

Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food

(2001/C 96 E/17)

(Text with EEA relevance)

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(Submitted by the Commission on 29 November 2000)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

measures governing food taken in the Member States and at Community level.

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95, 133 and 152(4)(b) thereof,

(6) In this regard, water is ingested as other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. It should therefore be considered to be food, without prejudice to the requirements established in Council Directives 80/778/EEC⁽¹⁾ and 98/83/EC⁽²⁾ on the quality of water intended for human consumption.

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

(7) The Community has chosen a high level of health protection as appropriate in the development of food law which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

(8) It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.

Whereas:

(1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(9) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that only safe food is placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health.

(2) A high level of protection of human life and health should be assured in the pursuit of Community policies.

(3) The free movement of food within the Community can be achieved only if food safety requirements do not differ significantly from Member State to Member State.

(10) In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.

(4) There are important differences in relation to concepts, principles and definitions of food in the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.

(11) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum because each element may have a potential impact on food safety.

(5) Accordingly, it is necessary to approximate these concepts, principles and definitions of food in the Member States so that they form a common basis for

⁽¹⁾ OJ L 229, 30.8.1980, p. 11; Directive as last amended by the Act of Accession of Austria, Finland and Sweden.

⁽²⁾ OJ L 330, 5.12.1998, p. 32.

- (12) Experience has shown that for this reason it is necessary to consider the production, manufacture and distribution of feed given to food-producing animals, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.
- (13) For the same reason, it is necessary to consider other practices and agricultural inputs at the level of primary production and their potential effect on the overall safety of food.
- (14) Measures adopted by the Member States and the Community governing food safety should not be based on the yardstick of general conjecture but on the basis of a risk analysis. Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.
- (15) Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected principles of risk analysis: risk assessment, risk management, and risk communication, provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.
- (16) In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.
- (17) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk-management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, ethical and environmental factors and the feasibility of controls.
- (18) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food. By adopting a uniform basis throughout the Community, the possibility of an improper use of this principle is diminished.
- (19) In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.
- (20) Experience has shown that the functioning of the internal market in food can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within feed and food businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.
- (21) It is necessary to ensure that a food or feed business including an importer can identify at least the business from whom the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.
- (22) A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, he should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas, this is either not explicit or else responsibility is assumed by the competent authorities of the Member State, through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.
- (23) Similar requirements should apply to feed and feed business operators.
- (24) Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, such Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise.
- (25) It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.
- (26) The safety and confidence of consumers within the Community, and in third countries, are of paramount importance. The Community is a major global trader in food and in this context it has entered into international trade agreements, it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe and wholesome foods in a non-discriminatory manner, following fair and ethical trading practices.

- (27) It is necessary to establish the general principles upon which food may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.
- (28) Food safety is of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.
- (29) The scientific and technical basis of Community legislation relating to the safety of food should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.
- (30) The scientific and technical issues in relation to food safety are becoming increasingly important and complex. The establishment of a European Food Authority, hereinafter referred to as 'the Authority', should reinforce the present system of scientific and technical support which is no longer able to respond to increasing demands on it.
- (31) It is therefore necessary to establish the Authority to serve as a mechanism for applying the general principles of food law, in particular by carrying out the risk assessments necessary for the adoption of Community measures governing food safety, in an independent, objective and transparent manner.
- (32) The Authority should take on the role of an independent scientific point of reference and in so doing should assist in ensuring the smooth functioning of the internal market. It may be called upon to give opinions on contentious scientific issues, thereby enabling Member States to take informed risk-management decisions necessary to ensure food safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food.
- (33) The Authority's role as an independent scientific point of reference means that a scientific opinion may be requested not only by the Commission, but also by the European Parliament and the Member States or a competent national body. Steps should also be taken to help avoid conflicting scientific opinions and, in the event of conflicting scientific opinions between several scientific bodies, procedures should be in place to solve the conflict or provide the risk managers with a transparent basis of scientific information.
- (34) The Authority should be an independent source of information and risk communication in order to improve consumer confidence.
- (35) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992⁽¹⁾ on general product safety. The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed. This revised system should be operated by the Authority. The system should not cover the early exchange of information in the event of a radiological emergency established in Council Decision 87/600/Euratom⁽²⁾.
- (36) The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food supply chain, which implies wide-ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food supply chain, animal health and welfare, plant health and nutrition.
- (37) Since some products authorised under food legislation such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should be covered by the Authority.
- (38) The Authority should provide scientific opinions concerning all genetically modified organisms within the meaning of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms⁽³⁾ whether or not intended for human or animal consumption, including the scientific assessment of their environmental impact in order to avoid duplicated scientific assessments and related scientific opinions on these organisms. However, it is necessary to avoid confusion of competence with the environmental fields as concerns genetically modified organisms that are not food or feed, therefore the Authority should be restricted in its mission in relation to genetically modified organisms that are not food or feed to scientific opinions.
- (39) The confidence of the Community institutions, the general public and interested parties in the Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency; cooperation with the Member States is also indispensable.

