

Law no. 412 from 18.10.2004 for amending the Law no. 150/2004 concerning food safety

Published in Official Gazette of Romania no. 990 from 27.10.2004

Romanian Parliament has adopted this Law:

Article 1. – Law no. 150/2004 concerning food safety, published in Official Gazette of Romania, First Part, no. 462 from 24.05.2004, is modified and amended as follows:

1. The title of the Law will be: LAW for food and feed safety

2. Paragraphs (1), (3) and (5) of the Article 1 will be:

“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 the diversity in the supply of food, ensuring the effective functioning of the internal market.

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

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

3. Article 11 is introduced after article 1 and will have the following content:

“Article 11. – National Sanitary Veterinary and Food Safety Authority, established by Government Ordinance no. 42/2004 regarding the organization of the sanitary-veterinary and food safety activity, approved with amendments by Law no. 214/2004, hereinafter the Authority, is the authority for regulation in the sanitary-veterinary and food safety field, which coordinates all the activities in this field, from producing of raw materials to the consumer. The Authority is the contact institution with European Food Safety Authority and is functioning in basis of structural, functional and decisional autonomy.”

4. Paragraphs (1) and (2) of the Article 2 will be:

“ 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 designated for human consumption.

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

Article 3 will be:

“ Article 3. - For the purposes of this law, the next terms are defined as:

a) "food legislation" means the laws and other administrative provisions governing food in general, and food safety in particular, including residues and contaminants in food and feed and it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals;

- b) "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 its 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) "feed" means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for feeding of animals;
- f) "feed business" means any undertaking whether for profit or not and whether public or private, carrying out any of the activities related to 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;
- g) 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;
- h) "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;
- i) "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;
- j) "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;
- k) "risk" means the probability of apparition of an adverse health effect and the severity of that effect, as a result of exposure to a danger;
- l) "risk analysis" means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
- m) "risk assessment" means a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization;
- n) "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;

o) "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;

p) "hazard" means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;

q) "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;

r) "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;

s) "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;

ş) "final consumer" – the last consumer of food which not use the food as a part of an operation or activity from the domain of activity of a company or unit with food business activity;”

6. The title of chapter II will be:

“CHAPTER II – General food legislation”

7. Article 4 will be:

- (1) “ Article 4. – (1) The provisions 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.
- (5) In base of this law, the Authority, in cooperation with the authorized institutions, will elaborate The specific legislation regarding food and feed safety.

8. The title of section 2 of chapter II will be:

SECTION 2

General principles

9. Article 5 will be:

Article 5. – (1) Food legislation 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 marketed according to the general principles and requirements in this Chapter.

(3) 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 comunity level.

10. Article 6 will be:

“Article 6. – (1) In order to achieve the general objective of a high level of protection of human health and life, food legislation is based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

(2) Risk assessment is 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 other relevant factors for risk management and precautionary principle, in order to achieve the general objectives regarding food legislation, established in Article 5.”

11. The title of section 3 of chapter II will be:

SECTION 3

Transparency principles

12. Article 9 will be:

“Article 9. – Evaluation, revision and amendments of food law, shall be open and transparent public consultation, directly or through the Authority, Health Ministry, National Consumers Protection Authority, Ministry of Agriculture, Forests and Rural Development, other competent authorities and institutions represented in Consultative Council of the Authority, except the cases where the urgency of the matter does not allow it.”

13. Article 10 will be:

“Article 10. – Without prejudice the national legislation regarding the access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for consumers or animal health the Authority along with the others competent authorities, take the necessary measures 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.

14. Article 11 will be:

“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.

15. Article 12 will be:

“ Article 12 – (1) Food and feed designated for export or re-export for placing on the market in a third country shall comply with the relevant requirements of food legislation, unless otherwise requested by the competent authority of the importing country or established by the legislation, standards, practice codes and other legally and administrative procedures 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 and situations in which the food or feed were not be placed on the market in Romania.

