministry of Health, that is, the Ministry of Agriculture and Forestry, shall adopt decisions by which the legal person or physical person entered in the register mentioned in Paragraph 8 of this Article shall, at their own request or when it is established that the facility no longer meets the conditions set by this Law and the regulations adopted on the basis of this Law, be stricken out of the register.

10) The content, form, and mode of keeping the register of the approved facilities shall be prescribed by the minister of agriculture and forestry in collaboration with the minister of health.

Article 27

The Temporary or Permanent Ban on the Activities for Which the Permit Is Issued

The Ministry of Health, that is, the Ministry of Agriculture and Forestry, may temporarily or permanently ban the activities in the facilities specified in Article 26, Paragraph 1 of this Law in the cases in which the following is established in the course of an inspection:

- that the facility was used contrary to the provisions of this Law;
- that this procedure is considered necessary or appropriate in order to protect human health.

Article 28

Facility Approval Fees

- 1) The applicant for the decision shall cover the expenses of issuing the decision approving the facilities that is described in Article 26, Paragraph 1 of this Law.
- 2) The Food Agency shall stipulate the mode of payment and the amount of the expenses of issuing the decisions approving the facilities.

VI THE RESPONSIBILITIES OF THE PERSON IN CHARGE OF THE FOOD BUSINESS OR THE CATTLE FEED BUSINESS CONCERNING THE SAFETY OF FOOD OR CATTLE FEED

Article 29

General Responsibility for the Safety of Food and Cattle Feed

The person in charge of the food business or cattle feed business must, in all the stages of production, processing, and distribution, ensure and systematically check that the food, that is, cattle feed, that is to be placed on the market, meets the prescribed requirements concerning the activity that is carried out.

Article 30

The Responsibilities Concerning Food or Cattle Feed That Does Not Meet the Prescribed Requirements

- 1) If the person in charge of the food business or cattle feed business has knowledge or reasonable doubts about the food or cattle feed that they imported, processed, manufactured, or distributed not meeting the safety requirements, they are obligated to initiate the procedure of preventing the placement of the food or cattle feed on the market, that is, of withdrawal of the food

or cattle feed from the market when the product is no longer under their direct control, and to inform the relevant bodies of this.

2) If the food or cattle feed has already reached the end consumer, the person in charge of the food business or cattle feed business must, in an efficient and accurate manner, inform the end consumers of the reasons for its withdrawal and, if necessary, request of the consumer to return the food or cattle feed they are already supplied with if the other measures are not sufficient for achieving a high level of health protection.

3) The person in charge of retail trade or distribution activity that has no direct influence on the packaging, labeling, or safety of food or cattle feed must, within the limits of their activity, initiate the procedure of withdrawing the food or cattle feed that does not meet the safety requirements from the market. The person in charge must provide information that is necessary for the food or cattle feed to be traced and cooperate in the measures that other participants in the food business or the cattle feed business are taking as well as cooperate with the relevant bodies.

4) If the person in charge of the food business or the cattle feed business has knowledge or reasonable doubts that the food or cattle feed that they placed on the market may be harmful to human health, they are obligated to immediately inform the relevant bodies of this and of the measures they have taken to prevent the risk to the end consumer.

5) The person in charge of the food business or the cattle feed business must not prevent any person from cooperating with the relevant bodies if such cooperation may prevent, reduce, or eliminate the risk from the food or cattle feed.

6) The persons in charge of the food business or the cattle feed business shall cooperate with the relevant bodies in the measures that are taken to reduce the risk posed by the food or cattle feed with which they supply or supplied the market.

Article 31

Requirements Concerning Traceability of Food and Cattle Feed

1) The traceability of food, cattle feed, an animal that produces food or serves for the production of food, a primary good of plant and animal origin, and any other substance that is intended to be incorporated or may be expected to be incorporated in food or cattle feed must be established in all the stages of production, processing, and distribution.

2) The persons in charge of the food business or the cattle feed business must be able to identify any legal or physical person that supplied them with food and cattle feed or any other substances that are intended to be incorporated or may be expected to be incorporated in food or cattle feed. To this end, they must establish databases and procedures that facilitate access to such information so they can be presented to the relevant bodies at their request. The person in charge of the food business or the cattle feed business must establish databases and procedures that facilitate identification of other legal or physical persons to which they delivered food or cattle feed and make this information accessible to the relevant bodies.

3) The persons in charge of the food business or the business with cattle feed are obligated to keep databases and secure procedures that will enable the identification of legal or physical persons from Paragraph 2 of this Article for the period of five years.

4) The food or cattle feed that has been placed on the market or is likely to be placed on the market must be labeled or otherwise identified by way of appropriate prescribed documentation or other information in order to ensure traceability.

Article 32

Requirements Concerning the Internal Control System Securing the Safety of Food or Cattle Feed

- 1) The person in charge of the food business or the cattle feed business shall apply the internal control system on the following principles:
 - identifying the hazards that endanger the safety of food or cattle feed and the procedures that are followed, and identifying the critical points in their facility on the basis of the procedures that are followed;
 - establishment and employment of methods of systematic monitoring and checking such critical points and methods for performing reparation activities in order to prevent the risk of hazard or reduce it to the minimum;
 - conducting analyses with the aim to test the methods of cleaning and disinfection and with the aim to test the meeting of the requirements regarding the safety of food or cattle feed;
 - keeping records of the critical points in the way that precludes erasing the data, which must be kept for five years.
- 2) If the results of the internal controls mentioned in Paragraph 1 of this Article reveal the existence of a considerably elevated risk for human health or the health of animals, it shall be considered that the food, that is, cattle feed, does not meet the safety requirements, and the person in charge of the food business or the cattle food business is obligated to take measures in line with Article 30 of this Law.
- 3) The minister of agriculture and forestry, that is, the minister of health, shall prescribe the requirements for the implementation of the internal control system measures specified in this Article.

VII NEW FOOD

Article 33

The New Food Categories

- 1) The following food categories are considered new food:
 - the food and food contents that contain or consist of genetically modified organisms (hereinafter referred to as: GMO);
 - the food and food contents that are produced from the GMO but do not contain the GMO;
 - the food or food contents with a new or intentionally modified primary molecular structure;
 - the food and food contents that consist of or are isolated from microorganisms, fungi, or algae;
 - the food or food contents that consist of or are isolated from plants or animals, with the exception of the food and food contents that are derived from traditional ways of multiplication or that have been long known to be safe for consumption;
 - the food and food contents on which the production procedure was applied that is not

used at present and in cases that such procedure causes significant changes in the contents or structure of food or food contents that influence its nutritional value, metabolism, or the level of unwanted substances.

- 2) The food categories listed in Paragraph 1 of this Article must not:
 - present a hazard to the health of the end consumer;
 - mislead the end consumer;
 - differ from the food or food contents that they are to replace, to the extent to which their normal consumption would be nutritionally unfavorable for the end consumer.

Article 34

Placing New Food on the Market

- 1) In order to place new food on the market for the first time, a permit shall be obtained in line with the provisions of this Law and the special regulation.
- 2) The permit described in Paragraph 1 of this Article shall be issued by the Ministry of Health with the consent of the Ministry of Agriculture and Forestry, on the basis of a previously obtained scientific opinion of the Committee for New Food and Cattle Feed Containing the GMO, which is to be established at the Food Agency.
- 3) The permit to place food and food contents that contain or consist of the GMO and the foods and food contents that were produced from the GMO but do not contain them is issued by the Ministry of Health with the consent of the Ministry of Agriculture and Forestry, on the basis of the previously obtained scientific opinion of the Committee for New Food and Cattle Feed Containing the GMO, which is to be established at the Food Agency.
- 4) The conditions and the procedure for the issuing of the permit mentioned in Paragraph 1 of this Article are prescribed by the minister of health with the consent of the minister of agriculture and forestry.