⁽¹⁾ OJ L 228, 11.8.1992, p. 24.

⁽²⁾ OJ L 371, 30.12.1987, p. 76.

⁽³⁾ OJ L 117, 8.5.1990, p. 15; Directive as last amended by Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

- (40) The Authority should have the means to perform all the tasks required to enable it to carry out its role.
- (41) It is necessary to ensure that there is effective monitoring of the Authority by the various Community institutions involved, and for this purpose its Management Board should include four representatives appointed by the European Parliament, four by the Council, and four by the Commission. The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations, appoint members of the Scientific Committee and Scientific Panels and appoint the Executive Director.
- (42) It is necessary to build up a relationship of confidence and transparency with the general public, and therefore the Management Board should include four representatives of consumers and industry.
- (43) The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively, in particular with regard to the networking system, and an Advisory Forum should be created for this purpose.
- (44) The Authority should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence. It is necessary to reorganise these Committees to ensure greater scientific consistency in relation to the food supply chain and to enable them to work more effectively. A Scientific Committee and Permanent Scientific Panels should therefore be set up within the Authority to provide these opinions.
- (45) In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure.
- (46) The Authority should also be able to commission scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States prevent duplication of effort. The Authority should take into account existing Community expertise and structures notably as concerns networks of scientific experts established under Community programmes for research and technological development (RTD) and by the Joint Research Centre. In addition, the Authority when planning its work should take due note of relevant actions undertaken by the Joint Research Centre and under Community RTD programmes.
- (47) The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the Authority should therefore be set up, in the form of a network coordinated by the Authority. Specific provisions for the adaptation of Community data collection networks already existing in the fields covered by the Authority are called for.
- (48) Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in the exercise of its policies. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance.
- (49) The establishment of the Authority should enable Member States to become more closely involved in scientific procedures; there should therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.
- (50) It is necessary to ensure that a balance is struck between the use of national organisations carrying out tasks for the Authority and the need to ensure for the purposes of overall consistency that such tasks are carried out in line with the criteria established for such tasks for the Authority. Existing procedures for the allocation of scientific tasks to the Member States, in particular with regard to the evaluation of dossiers presented by industry for the authorisation of certain substances, products or procedures, should be re-examined within a year to take into account the establishment of the Authority and the new facilities it offers.
- (51) The independence of the Authority and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information. However, the Commission remains fully responsible for communicating risk management measures; the appropriate information should therefore be exchanged between the Authority and the Commission.
- (52) Appropriate cooperation with the Member States is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.
- (53) In addition to its operating principles based on independence and transparency, the Authority should be an organisation open to contacts with consumers and other interested groups and should be able to arrange their involvement in some of its work, in accordance with its own rules.