(3) Where the provisions of a bilateral agreement concluded between Romania and a third country, food and feed exported from Romania must comply with the mentioned provisions.

16. Article 13 will be:

“Article 13. – In food trade, the Authority, along with the other competent authorities, where appropriate, has the following obligations:

a) to contribute to development of technical norms for food and feed and development of standards for food safety;

b) to promote and to coordinate the activities regarding standards for food and feed developed by international governmental and non-governmental organisations;

c) to contribute, if necessary, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;

d) to 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) to promote consistency between international technical standards and food legislation in order to ensure a high level of protection.

17. The title of section 5 of the Chapter II will be:

SECTION 5

General requirements of food legislation

18. Article 14 will be:

“Article 14. – For ensuring food safety the following requirements must 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.
- h) the conformity of a food with specific provisions applicable to that food will not be an obstacle for the Authority, along with the other competent authorities, when is necessary, to take measures for imposing restrictions to placing on the market or to withdraw where there are reasons to suspect that despite such conformity, the food is unsafe.

19. Article 15 will be:

“Article 15. – Requirements for feed safety are:

- 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.
- e) conformity of feed with the special provisions applicable, shall not hinder the Authority along with the others competent institutions in food safety domain to take measures to impose restrictions concerning placing on the market or to ask for withdraw in case there are reasons to suspect that despite this conformity, feed is unsafe.

20. Article 16 will be:

Article 16. –Without prejudice to specific provisions of food legislation, 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.

21. Article 17 will be:

“Article 17. – (1) Food and feed business operators must take the necessary measures to ensure that foods or feeds satisfy the requirements of food and feed legislation, which is relevant for their activities, to check if those requirements are realized and to ensure the implementation of the management system of food safety according to the principles regarding risk analysis and critical control points (Hazard Analysis and Critical Control Point – HACCP), in all stages of production, preparation and distribution, in their own business

(2) The Authority must ensure the enforcement of food legislation. This coordinates the activity of competent authorities in the field of food safety, controls and check the observance of food legislation by the operators with food and feed activity , and the implementation of the management system for food safety according to the principles regarding risk analysis and critical control points (Hazard Analysis and Critical Control Points- HACCP), in all stages of production, preparation and distribution. In this view, the Authority must maintain a control system and other necessary activities , including public communication regarding food and feed safety and risk, surveillance of food and feed safety and other monitoring activities in order to cover all the stages of production, preparation and distribution.

(3) The measures and penalties applicable for violations of food and feed legislation will be laid down according to the law. The measures and penalties must be efficient, proportionate and discouraging. “

22. Article 18 will be:

“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 Authority on demand.

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

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

23. Article 19 will be:

“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 Authority 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) Any 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, and/or the Authority.

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

(4) Food business operators must cooperate with the Authority as regards the actions taken to avoid or reduce risks posed by a food which they supply or they have supplied.

24. Article 20 will be:

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 Authority thereof. In these circumstances or, in the case of Article 15(c), feed that not satisfies the requirements of feed safety shall be destroyed, unless the Authority decide otherwise. 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.

(2) Any feed business operator responsible for retail or distribution activities shall initiate the procedures for withdraw from the market products not in compliance with the feed-safety requirements, within the limits of its respective activities, will supply informations for their traceability and participate to the actions taken by producers, processors and/or Authority, along with the other competent authorities .

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

- (4) Feed business operators shall collaborate with the Authority on action taken in order to eliminate or reduce the risks posed by a feed which they supply or they had supplied

After Article 22 , Article 22.1 is inserted and will have the following content:

Article 22.1. – By order of the president of the Authority, or by common order with other empowered institutions by law, according to competency domain, specific norms for application of this law will be developed.

Article II – Law no. 150/2004 regarding food safety, published in Official Gazette of Romania. Part I, no 462 from 24 May 2004, amended by the present Law, will be republished and the texts will be renumbered.

This Law was adopted by The Romanian Parliament by respecting the dispositions of Article 75 and 76(2) of The Constitution of Romania, republished.