Article 35

The Register of Permits for Placing New Food on the Market

- 1) The Ministry of Health shall keep a register of the permits for placing new food on the market.
- 2) The contents, form, and mode of keeping the register described in Paragraph 1 of this Article shall be prescribed by the minister of health.

Article 36

Banning the Placement of New Food on the Market

- 1) The Ministry of Health, with the consent of the Ministry of Agriculture and Forestry, shall permanently ban the market placement of new food, especially food and food contents that contain or consist of the GMO if it is established, on the basis of a scientific risk assessment, that they are harmful to human health.
- 2) In case scientific dilemmas are present with regard to harmful effects of the new food, particularly the food and food contents that contain or consist of the GMO, on human health, the

relevant bodies mentioned in Paragraph 1 of this Article may temporarily ban its placement on the market in order to prevent or reduce their possible negative effects on human health.

VIII CATTLE FEED THAT CONTAINS OR CONSISTS OF THE GMO

Article 37

Placing Cattle Feed That Contains or Consists of the GMO on the Market

- 1) In order to place cattle feed and cattle feed contents that contain or consist of the GMO on the market for the first time, a permit must be obtained in line with the provisions of this Law and the special regulation.
- 2) The permit mentioned in Paragraph 1 of this Article shall be issued by the Ministry of Agriculture and Forestry, on the basis of a previously obtained scientific opinion of the Committee for New Food and Cattle Feed Containing the GMO, which is to be established at the Food Agency.
- 3) The conditions and the procedure for the issuing of the permit specified in Paragraph 1 of this Article shall be prescribed by the minister of agriculture and forestry.

Article 38

The Register of Permits for Placing Cattle Feed That Consists of or Contains the GMO on the Market

- 1) The Ministry of Health shall keep a register of the permits for placing cattle feed and cattle feed contents that contain or consist of the GMO on the market.
- 2) The contents, form, and mode of keeping the register specified in Paragraph 1 of this Article shall be prescribed by the minister of agriculture and forestry.

IX THE QUALITY OF FOOD AND CATTLE FEED

Article 39

The Quality of Food

- 1) The persons responsible for the food business and consumers shall be allowed to produce, place on the market, and buy food that corresponds to the prescribed quality and the food for which quality requirements are not prescribed if the food corresponds to the safety provisions.
- 2) The minister of agriculture and forestry shall prescribe the implementation regulations that regulate the quality of food, when they deem this necessary, in order to do the following:
 - prevent the activities described in Article 10 of this Law;
 - protect the economic interests of the consumers;
 - enable the consumers to make a choice regarding the food they consume;
 - introduce order on the food market.
- 3) The implementation regulations specified in Paragraph 2 of this Article determine the

requirements relating to the following:

- food classification, categorization, and terminology;
- the sensory characteristics and the contents of food;
- the type and quantity of primary goods, additives, and other materials that are used in the production and processing of food;
- the technological procedures that are followed in the production and processing of food;
- the methods of sampling and analytical methods for controlling food quality;
- putting up the prices of food;
- additional or specific information that should be stated on the food label.

Article 40

The Quality of Cattle Feed

- 1) The persons responsible for the cattle feed business shall be allowed to produce and place on the market the cattle feed that corresponds to the prescribed quality.
- 2) The minister of agriculture and forestry shall prescribe the regulations on the quality of cattle feed.

X THE MARK OF TRADITIONAL REPUTE, THE MARK OF GEOGRAPHICAL ORIGIN, AND THE MARK OF ORIGINALITY OF THE FOOD

1. The Mark of Traditional Repute of the Food

Article 41

- 1) The food may bear the "traditional repute" mark if it is produced by using traditional primary goods, or if it contains traditional ingredients, or if it was produced or processed in a traditional way and has characteristics that make it different from other similar food that falls under the same category.
- 2) The use of the mark of traditional repute is the collective right of all those who meet the conditions from Paragraph 1 of this Article.
- 3) The minister of agriculture and forestry shall prescribe the conditions and the procedure for the recognition of special characteristics of food and shall establish a Commission for Awarding the "Traditional Repute" Mark.

Article 42

- 1) The Ministry of Agriculture and Forestry shall keep the following registers:
 - the Register of Agricultural Food Products Bearing the "Traditional Repute" Mark;
 - the Register of Legal Persons, Physical Persons, or Associations of Producers and/or Processors That Use the "Traditional Repute" Mark.
- 2) The minister shall prescribe the conditions that the legal and physical persons or associations from Paragraph 2 of this Article must meet, as well as the contents, form, and mode of keeping the

registers.

Article 43

- 1) The Ministry of Agriculture and Forestry shall issue a decision on the entry in the register described in Article 42, Paragraph 2 of this Law, based on the claim of a legal person, a physical person, or an association if the legal person, physical person, or association meet the conditions prescribed by this Law and the regulations adopted on the basis of this Law.
- 2) The Ministry of Agriculture and Forestry shall, by way of a decision, strike out from the register the legal person, physical person, or association entered in the register described in Article 42, Paragraph 2 of this Law, at their own request, that is, when it establishes that they ceased to meet the conditions prescribed by this Law and the regulations adopted on the basis of this Law.

2. The Mark of Geographical Origin and the Mark of Originality of the Food

Article 44

The Mark of Geographical Origin of the Food

- 1) The mark of geographical origin is the name of the geographical area -- in exceptional cases, of a state -- that is used to mark the food the production or processing or preparation for the market of which takes place in the place of its origin.
- 2) The mark of geographical origin can be used to protect the following food:
 - the food that originates from a certain geographical area;
 - the food that has special quality, repute, or other characteristics that result from the influence of a certain geographical area.
- 3) The minister of agriculture and forestry shall regulate the areas and conditions stated in Paragraph 2 of this Article, as well as the form, contents, and mode of control of the mark.

Article 45

The Mark of Originality

- 1) The mark of originality is the name of a geographical area -- in exceptional cases, of a state -- that is used to mark the food that originates from a certain geographical area in its entirety.
- 2) The mark of originality can be used to protect the following food:
 - the food whose characteristics are exclusively or mostly the result of natural and human factors and whose entire production, processing, and preparation for the market takes place in the place of its origin.
- 3.) The mark of originality can also be used to protect the food the primary goods for whose production originate from an area broader or different from the processing area, under the condition that the area of production of primary goods is limited, that special conditions for producing primary goods are present, and that inspections are carried out that facilitate the meeting of the special conditions.
- 4) The mark of originality can also be used to protect traditional geographical or non-

geographical names of food that indicate a certain geographical origin, under the condition that the food meets the conditions contained in Paragraphs 2 and 3 of this Article.

5) The minister of agriculture and forestry shall regulate the mode of production, processing or preparation for the market, the areas specified in Paragraph 2 of this Article, the form and content of the mark, and the mode of control.

Article 46

The Right to Use the Mark of Geographical Origin and the Mark of Originality

1) The mark of geographical origin and the mark of originality can only be used for the food they relate to.

2) The use of the marks from Paragraph 1 of this Article is the collective intellectual ownership right, and may be used by all the producers and processors of food as long as they meet the prescribed conditions.

3) A foreign legal person or physical person may be granted the marks specified in Paragraph 1 of this Article on the basis of an international agreement on mutual protection of marks that obligates the Republic of Croatia.

4) The protection of the right to use the mark of geographical origin and the mark of originality shall be carried out in line with the provisions of this Law and the provisions of special regulations.

Article 47

The Protection of the Rights by the Courts

Regulations on intellectual ownership are applied for the court protection of the rights concerning the food whose marks of geographical origin and marks of originality are acknowledged in line with this Law.

Article 48

The Ban on Misleading

1) The marking, presentation, and advertising of food must not, with text or picture or in any other way, mislead the consumer with regard to the marks of geographical origin or the marks of originality.