(54) The Authority should be financed by the Community budget. However, in the light of experience acquired, in particular with regard to the processing of authorisation dossiers presented by industry, the possibility of fees should be examined within three years after the entry into force of the Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the Communities are concerned; moreover, the auditing of accounts should be undertaken by the Court of Auditors.

(55) It is necessary to allow for the participation by European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.

(56) Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, should be subject to common measures in the event of a serious risk to human health. Such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of food representing a serious risk to human health.

(57) Recent food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crises management. These organisational procedures should make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information; therefore, revised procedures should take into account the Authority's responsibilities and should provide for its scientific and technical assistance in the event of a food crisis.

(58) In order to ensure a more effective, comprehensive approach to the food chain, a Committee on Food Safety and Animal Health should be established to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs, the Standing Committee for Feedingstuffs and the Standing Committee on Plant Health. Accordingly, Council Decisions 68/361/EEC⁽¹⁾, 69/414/EEC⁽²⁾, 70/372/EEC⁽³⁾ and 76/894/EEC⁽⁴⁾, should be repealed.

(59) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of

28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽⁵⁾, they should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.

(60) Without prejudice to the obligation of the Member States to ensure compliance with the requirements laid down in this Regulation, a provision should be established to avoid creating legal uncertainty as to existing Community and national measures governing food.

(61) It is important to avoid confusion between the missions of the Authority and the European Medicinal Evaluation Agency (EMA) established by Council Regulation (EEC) No 2309/93⁽⁶⁾. Consequently, it is necessary to establish that this Regulation is without prejudice to the competence conferred on the EMA by Community legislation, including powers conferred by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin⁽⁷⁾.

(62) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objectives of this Regulation to provide for definitions, principles and measures for food legislation in the Community and to establish a European Food Authority. This Regulation confines itself to what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Aim and scope

1. This Regulation provides the basis for the assurance of a high level of protection of human life and health and consumers' interest in relation to food, whilst ensuring the effective functioning of the internal market. It establishes common principles, definitions and responsibilities, a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food safety.

⁽⁵⁾ OJ L 184, 17.7.1999, p. 23.

⁽⁶⁾ OJ L 214, 24.8.1993, p. 1; Regulation as amended by Regulation (EC) No 649/1998 (OJ L 88, 24.3.1998, p. 7).

⁽⁷⁾ OJ L 224, 18.8.1990, p. 1; Regulation as last amended by Commission Regulation (EC) No 2391/2000 (OJ L 276, 28.10.2000, p. 5).

⁽¹⁾ OJ L 255, 18.10.1968, p. 23.

⁽²⁾ OJ L 291, 19.11.1969, p. 9.

⁽³⁾ OJ L 170, 3.8.1970, p. 1.

⁽⁴⁾ OJ L 340, 9.12.1976, p. 25.

2. For the purposes of paragraph 1, this Regulation lays down the general definitions and principles governing food and feed in general, and food and feed safety in particular, in the Community.

It establishes the European Food Authority.

It lays down procedures for matters with a direct or indirect impact on food safety.

3. This Regulation shall apply to all stages of production and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for domestic consumption.

Article 2

Definition of 'food'

'Food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or expected to be ingested by humans.

It includes drink, chewing gum and any substance intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water, without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

It shall not include:

- (a) feed;
- (b) live animals unless they are prepared, packaged and/or served for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directive 65/65/EEC ⁽¹⁾;
- (e) cosmetics within the meaning of Council Directive 76/768/EEC ⁽²⁾;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC ⁽³⁾;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961 and the United Nations Convention on Psychotropic Substances, 1971.

