

Law No. 150 from 14.05.2004 concerning food safety

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The Romanian Parliament has adopted this law

Chapter I General provisions

Article 1. (1) This law provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.

(2) It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

(3) Having regard of paragraph 1, this law lays down the general principles governing food and feed in general, and food and feed safety in particular.

(4) It lays down procedures for matters with a direct or indirect impact on food and feed safety.

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

Article 2

(1) For the purposes of this law "food or foodstuff" means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

(2) "Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

(3) "Food" shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products
- (e) cosmetics
- (f) tobacco and tobacco products
- (g) narcotic or psychotropic substances
- (h) residues and contaminants.

Article 3

For the purposes of this law:

1. "food law" means the laws, regulations and administrative provisions governing food in general, and food safety in particular, it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;

2. "food business" means any activity related to any stage of production, processing and distribution of food;

c) company or unit with food business activity – any unit regardless of obtaining or not a benefit from it's activity, public or private, which carries out any of the activities regarding production, processing and distribution of food;

- d) "food business operator" means the natural or legal person responsible for ensuring that the requirements of food law are met within their own food business;
- e) "food business employee" – a natural person obliged to apply within the activity carried out in a company or unit, the principles of food laws;
- f) "feed" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
- g) "feed business" means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;
- h) feed business activity – any feed production, processing, storage, transport or distribution activity, including the activity of any farmer which produces, processes or stores feed intended for animals in his own exploitation;
- i) "feed business operator" means the natural or legal person responsible for ensuring that the requirements of food law are met within the feed business under his control;
- j) "feed business employee" – a natural person obliged to apply within the activity carried out in a company or unit, the principles of feed laws;
- k) "retail" means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centers and wholesale outlets;
- l) "placing on the market" means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
- m) "risk" means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
- n) "risk analysis" means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
- o) "risk assessment" means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
- p) "risk management" means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;
- r) "risk communication" means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
- s) "hazard" means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
- §) "traceability" means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;
- t) "stages of production, processing and distribution" means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;
- ü) "primary production" means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;

u) "final consumer" – natural person or a group of natural persons who independently consumes a foodstuff as it is defined under this law.

CHAPTER II

Food law

SECTION 1

Scope

Article 4.

- (1) The dispositions of food law are applied to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.
- (2) The general principles laid down in Articles 5 to 10 shall form a general framework to be followed when measures are taken.
- (3) Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.
- (4) Till 1 January 2007 and by way of derogation of paragraph (3), the legislation in force shall apply in accordance with the principles set out in articles 5-10.

The specific legislation regarding food and feed will be elaborated in base of this law.

SECTION II

General principles

Article 5.

- (1) Food law pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection and welfare of animals, plant health and the environment.
- (2) Food law aims to achieve the free movement of manufactured food and feed or marketed according to the general principles and requirements in this Chapter.

In the process of elaboration and adapting the food legislation, the existing or in adoption international standards will be taken into account, except the cases when this standards or their provisions will not be an adequate or efficient way in obtaining the objectives of this legislation, or if there is a scientific motivation or where those can determine a different level of protection than the one established at community level.

Article 6

- (1) In order to achieve the general objective of a high level of protection of human health and life, food law is based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
- (2) Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
- (3) Risk management take into account the results of risk assessment, and in particular, the opinions of the Veterinary and Food Safety Agency, other factors legitimate to the matter under consideration and the precautionary principle .

Article 7

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

- (2) Measures adopted on the basis of paragraph 1 shall be proportionate with the possible effects of risk and shall not restrict more than is necessary the trade with foodstuffs in order to ensure a high level of health protection by taking into account technical and economical possibilities and other relevant factors.

The measures adopted in basis of paragraph 1 are reviewed within a reasonable period of time, depending on the nature of the risk to life or health, identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Article 8

Food law aims to protect the interests of consumers and provide them the necessary informations in order to make an informed choice of foods they consume and aim at the prevention of :

- (a) fraudulent or deceptive practices;
- (b) the adulteration of food;
- (c) any other practices which may mislead the consumer.

SECTION 3 PRINCIPLES OF TRANSPARENCY

Article 9

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

Article 10

Where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health determined by a food or feed depending on the nature, seriousness and extent of that risk public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

SECTION IV GENERAL OBLIGATIONS OF FOOD TRADE

Article 11

Food and feed imported for placing on the market in Romania shall comply with the requirements of food legislation or the ones provided in agreements between Romania and the exporting country.

Article 12

- (1) Food and feed exported or re-exported shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws in force in the importing country.
- (2) In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market.
- (3) Where the provisions of a bilateral agreement concluded between Romania and other state, food and feed exported from Romania must comply with the provisions of that agreement.

Article 13

In food trade, the competent authorities has the following obligations:

- (a) contribute to the development of technical standards for food and feed and sanitary and phytosanitary standards;
- (b) ensure the coordination of work on food and feed standards adopted by international governmental and non-governmental organisations;
- (c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;
- (d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;
- (e) promote consistency between international technical standards and food law in order to ensure a high level of protection.

SECTION V

General requirements

Article 14

To ensure the food safety, the next requirements will be respected:

- a) foods shall not be marketed if they are unsafe;
- b) foods are considered unsafe if they are not injuriously for health or inadequate to human consumption;
- c) In determining whether any food is unsafe, regard shall be had to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.
- d) In determining whether any food is injurious to health, regard shall be had to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations, to the probable cumulative toxic effects and to the particular health sensitivities of a specific category of consumers.
- e) In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
- f) Where a food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
- g) Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

Article 15

For ensuring feed safety, the following requirements will be respected:

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

- b) Feed shall be deemed to be unsafe for its intended use if it is considered to have an adverse effect on human or animal health or if it make the food derived from food-producing animals unsafe for human consumption;
- c) Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirements;
- d) Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

Article 16

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

Article 17

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

The competent authorities shall enforce food law. Those monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other control activities covering all stages of production, processing and distribution.

- (3) Measures and penalties applicable to infringements of food and feed law are established on legal basis. The measures and penalties must be effective, proportionate and dissuasive.

Article 18

- (1) The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.
- (2) Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.
- (3) Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

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

Article 19

- (1) If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.
- (2) A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.
- (3) Any food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operator shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply.

Article 20

- (1) If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(c), that feed shall be destroyed, unless the competent authorities decide otherwise.
- (2) The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.
- (3) Any feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, will withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.
- (4) Any feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from feed placed on market.
- (5) Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply.

Article 21

The responsibility concerning food and feed safety goes to food and feed industry agents and operators.

Article 22

The Veterinary and Food Safety Agency will elaborate regulations regarding rapid alert system and crisis management in emergency situations.

SECTION 6
Final provisions

Article 23

This law enter into force in 30 days from its publication in Official Gazette of Romania,

This law was adopted by Senate in 4 March 2004 taking into account the provisions of Article 76(2) of The Constitution of Romania, republished.