2) Misleading with regard to the marks of geographical origin or the marks of originality is primarily considered to be the following:

-- the use of a mark denoting food that was not produced, processed, or prepared for the market in line with the regulations that facilitate the use of the mark of the geographical area; moreover, if the real origin of the food is additionally marked, and if the mark containing the name of the geographical area is used;

-- the use of a translation of a mark, that is, the mark being accompanied by terms such as "type", "style", "imitation", and the like.

Article 49

The Procedure of Securing Protection of the Mark of Geographical Origin and the Mark of Originality of Food

- 1) The procedure of acknowledging the protection of the mark of geographical origin and the mark of originality of food shall be conducted by the Ministry of Agriculture and Forestry.
- 2) The procedure of acknowledging the protection specified in Paragraph 1 of this Article shall begin on the basis of an application submitted by the producer or processor of the food, who pays the prescribed fees.
- 3) The minister of agriculture and forestry shall prescribe the conditions and procedure for the acknowledgement of the protection of the mark of geographical origin and the mark of originality of food, the contents of the application, the conditions for submitting the applications, and the fees.
- 4) The minister of agriculture and forestry shall establish the Commission for the Acknowledgement of the Protection of the Mark of Geographical Origin and the Mark of Originality of Food.

Article 50

- 1) The Ministry of Agriculture and Forestry shall keep the following registers:
 - the Register of Marks of Geographical Origin and the Marks of Originality of Food;
 - the Register of Users of Marks of Geographical Origin and the Marks of Originality of Food.
- [2) is not provided]
- 3) The minister shall prescribe the conditions that the legal persons, physical persons, or associations described in Paragraph 2 of this Article must meet, as well as the content, form, and mode of keeping the registers.

Article 51

- 1) The Ministry of Agriculture and Forestry shall adopt the decision on entering in the register from Article 50 of this Law, on the basis of an application filed by a legal person, a physical person, or an association if the legal person, physical person, or association meets the conditions prescribed by this Law and the regulations adopted on the basis of this Law.
- 2) The Ministry of Agriculture and Forestry shall strike out the legal person, physical person, or association entered in the register described in Article 50, Paragraph 2 of this Law, from the register at their own request, that is, if it establishes that they ceased to meet the conditions prescribed by this Law and the regulations adopted on the basis of this Law.

XI LABELING OR MARKING FOOD AND CATTLE FEED

Article 52

General Requirements for Labeling or Marking Food and Cattle Feed

- 1) The food and cattle feed that is placed on the market of the Republic of Croatia must have

a label.

- 2) A label shall include all written marks, the manufacturer's brand, the trademark, the brand name, and the image or symbol that relate to food or cattle feed and that are put on the packaging, sticker, or tag, as well as the documents and notices that accompany or relate to the food or cattle feed.
- 3) The label must be written in the Croatian language; it must be noticeable, legible, and intelligible.
- 4) The label must contain at least the following data:
 - the name of the food or the cattle feed under which the food or cattle feed is being sold;
 - a list of ingredients;
 - the quantity of certain ingredients or the category of ingredients;
 - the net quantity, in the case of packaged food or cattle feed;
 - the date of expiry;
 - the storage conditions, where necessary, that is, where they may influence the durability of the food or cattle feed;
 - the name or business name and address of the producer of the food or cattle feed or the subject that packages the food or cattle feed and/or places it on the market;
 - in the case of imported products, in addition to the name or business name and address of the producer, the name and address of the seat of the importer and the country of origin are also necessary;
 - the details concerning the place of origin in the cases in which failure to state them may significantly mislead the consumer as to the real origin;
 - the instructions for use, where necessary.

Article 53

Labeling or Marking the Food

- 1) The data on the label and the mode of labeling or marking the food must be such so as not to mislead the consumer, particularly with regard to the following:
 - the characteristics of the food, of its nature, identity, qualities, composition, quantity, durability, and the method of its preparation or production;
 - ascribing to the food the effects and characteristics that the food does not possess;
 - leading the consumer to believe that the food has certain special characteristics while the fact is that all similar foods have such characteristics.
- 2) The labeling and the mode of labeling, in line with the special regulations that are applied to natural mineral waters and the food for special dietary needs, shall not ascribe to any food the characteristics involving prevention, treatment, or curing of diseases nor shall such characteristics be referred to.
- 3) The bans and limitations specified in Paragraph 1 of this Article also relate to:
 - the presentation of the food, particularly its form, appearance, or packaging, the materials that are used for packaging, and the mode and place in which the food is arranged and displayed;
 - the advertising of the food.

Article 54

The Food Labeling Regulations

- 1) The minister of agriculture and forestry, with the consent of the minister of health, shall adopt a regulation regulating the labeling or marking, presentation, advertising, and stating the nutritional values of the food.
- 2) The minister of agriculture and forestry may, with regulations adopted on the basis of this Law, determine the following:
 - that certain information relating to the food be on the label when packaged food is involved or that they be otherwise stated when food that is not packaged is involved;
 - that specific information relating to the food be labeled in some other way;
 - that the usual meanings of the name under which the food was placed on the market be determined;
 - specific requirements that relate to the labeling or marking of a set group of products.

Article 55

The Labeling or Marking of Cattle Feed

The labeling of cattle feed must meet the general requirements contained in Article 52 of this Law and the regulation adopted by the minister of agriculture and forestry on the basis of this Law.

Article 56

The Labeling or Marking of New Food

- 1) In addition to the general requirements for the labeling or marking contained in Article 52 of this Law, the label of the new food placed on the market of the Republic of Croatia must also contain specific additional information in order for the consumers to be informed of all the characteristics of the food that make the new food or its contents no longer equivalent to the existing food or food contents.
- 2) In this case the label must contain data on the changed characteristics and it must state the method with the employment of which this characteristic was achieved.
- 3) The label, packaging, and accompanying documentation of the food and food contents containing the GMO must contain a visible mark stating that the food or the food contents contain or consist of the GMO.
- 4) The mark must clearly state, "genetically modified organism", or contain the following sentence: "This product contains a genetically modified organism".
- 5) The label, packaging, and the accompanying documentation of the food and the food contents that originate from the GMO but do not contain them must clearly state that the food or the food contents originate from the GMO.
- 6) The mark must contain the following sentence: "This product originates from the GMO."
- 7) The minister of health, with the consent of the minister of agriculture and forestry, shall prescribe more detailed requirements concerning the labeling of the new food by way of an implementation regulation.

Article 57

The Labeling or Marking of the Cattle Feed Containing or Consisting of the GMO

- 1) The cattle feed and the cattle feed contents that contain or consist of the GMO and that have been placed on the market of the Republic of Croatia must, in addition to meeting the general requirements concerning labeling or marking contained in Article 52 of this Law, bear a visible mark on their label, packaging, and accompanying documentation, stating that they contain or consist of the GMO.
- 2) The mark must clearly state, "genetically modified organism" or contain the following sentence: "This product contains a genetically modified organism."
- 3) The minister of agriculture and forestry shall prescribe more detailed requirements concerning the labeling of cattle feed and cattle feed contents that contain or consist of the GMO by way of an implementation regulation.

XII THE OFFICIAL CONTROL OF FOOD SAFETY AND CATTLE FEED SAFETY

Article 58

The Official Control of Food Safety and Cattle Feed Safety

The official control of the safety of food and of cattle feed shall include one or more of the following activities:

- inspection control;
- sampling and analysis;
- inspection of written material and documents;
- inspection of records as stated in Article 31 of this Law;
- inspection of the internal control systems and the records as described in Article 32 of this Law;
- inspection of the health and hygiene of the personnel and objects that come into direct contact with the food.

