

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

CHAPTER II

GENERAL FOOD LAW

Article 4

Scope

- 1 This Chapter relates 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 principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature 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 Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.

SECTION 1

GENERAL PRINCIPLES OF FOOD LAW

Article 5

General objectives

- 1 Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.
- 2 Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.
- 3 Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.

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Article 6

Risk analysis

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

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

3 Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.

Article 7

Precautionary principle

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 protection chosen in the Community 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 and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be 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

Protection of consumers' interests

1 Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

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

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SECTION 2

PRINCIPLES OF TRANSPARENCY

Article 9

Public consultation

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

Article 10

Public information

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, 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 3

GENERAL OBLIGATIONS OF FOOD TRADE

Article 11

Food and feed imported into the Community

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

Article 12

Food and feed exported from the Community

1 Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

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

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of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2 Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.

Article 13

International standards

Without prejudice to their rights and obligations, the Community and the Member States shall:

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

SECTION 4

GENERAL REQUIREMENTS OF FOOD LAW

Article 14

Food safety requirements

- 1 Food shall not be placed on the market if it is unsafe.
- 2 Food shall be deemed to be unsafe if it is considered to be:
 - a injurious to health;
 - b unfit for human consumption.
- 3 In determining whether any food is unsafe, regard shall be had:
 - a to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
 - b to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.
- 4 In determining whether any food is injurious to health, regard shall be had:

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- a not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
- b to the probable cumulative toxic effects;
- c to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

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

6 Where any food which is unsafe is part of a batch, lot or consignment of food of the same class 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.

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

8 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.

9 Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 15

Feed safety requirements

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

- 2 Feed shall be deemed to be unsafe for its intended use if it is considered to:
- have an adverse effect on human or animal health;
 - make the food derived from food-producing animals unsafe for human consumption.

3 Where a feed which has been identified as not satisfying the feed safety 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 requirement.

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

5 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.

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6 Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

Article 16

Presentation

Without prejudice to more specific provisions of food law, 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

Responsibilities

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

2 Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, 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 monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

Article 18

Traceability

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.

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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.

4 Food or feed which is placed on the market or is likely to be placed on the market in the Community 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.

5 Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

Article 19

Responsibilities for food: food business operators

1 If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and 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, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3 A 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. Operators 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.

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

Article 20

Responsibilities for feed: feed business operators

1 If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if

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necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

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

3 A 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 a feed.

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

Article 21

Liability

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products⁽¹⁾.

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- (1) [OJ L 210, 7.8.1985, p. 29](#). Directive as last amended by Directive 1999/34/EC of the European Parliament and of the Council ([OJ L 141, 4.6.1999, p. 20](#)).

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