Article 59

The Jurisdiction of the Inspectorates

- 1) The inspection control the aim of which is to perform official control of food safety and cattle feed safety shall be carried out by sanitary inspectors, that is, veterinary inspectors, and by border sanitary inspectors, that is, border veterinary inspectors, in line with the jurisdiction determined in Appendix 1 to this Law.
- 2) The inspection control, as described Paragraph 1 of this Article, shall be carried out in line with the provisions of this Law and special regulations if they are not contrary to the provisions of this Law.
- 3) The inspection control, as specified in Paragraph 1 of this Article, must include all the stages

of production, processing, and distribution.

Article 60

The General Principles of Inspection Control

- 1) The inspection control of food safety and cattle feed safety described in Article 59, Paragraph 1 of this Law must be carried out as follows:
 - on a regular basis and in line with the priorities set by way of risk assessment;
 - whenever the suspicion is present that the requirements have not been met.
- 2) The inspection control must be carried out with the use of measures appropriate to the subsequent aim.
- 3) The inspection control should be carried out without prior announcement.

Article 61

The Contents of the Inspection Control

- 1) The following shall be the subject of the inspection control, which shall be carried out with the aim to officially control the safety of food and cattle feed:
 - the location of the facility -- the state of the facility, the offices, the area surrounding the production plants, the vehicles, the plants, and the equipment that is used in the food business and cattle feed business, and, especially, the conditions for the approval of the facility as set in Article 26 of this Law;
 - the primary goods, contents, technological aids, and other substances used for the preparation and production of food or cattle feed;
 - the semi-finished goods;
 - the objects that come into direct contact with the food;
 - the cleaning and maintenance agents and the procedures that are followed in the food business and the cattle feed business;
 - the procedures that are followed in the making or processing of food or cattle feed;
 - the food preservation methods.
- 2) The inspection control described in Paragraph 1 of this Article is carried out in the following way:
 - through talks with the person in charge and the persons employed with the person in charge;
 - by reading the values recorded by the instruments that were installed by the person in charge;
 - by taking measurements, which is carried out by the relevant inspectors specified in Article 59, Paragraph 1 of this Law, using their own instruments or instruments installed by the person in charge;
 - by using the information contained in the written materials and documents that are kept by the person in charge of the food business or the cattle feed business.

Article 62

Inspecting the Hygiene of the Persons and Objects That Come Into Contact With the Food

- 1) The persons who, in the course of doing their jobs, come into direct or indirect contact with the food, as well as their work clothes and footwear, and the objects that come into direct or indirect contact with the food shall be liable to be inspected by the sanitary inspectorate.
- 2) The purpose of the inspection contained in Paragraph 1 of this Article shall be to inspect whether the persons, their work clothes and footwear, and the objects that come into direct contact with the food meet the health and hygiene requirements.

Article 63

Taking Samples for Laboratory Analysis

Samples of primary goods, contents, technological aids, and other substances that are used in preparation and production of food or cattle feed, semi-finished goods, prepared food and cattle feed, objects that come into direct contact with food, and cleaning and maintenance agents that are used in the food business or cattle feed business may be taken for laboratory analyses for the purposes of official control of the safety of food or cattle feed, within the framework of inspection control.

XII OFFICIAL CONTROL OF THE QUALITY OF FOOD AND CATTLE FEED

Article 64

Official Control of the Quality of Food and Cattle Feed

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

- inspection control;
- sampling and analysis;
- inspection of the label, written materials, and documents.

Article 65

The Jurisdiction of the Inspectors

- 1) For the purposes of official control of the quality of food and cattle feed, the inspection control shall be carried out by the economic inspector of the State Inspectorate in Retail Trade, in line with the provisions of this Law.
- 2) As an exception to Paragraph 1 of this Article, inspection control may be carried out in the production process, for the purposes of official control of the quality of the food bearing the protected mark of geographical origin, the mark of originality, and the mark of traditional repute, as well as of the food for which this is prescribed by a special regulation.
- 3) The agricultural inspectors of the Ministry of Agriculture and Forestry and the legal persons authorized by the minister of agriculture and forestry shall carry out the inspection control in production for the purposes of official control of the quality of the food from Paragraph 2 of this

Article.

Article 66

The General Principles of Inspection Control

- 1) Inspection control for the purposes of official control of the quality of food and cattle feed must be carried out as follows:
 - on a regular basis;
 - whenever a suspicion is present that the prescribed requirements are not being met.
- 2) Inspection control must be carried out with the employment of measures appropriate to the subsequent aim.
- 3) Inspection control must be carried out without prior notification.

Article 67

The Contents of Inspection Control

- 1) The inspection control specified in Article 65, Paragraph 1, which is carried out for the purposes of official control of the quality of food and cattle feed shall include the following:
 - inspection of the authenticity of the data and claims of the characteristics of the food and cattle feed, and of the meeting of the requirements concerning labels or marks;
 - examination of the contents of prepared food and cattle feed.
- 2) The inspection control specified in Article 65, Paragraph 2, which is carried out for the purposes of official control of the quality food shall includes the following:
 - control of the production conditions and processing conditions with regard to the quality of food;
 - control of the origin of the primary goods and ingredients that are used in the production and preparation of food;
 - control of the contents of the food;
 - control of the technological procedures that are followed in the production and preparation of food.
- 3) The inspection control specified in Paragraph 1 and Paragraph 2 of this Article shall be carried out in the following way:
 - through talks with the person in charge and the persons employed with the person in charge;
 - by taking measurements, which is carried out by the relevant inspectors from Article 65 of this Law, using their own instruments or instruments installed by the person in charge;
 - by using the information contained in the written materials and documents that are kept by the person in charge of the food business or the cattle feed business.
- 4) The implementation regulation issued by the minister of agriculture and forestry shall prescribe in more detail the mode and contents of the inspection control in the production of food with the protected mark of geographical origin, the mark of originality, and the mark of traditional repute.

Article 68

Taking Samples for Laboratory Analysis

Samples of food and cattle feed may be taken for laboratory analyses for the purposes of official control of the quality of food or cattle feed, within the framework of inspection control.

XIV THE GENERAL PROVISIONS REGULATING THE OFFICIAL CONTROL OF FOOD AND CATTLE FEED

Article 69

Authorized Legal Persons

- 1) The Ministry of Agriculture and Forestry, that is, the Ministry of Health, may authorize a legal person to carry out inspection control activities listed in this Law as a legal person with public authority.
- 2) The relevant bodies mentioned in Paragraph 1 of this Article shall publish a list of the authorized legal persons in Narodne Novine.

Article 70

General Provisions

- 1) The authorized bodies mentioned in Article 69, Paragraph 1, shall issue, to the relevant inspector and legal person, that is, the authorized person within the legal person with public authority (hereinafter referred to as: authorized official person), a certificate of authorization to carry out inspection control.
- 2) When the authorized official person, in the course of inspection control, discovers or suspects that the provisions of this Law have been violated, they will take the necessary measures with the aim to have the person in charge of the food business or cattle feed business rectify the established irregularities.
- 3) The owner, proprietor, person in charge, employee in the facility, or another person found at the facility that the authorized official person mentioned in Paragraph 1 of this Article entered must not do the following:
 - deny information or assistance;
 - knowingly issue a false statement.
- 4) No one may disturb the authorized official person in performing their duties.
- 5) No one may take any measures prescribed by this Law with the aim to rectify the established irregularities without the written consent of the authorized official person.
- 6) The authorized official person is obligated to carry out inspection control in line with their authorization and the duties and responsibilities based on this Law and special regulations, unless they are contrary to this Law.

Article 71

The Authority of the Authorized Official Person

- 1) The authorized official person described in Paragraph 1, Article 70, may do the following:
 - enter the facility believed to store, process, or package food or cattle feed at any time, which includes the time during which work operations are under way, and carry out an inspection with the aim to establish the existence, nature, and scope of any trade or business concerning food or cattle feed;
 - inspect any food or cattle feed in any of the facilities they believe are subject to the provisions of this Law, take samples of food or cattle feed, and inspect anything they believe has been used or may be used for the production of any food or cattle feed;
 - stop, search, or detain a vehicle, vessel, or aircraft they believe to be transporting food or cattle feed, inspect the food or cattle feed, and take samples of it;
 - open and inspect the container or package they believe contains food or cattle feed, examine the contents, and take samples;
 - request to see the books, documents, or other records kept in any media that they believe contain any information important for the implementation of the provisions of this Law, with regard to any food or cattle feed, and make copies or take excerpts from the documents;
 - confiscate and keep the food or cattle feed if they believe that the provisions of this Law or the conditions of the approval issued in line with this Law have been violated;
 - perform any other activities they are authorized for in line with special regulations.

Article 72

The Duties of the Authorized Official Persons

- 1) The authorized official person is obligated, in exercising their authority established by Article 71 of this Law, and at the request of the person to whom these activities relate, to do the following:
 - present their certificate of authority issued in line with the provisions of Article 69 of this Law;
 - return the food or cattle feed they confiscated once they have ensured that it meets the requirements set by this Law;
 - in case the food or cattle feed does not meet the requirements set by this Law and when the owner or proprietor of the food or cattle feed agrees that they be destroyed or removed, determine the way it will be removed or destroyed;
 - organize the destruction or removal of the food or cattle feed when the approval described in Item 3 of this Paragraph and this Article is not given.

Article 73

The Responsibilities of the Authorized Official Persons

- 1) No information that relates to the activity of the person in charge and that the authorized official person came across in the course of official controls, or that relates to risk analysis, can be revealed without the written consent of the person in charge that carries out the activities, except in the following cases:

- a) when this is necessary for the implementation of this Law and when the minister of agriculture and forestry, that is, the minister of health, approves it;
- b) when this is necessary to follow any procedure that follows a report on the inspection control.

Article 74

The Annual Program of Inspections and Reports

- 1) Annual programs for official controls shall be prepared for the carrying out of inspection controls, and shall contain the following:
 - the number and type of the inspection controls that are planned;
 - the number and type of the facilities to be included in the inspection control;
 - the criteria that were applied in the preparation of the program.
- 2) Annual reports on the official controls that have been done shall be prepared, and they shall contain the following:
 - the number and type of the inspection controls that have been carried out;
 - the number and type of the facilities that were included in the inspection control;
 - the information about offenses and criminal acts;
 - the measures taken in the cases the requirements determined on the basis of this Law were not met.
- 3) The Ministry of Agriculture and Forestry or the Ministry of Health -- depending on the jurisdiction -- shall prepare the programs and reports from Paragraphs 1 and 2 of this Article that relate to official control of the safety of food and cattle feed, and the Management Council of the Food Agency shall approve them and forward them to the Government of the Republic of Croatia.
- 4) The State Inspectorate, that is, the Ministry of Agriculture and Forestry, shall prepare the programs and reports described in Paragraphs 1 and 2 of this Article that relate to the official control of the quality of food and cattle feed, and the Government of the Republic of Croatia shall endorse them.

XV THE OFFICIAL EXAMINATION LABORATORIES AND REFERENCE LABORATORIES

Article 75

The Laboratory Analyses of Samples

- 1) The laboratory analyses of the samples that are taken in line with Articles 63 and 68 of this Law shall, for the purposes of official control, be conducted in official examination laboratories authorized by the minister of agriculture and forestry and the minister of health, depending on the jurisdiction (hereinafter referred to as examination laboratories), in line with special regulations.
- 2) The samples shall be taken and delivered to the examination laboratories by the relevant authorized inspector, as stated in Article 59, Paragraph 1, and Article 65, Paragraph 1 and 3, of this Law.
- 3) The expenses of the analyses shall be covered by the relevant body. In case the food or

cattle feed does not meet the requirements prescribed by this Law and/or does not correspond to the information stated on the label, the expenses shall be covered by the legal person or physical person that produces the food or cattle feed and/or places it on the market.

4) The relevant bodies specified in Paragraph 1 of this Article shall publish a list of the examination laboratories in Narodne Novine.

Article 76

The Official Examination Laboratories

1) The examination laboratories authorized to conduct analyses for the purposes of official control must meet the *General Requirements for the Qualification of the Examination and Measurement Laboratories* specified in HRN EN ISO/IEC 17025.

2) The minister of agriculture and forestry, that is, the minister of health, shall, on the basis of this Law and with the consent of the director of the State Institute for Standards and Measures, prescribe the regulations that, through accepted norms, regulate the special conditions that the examination laboratories must meet, as well as the procedure of evaluation and authorization of the examination laboratories.

3) The accreditation, evaluation, and authorization of the examination laboratories may relate to individual analyses or groups of analyses, and to individual types of food.

4) The examination laboratories authorized by the relevant bodies, as specified in Article 71, Paragraph 1 of this Law, are obligated to take part in the appropriate programs of qualification testing.

5) Any divergence from the mode of application of the Norm specified in Paragraph 1 of this Article shall be considered inappropriate and can only be endorsed with a special approval of the Food Agency.

Article 77

The Reference Laboratories

1) The minister of agriculture and forestry, that is, the minister of health, shall select one laboratory as the reference laboratory for each analysis that is conducted for the purposes of official control of the safety or quality of food or cattle feed.

2) The reference laboratories must meet the *General Requirements for the Qualification of the Examination and Measurement Laboratories* specified in HRN EN ISO/IEC 17025.

3) The reference laboratories described in Paragraph 1 of this Article shall do the following:

-- advise the Ministry of Agriculture and Forestry and the Ministry of Health, depending on the jurisdiction, in the course of authorization of the examination laboratories that are qualified to conduct analyses for the purposes of official control;

-- coordinate and provide support, including training and other services, to the activities of the examination laboratories concerning technical standards and methodologies of the analyses they conduct;

-- organize parallel tests of standardized samples and take part in them, at the national and international level, for the purposes of monitoring the qualifications of the examination laboratories;

- ensure that the examination laboratories apply the internal system of ensuring quality operation (which includes evaluating the method, keeping records, storing reagents, safety, and routine calibration of the equipment);
 - convey information to the relevant bodies and other laboratories that conduct analyses of food and cattle feed, regardless of whether the analyses were conducted for the purposes of official control.
- 4) The expenses of financing the reference laboratories for carrying out the activities stated in Paragraph 2 of this Article shall be covered by the Ministry of Agriculture and Forestry, that is, the Ministry of Health.
 - 5) The relevant bodies specified in Paragraph 1 of this Article shall publish the list of the reference laboratories in Narodne Novine.

XVI CRISIS MANAGEMENT AND EMERGENCIES MANAGEMENT

Article 78

Urgent Measures for Securing the Safety of Food and Cattle Feed

- 1) When the relevant bodies establish that food, that is, cattle feed, presents a serious risk to human health, the health of animals, or the environment, and that the risk cannot be eliminated in a satisfactory way, one or more measures specified in Paragraphs 2 and 3 of this Article may be taken, depending on the seriousness of the situation.
- 2) In case food or cattle feed of local origin is in question, the measures stated in Paragraph 1 of this Article may be as follows:
 - temporary ban on placing the food on the market or on the use of the food;
 - temporary ban on placing the cattle feed on the market or on the use of the cattle feed;
 - determining special conditions for the above mentioned food or cattle feed;
 - other appropriate temporary measures.
- 3) In case imported food or cattle feed is in question, the measures stated in Paragraph 1 of this Article may be as follows:
 - temporary ban on the import of the food or cattle feed from the country or part of the country of import or the transit country;
 - determining special measures for the above mentioned food or cattle feed from the country or part of the country of import or the transit country;
 - other appropriate temporary measures.

Article 79

General Crisis Management Plan

- 1) The Food Agency, in cooperation with the Ministry of Health and the Ministry of Agriculture and Forestry, must prepare a general crisis management plan in the sphere of food safety, that is, cattle feed safety.
- 2) The plan described in Paragraph 1 of this Article shall specify the types of risk that originates from food or cattle feed and may directly or indirectly present a hazard to human health,

and that is not likely to be eliminated or reduced to an acceptable level with the implementation of the existing provisions of this Law, or that will not be manageable in an appropriate way with the implementation of the provisions contained in Chapter XII of this Law.

3) The plan specified in Paragraph 1 of this Article shall also establish the practical activity necessary for crisis management, which includes organization of the crisis unit in the relevant bodies, employing personnel following the principle of transparency, and formulating the communication strategy.

XVII THE CROATIAN FOOD AGENCY

Article 80

General Provisions

- 1) The Croatian Food Agency shall carry out professional activities, in the context of this Law regarding control of the safety of food and cattle feed. [as provided in the original text]
- 2) The Food Agency shall be established by the Government of the Republic of Croatia by way of a decree.
- 3) The Food Agency is a legal person.
- 4) The seat of the Food Agency shall be in Zagreb.
- 5) In carrying out the activities determined by this Law the Food Agency shall be independent and shall answer to a special committee that shall be established with the Government of the Republic of Croatia, and shall consist of the prime minister, the minister of agriculture and forestry, and the minister of health (hereinafter referred to as: the Committee).
- 6) The Food Agency may transfer the authority to carry out certain activities from its jurisdiction to the Croatian Public Health Institute and the Croatian Veterinary Institute, as well as to other legal persons.
- 7) The funds for the operation of the Food Agency shall be secured from the state budget of the Republic of Croatia and from the Food Agency's own income.
- 8) The Food Agency shall adopt a statute that shall be endorsed by the Government of the Republic of Croatia.

Article 81

The Tasks of the Food Agency

- 1) Within the framework of risk analysis with regard to the safety of food and cattle feed and in line with the principles stated in Chapter II of this Law, the Food Agency shall perform the following:
 - risk assessment;
 - risk notification;
 - risk management.
- 2) The laboratories of the Croatian Public Health Institute and the Croatian Veterinary Institute shall participate in the process of risk assessment that the Food Agency shall carry out, to which purpose they will monitor the safety of food and cattle feed.

3) Within the framework of carrying out activities regarding risk assessment, the Food Agency shall take part in and coordinate the activities carried out by the Ministry of Agriculture and Forestry and the Ministry of Health, which especially relates to the activities concerning inspection control of the safety of food and cattle feed that the relevant inspections specified in Article 59 of this Law shall carry out.

4) In addition to the activities specified in Paragraph 1 of this Article, the Food Agency shall also carry out additional activities that include:

-- providing scientific opinions to the Ministry of Agriculture and Forestry and the Ministry of Health, depending on the jurisdiction, to the persons in charge of food business and cattle feed business, and to consumers, with regard to the hazards pertaining to food and cattle feed;

-- promotion and coordination of the establishment of a unified risk assessment and the methodology of official control for the spheres of safety of food and cattle feed in all the stages of production, processing, and distribution;

-- preparation of scientific studies necessary for the promotion of risk assessment for the spheres of the safety of food and the safety of cattle feed;

-- research, collection, comparison, analysis, and summary of scientific and technical data for the spheres of the safety of food and the safety of cattle feed;

-- taking steps toward identifying and characterizing the new risks with regard to the safety of food and the safety of cattle feed;

-- establishment of a network of institutions that take part in activities linked to the safety of food and the safety of cattle feed;

-- providing scientific and technical assistance with regard to emergencies when this is required by the Government of the Republic of Croatia.

4) The Food Agency shall be in charge of the alarm system, to which purpose it shall receive and forward all the information connected to food hazards, and shall establish a central information system for the exchange of information with other institutions that take part in risk assessment and risk management in the Republic of Croatia, as well as with other relevant institutions abroad.

5) In addition to the activities specified in Paragraphs 1, 2, 3, and 4 of this Article, the Food Agency shall also carry out other activities specified by this Law.

Article 82

The Bodies of the Food Agency

The bodies of the Food Agency are as follows:

- the Management Council;
- the director;
- the Advisory Council;
- the Scientific Council and the Scientific Committees.

Article 83

The Composition and the Mandate of the Management Council

1) The Management Council shall consist of nine members who shall be proposed by the Committee and appointed by the Government of the Republic of Croatia.

- 2) The Management Council shall include two representatives of the Ministry of Agriculture and Forestry, two representatives of the Ministry of Health, one representative of the Croatian Veterinary Institute, one representative of the Croatian Public Health Institute, while the remaining three members of the Management Council shall be selected from the list of candidates that shall be put together after a public competition for membership in the Management Council is published in the media.
- 3) The mandate of the members shall be four years with the option of one renewal.
- 4) The Management Council shall appoint one of its members chairperson, who cannot be the director of the Food Agency. The mandate of the chairperson shall be two year with the option of one renewal.
- 5) The director shall take part in the sessions of the Management Council but shall not have the right to vote.
- 6) The Management Council shall invite the chairperson of the Scientific Council to attend the sessions, at which the chairperson shall not have the right to vote.
- 7) The Management Council may also invite other distinguished persons with renowned scientific and technical qualities to take part in the work of the Management Council, but these invitees shall not have the right to vote.
- 8) The Management Council shall have a Secretary's Office.

Article 84

General Criteria for the Appointment of the Managerial Staff and Members of the Management Council

In making the decisions with regard to the appointment of members of the Management Council of the Food Agency the following shall be taken into account:

- the representation of all the institutions and groups that have an interest in food safety, that is, cattle feed safety;
- ensuring an adequate scope of skills, knowledge, and experience among the members of the Agency;
- possible financial interests and other interests that the person put forward as a candidate may have and that may prevent them from carrying out their duties in an unbiased manner.

Article 85

The Duties of the Management Council

The Management Council shall do the following:

- adopt decisions by way of the majority of votes of its members, in which the chairperson shall have the decisive vote;
- approve, that is, adopt the internal procedural regulations of the Food Agency and its constituent parts;
- adopt the Food Agency's financial regulations that establish the procedure of withdrawal and implementation of the financial budget of the Food Agency from the state budget, in accordance with the Law on the Implementation of the State Budget of the Republic of Croatia;
- convene at the invitation of the chairman or director, or at the request of at least one

third of its members;

- ensure that the Food Agency carries out its duties and tasks that are assigned to it in line with this Law and the Decree issued by the Government of the Republic of Croatia;
- adopt, by 31 January each year, the program of the operation of the Food Agency for the following year, and a program for several years, which may be changed;
- ensure that the Food Agency's work programs are in line with the legislation and the Croatian Government's policy of priorities in the sphere of food safety;
- adopt, by 30 March each year, a general report on the operation of the Food Agency in the previous year;
- make the agenda, minutes, and other documents from the Management Council meetings, including the Food Agency's internal regulations, the procedural regulations of the Management Council, and the financial regulations of the Food Agency available to the public as soon as possible.

Article 86

The Director

- 1) The director and the deputy director shall be selected by the Management Council from among qualified candidates put forward by the minister of agriculture and forestry and the minister of health, after they apply for the public competition published in the media.
- 2) The mandate of the director and the deputy director shall be five years and may be renewed.
- 3) The director and deputy director may be replaced following the decision of the majority in the Management Council.
- 4) The director shall be the legal representative of the Food Agency and shall be responsible for the following:
 - daily management of the Food Agency;
 - preparing proposed programs of the Agency's operation;
 - implementation of the work programs and the decisions adopted by the Management Council;
 - ensuring adequate scientific, technical, and administrative support to the Scientific Council and the Scientific Committees;
 - the operation of the Food Agency in relation to fulfilling tasks in line with the requirements of this Law;
 - preparing reports on income and expenditure, and on the implementation of the budget of the Food Agency;
 - employing appropriate personnel in the Food Agency;
 - developing and maintaining contact with the Ministry of Agriculture and Forestry and the Ministry of Health;
- 5) Each year the director shall propose the following to the Management Council for adoption:
 - the draft annual report on all the activities of the Food Agency in the previous year;
 - draft operation programs;
 - the draft annual financial report for the previous year;
 - the draft budget for the following year.
- 6) After the Management Council adopts the documents specified in Paragraph 5 of this Article, the director shall submit them to the Government of the Republic of Croatia.

7) The director shall approve the Food Agency's financial expenses and inform the Management Council of the Food Agency's activities.

Article 87

The Advisory Council

- 1) The Advisory Council shall consist of 12 to 24 representatives of organizations and groups that have interests in the sphere of food safety, that is, cattle feed safety.
- 2) The Management Council shall select the members of the Advisory Council from the list of candidates who applied for the public competition for membership in the Advisory Council, which shall be published in the media.
- 3) The members of the Advisory Council cannot be members of the Management Council, the Scientific Committees, or the Scientific Council, or employees of the Government of the Republic of Croatia.
- 4) The Advisory Council shall advise the director in his duties as specified by this Law, especially in the following:
 - in preparing the proposed program of the operation of the Food Agency;
 - in giving priority to the requests for scientifically based opinions.
- 5) The Advisory Council shall represent the mechanism for exchange of information on potential risks and for the pooling of knowledge. The Advisory Council shall facilitate cooperation among the relevant bodies and other groups that have interests in the sphere of food safety, that is, cattle feed safety.
- 6) The Advisory Council shall especially take part in the following activities:
 - in the communication between the Food Agency and other institutions, in the circumstances in which this is necessary;
 - in developing and promotion of networks of institutions that are active in the sphere of food safety and cattle feed safety;
 - in risk notification when the Food Agency identifies or otherwise receives information about the appearance of a risk.
- 7) The Advisory Council shall be chaired by the director of the Food Agency.
- 8) The Advisory Council shall convene on a regular basis, at the invitation by the chairperson or at the request of at least one third of its members, and at least four times a year.
- 9) The operative activities of the Advisory Council shall be determined by internal regulations of the Food Agency and shall be available to the public.
- 10) The Food Agency shall provide the necessary technical and logistic support to the Advisory Council, and provide the Secretary's Office for the Advisory Council's sessions.
- 11) The Advisory Council may call on representatives of other bodies to take part in the operation of the Advisory Council, who shall not have the right to vote.

Article 88

The Scientific Council and the Scientific Committees

- 1) The Scientific Council and the permanent Scientific Committees shall be responsible for making and proposing the scientific opinions of the Food Agency, within the framework of their

jurisdictions.

2) The Scientific Council shall make its own regulations on the activities with regard to the preparation of scientific opinions in the sphere of food safety, that is, cattle feed safety, which the Management Council of the Food Agency shall endorse, and which shall regulate specifically the following:

- how many consecutive times a member may carry out their duties in the Scientific Council or the Scientific Committee;
- the number of members in each Scientific Committee;
- the way in which the tasks and requirements for obtaining scientific opinions are given to the Scientific Council and the Scientific Committees;
- forming and organizing task forces of the Scientific Council and the Scientific Committees, and the possibility of including external experts in the task forces;
- the possibility of inviting observers to attend the meetings of the Scientific Council and the Scientific Committees;
- the possibility of organizing public debates.

3) The Scientific Council shall consist of the chairpersons of the Scientific Committees and six independent science experts who do not belong to any of the Scientific Committees.

4) The Scientific Committees shall consist of independent science experts from the following areas:

- natural sciences (biologists, microbiologists, geneticists, biochemists, molecular biologists);
- biomedicine and health (the sphere of public health, medicine, veterinary medicine);
- biotechnical sciences (food technologists, biotechnologists, agronomists);
- other scientists from other relevant areas.

5) The following Scientific Committees shall be established at the Food Agency:

- the committee for food additives, aromas, processing aids, and materials that come into contact with food;
- the committee for additives and products or substances that are used in the production of cattle feed;
- the committee for the health of plants, for products for the protection of plants, and their residues;
- the committee for new food and for the cattle feed that contains GMO;
- the committee for nutrition and allergies, and for dietetic products;
- the committee for biological hazards;
- the committee for contamination in the food chain;
- the committee for the health and welfare of animals.

5) The number of the Scientific Committees and their names may be changed, in view of technical and scientific development, by a decision adopted by the Management Council.

6) When a subject on which the Scientific Council should provide its opinion is not within the jurisdiction of any of the Scientific Committees, the Scientific Council shall appoint an ad hoc task force for this purpose.

7) The members of the Scientific Council who are not members of the Scientific Committees, as well as the members of the Scientific Committees, shall be selected by the Management Council, at the proposal of the director, from the list of candidates made after they apply for the public competition published in the media and the appropriate scientific magazines.

8) The mandate of the members of the Scientific Council and the Scientific Committees shall

last three years and may be renewed.

- 9) The Scientific Council and the Scientific Committees shall elect a chairperson and deputy chairperson from among the members.
- 10) The Scientific Council and the Scientific Committees shall make decisions based on the majority of the votes of their members, and the opinion of the minority shall be recorded.
- 11) Representatives of the Food Agency have the right to attend the sessions of the Scientific Council, the Scientific Committees, and their task forces. They may provide assistance in explanations or by providing information, but they may not influence the discussions.

Article 89

Scientific Opinions

- 1) The Scientific Council shall provide scientific opinions in the following cases:
 - at the request of the Management Council, concerning any issue within its jurisdiction, and in all the cases for which the national legislation envisages consulting the Scientific Council;
 - on its own initiative and on the issues from within its jurisdiction.
- 2) The requests stated in Paragraph 1 of this Article must be accompanied by all the necessary information that explain which scientific issue is involved.
- 3) The Scientific Council shall provide a scientific opinion within the period stated in the request for a scientific opinion, except in the cases in which objective circumstances preclude this.
- 4) In case several different requests are submitted with regard to the same issue, or in case the request is not in line with Paragraph 2 of this Article, or when the request is unclear, or when the Scientific Council has already provided an opinion of a certain issue and decided that there was no new information to consider, it may either reject the request or propose that it be changed and amended in agreement with the director. The rejection must be explained to the Management Council.

Article 90

Conflicting Scientific Opinions

- 1) The Scientific Council shall work toward establishing, in the early stages, the possible cause of conflict between its scientific opinions and the scientific opinions provided by other bodies that work on similar tasks in the Republic of Croatia or in another country.
- 2) In the case described in Paragraph 1 of this Article, the Scientific Council shall contact the above mentioned body in order to facilitate exchange of all the relevant scientific information and to identify the potentially disputable scientific issues.

Article 91

Fees and Expenses

- 1) The Food Agency shall compensate the members of the Management Council and the Advisory Council for the accounted expenses they incurred in the course of performing their duties

for the Food Agency, but they shall not receive separate payment for their services.

2) The members of the Scientific Council and the Scientific Committees shall receive fees for their services, and the expenses they incur in the course of performing their duties for the Food Agency shall also be compensated.

3) The amounts of the expenses and fees that the Food Agency shall pay to the appointed members who take part in the operation of the Management Council, the Advisory Council, the Scientific Council, and the Scientific Committees must be stated in the Food Agency's annual financial report.

XVIII THE PENALTY CLAUSES

Article 92

1) A legal person shall be penalized with a fine ranging from 50,000 kuna to 100,000 kuna in the following cases:

- if they place food on the market contrary to Article 11, Paragraph 1 of this Law;
- if they place cattle feed on the market contrary to Article 15, Paragraph 1 of this Law;
- if they carry out an activity in a facility that has not been approved, contrary to Article 26, Paragraph 1 of this Law;
- if they carry out an unapproved activity in a facility, contrary to Article 26, Paragraph 7 of this Law.

2) For offenses specified in Paragraph 1 of this Article the physical person that carries out the above mentioned activities and the person in charge within the physical person shall be penalized with a fine ranging from 5,000 kuna to 10,000 kuna.

Article 93

1) The legal person shall be penalized with a fine ranging from 30,000 kuna to 70,000 kuna in the following cases:

- if they carry out activities contrary to Article 14, Paragraphs 1 and 2 of this Law;
- if they carry out activities contrary to Article 30 of this Law;
- if they fail to establish systems that facilitate traceability of food, that is, cattle feed, from Article 31 of this Law;
- if they fail to establish internal control systems specified in Article 32 of this Law;
- if they use the "traditional repute" mark contrary to Article 41, Paragraph 1 of this Law;
- if they use the mark of geographical origin and the mark of originality contrary to Article 46, Paragraphs 1 and 2 of this Law;
- if they mark, present, or advertise food bearing the mark of geographical origin or the mark of originality contrary to Article 48, Paragraphs 1 and 2 of this Law;
- if they carry out activities contrary to Article 52 of this Law;
- if they label or mark, present, or advertise food or cattle feed contrary to Article 53 of this Law.

2) For offenses specified in Paragraph 1 of this Article the physical person that carries out the above mentioned activities and the person in charge within the physical person shall be penalized

with a fine ranging from 5,000 kuna to 10,000 kuna.

Article 94

- 1) The legal person shall be penalized with a fine ranging from 100,000 kuna to 500,000 kuna in the following cases:
 - if they place new food on the market contrary to Article 34, Paragraph 1 of this Law;
 - if they place on the market cattle food that contains or consists of the GMO contrary to Article 37, Paragraph 1 of this Law;
 - if they label or mark new food contrary to Article 56 of this Law;
 - if they label or mark cattle feed that contains or consists of the GMO contrary to Article 57 of this Law.
- 2) For offenses specified in Paragraph 1 of this Article the physical person that carries out the above mentioned activities and the person in charge within the physical person shall be penalized with a fine ranging from 5,000 kuna to 10,000 kuna.

Article 95

The physical person who acts contrary to Article 70, Paragraphs 3, 4, and 5 of this Law shall be penalized with a fine ranging from 5,000 kuna to 10,000 kuna.

XIX TRANSITIONAL PROVISIONS AND CONCLUDING PROVISIONS

Article 96

- 1) The minister of agriculture and forestry shall, within a year from the day this Law comes into force, endorse the implementation regulations specified in the following Articles of this Law:
 - Article 16, Paragraph 2 of this Law;
 - Article 24, Paragraphs 1 and 3 of this Law;
 - Article 37, Paragraph 3 of this Law;
 - Article 38, Paragraph 2 of this Law;
 - Article 40, Paragraph 2 of this Law;
 - Article 54, Paragraph 1 of this Law;
 - Article 55 of this Law;
 - Article 57, Paragraph 3 of this Law.
- 2) The minister of health shall, within a year from the day this Law comes into force, endorse the implementation regulations specified in the following Articles of this Law:
 - Article 14, Paragraph 3 of this Law;
 - Article 34, Paragraph 4 of this Law;
 - Article 35, Paragraph 2 of this Law;
 - Article 56, Paragraph 7 of this Law.

Article 97

- 1) The minister of agriculture and forestry shall, within two years from the day this Law comes

into force, endorse the implementation regulations specified in the following Articles of this Law:

- Article 26, Paragraph 10 of this Law;
 - Article 39, Paragraphs 2 and 3 of this Law.
- 2) The minister of agriculture and forestry, that is, the minister of health shall, within two years from the day this Law comes into force, endorse the implementation regulations specified in the following Articles of this Law:
- Article 17 of this Law;
 - Article 22, Paragraph 3 of this Law;
 - Article 26, Paragraph 3 of this Law;
 - Article 32, Paragraph 3 of this Law.

Article 98

The minister of agriculture and forestry shall, within three years from the day this Law comes into force, endorse the implementation regulations specified in the following Articles of this Law:

- Article 41, Paragraph 3 of this Law;
- Article 42, Paragraph 2 of this Law;
- Article 44, Paragraph 3 of this Law;
- Article 45, Paragraph 5 of this Law;
- Article 49, Paragraph 3 of this Law;
- Article 50, Paragraph 3 of this Law;
- Article 65, Paragraph 4 of this Law;
- Article 76, Paragraph 2 of this Law.

Article 99

- 1) The implementation regulations from Articles 96 and 97 of this Law, except in the case of the regulations from Article 97, Paragraph 1, Item 2, Article 96, Paragraph 1, Item 4, and Article 98, shall be endorsed following the previously obtained opinion of the Food Agency.

Article 100

- 1) The Government of the Republic of Croatia shall pass a decree on the establishment of the Food Agency as specified in Article 80, Paragraph 2 of this Law, within six months from the day this Law comes into force.
- 2) The Food Agency shall, within a year from the day this Law comes into force, be organized for the purposes of carrying out the activities specified in Article 81, Paragraphs 1, 2, and 3 of this Law.
- 3) The Food Agency shall, within two years from the day this Law comes into force, take over the activities specified in Article 26, Paragraphs 1, 2, 6, 8, and 9, and Article 81, Paragraph 4 of this Law.
- 4) The Food Agency shall, within three years from the day this Law comes into force, take over the activities specified in Article 13, Article 20, Article 75, and Article 77 of this Law.

Article 101

The deadline for the establishment of the internal control system specified in Article 32 of this Law is three years from the day this Law comes into force.

Article 102

The implementation of the provisions specified in Article 76, Paragraph 1, and Article 77, Paragraph 2 of this Law shall begin three years after the day this Law comes into force.

Article 103

The permits for placing on the market new food, as specified in Article 34 of this Law, and cattle feed that contains or consists of the GMO, as specified in Article 37 of this Law, shall not be issued until the implementation regulations described in Article 34, Paragraph 4, Article 35, Paragraph 2, Article 37, Paragraph 3, and Article 38, Paragraph 2 of this Law are endorsed.

Article 104

Until the implementation regulations described in Articles 96, 97, and 98 of this Law are endorsed, the implementation regulations endorsed on the basis of the Law on the Safety and Supervision of Foodstuffs and Objects of General Use (Narodne Novine 1/97), the Law on Veterinary Medicine (Narodne Novine 70/97 and 105/01), the Law on Standardization (Narodne Novine 55/96), the Law on Cattle Breeding (Narodne Novine 70/79), and the Law on the Marks of Geographical Origin of Products and Services (Narodne Novine 78/99) shall remain in force.

Article 105

- 1) The Law on Cattle Breeding (Narodne Novine 70/79) shall be harmonized with the provisions of this Law within a year from the day this Law comes into force.
- 2) The Law on the Safety and Supervision of Foodstuffs and Objects of General Use (Narodne Novine 1/97), the Law on Veterinary Medicine (Narodne Novine 70/97 and 105/01), the Law on Standardization (Narodne Novine 55/96) shall be harmonized with the provisions of this Law within two years from the day this Law comes into force.
- 3) The Law on the Marks of Geographical Origin of Products and Services (Narodne Novine 78/99) shall be harmonized with the provisions of this Law within three years from the day this Law comes into force.

Article 106

On the day this Law comes into force the provisions contained in Articles 14, 15, 16, 17, and 18 of the Law on State Inspectorate (Narodne Novine 76/99) shall no longer be valid.

Article 107

The Law shall come into force seven days after it is published in Narodne Novine.

[the following was not marked for translation and was omitted:

**Appendix 1: THE CATEGORIES OF CONTROL WITHIN THE JURISDICTION OF THE
SANITARY INSPECTORATE AND OF THE VETERINARY INSPECTORATE
EXPLANATIONS OF CERTAIN PROVISIONS OF THE DRAFT PROPOSED BILL ON
FOOD]**