Article 3

Other definitions

For the purposes of this Regulation:

- 1. 'food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, in the Community; it covers all stages of production and distribution of food, and also feed where feed may have an adverse effect on food safety;
- 2. 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to the stages of production and distribution of food;
- 3. 'food business operator' means the person or persons responsible for ensuring that the requirements of food law are met within the food business under their control;
- 4. 'feed' or 'feedingstuff' means products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from industrial preparation thereof, intended for oral feeding to food-producing animals;
- 5. 'feed business' means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage or distribution of feed including any agricultural producer producing, processing or storing feed for feeding to food animals on his own holding;
- 6. 'feed business operator' means the person or persons responsible for ensuring that the requirements of food law are met within the feed business under their control;
- 7. 'retail trade' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes mass catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;
- 8. '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, to third parties, and the sale and other forms of transfer themselves;
- 9. 'official control' means any inspection, verification audit, sampling, laboratory examination or analysis or other means of performing controls by the competent authority of the Member States or their agents or by the services of the Commission with a view to ensuring compliance with food law and to protecting human health and consumer interests;

⁽¹⁾ OJ 22, 9.2.1965, p. 369/65.

⁽²⁾ OJ L 262, 27.9.1976, p. 169.

⁽³⁾ OJ L 359, 8.12.1989, p. 1.

10. 'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
11. 'risk analysis' means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
12. 'risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
13. '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;
14. '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;
15. 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
16. 'traceability' means the ability to trace a food, feed, food-producing animal or ingredient, through all stages of production and distribution;
17. 'all stages of production and distribution' means all stages from and including the primary production of a food, up to and including its sale or supply to the final consumer and, where relevant to food safety, the production, manufacture and distribution of feed;
18. 'unfit for human consumption or contaminated' means that 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;
19. 'primary production' means the production, rearing or growing of primary products up to and including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing.

CHAPTER II

GENERAL FOOD LAW*Article 4***Scope**

This Chapter shall relate to all stages of the production and distribution of food and to feed produced for, or fed to, food-producing animals.

The general principles laid down in Articles 5 to 8 shall form a general framework of a horizontal nature to be followed when new measures are established.

Section 1

Principles of and requirements of food law*Article 5***General objectives**

1. Food law shall pursue one or more of the general objectives of the protection of human life, health or safety, the protection of consumers' interests, and other objectives, including, where appropriate, the protection of the environment, the protection of animal health, life and welfare and the protection of plant health and life.

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 there is a scientific justification, or where they would result in a different level of protection than the one determined as appropriate in the Community.

*Article 6***Protection of health**

1. Food law shall aim to achieve a high level of health protection, and 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 European Food Authority established in Article 21, and other factors as legitimate to the matter under consideration.

*Article 7***Precautionary principle**

1. In those specific circumstances where, following an assessment of available pertinent information, a risk to 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.

2. Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of foods, 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 9***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 and distribution, where necessary under the conditions laid down pursuant to paragraph 5.

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 other businesses to whom 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, 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 shall be adopted in accordance with the procedures laid down in Article 57(2).

*Article 10***Responsibilities**

1. Food and feed business operators at all stages of production and distribution within the businesses under their control shall ensure that foods or feeds satisfy the relevant requirements of food law and shall put in place systems and procedures to verify and monitor 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 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 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 11***Liability**

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC⁽¹⁾ concerning liability for defective products.

⁽¹⁾ OJ L 210, 7.8.1985, p. 29.

Section 2

Requirements of food safety

Article 12

Food safety requirements

1. Only food that is safe under normal and reasonably foreseeable conditions of use shall be placed on the market.

2. Food shall be considered as unsafe if it is:

(a) potentially injurious to health;

(b) unfit for human consumption or contaminated.

3. The safety of food shall be considered at all stages of production and distribution, taking into account, at each stage, its normal and reasonably foreseeable conditions of use.

4. In determining whether any food is potentially injurious to health, regard shall be had:

(a) to the normal and reasonably foreseeable conditions of use of the food so that the food does not present a risk which is unacceptable or which is inconsistent with the high level of protection for the health of a person consuming the food;

(b) not only to the possible immediate or short term effect of that food on the health of a person consuming it, but also to the potential cumulative toxic effects of a food on the health of a person, or on subsequent generations of a person consuming that food in ordinary quantities;

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

5. In determining whether the food is safe, consideration shall also be given 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, and whether, despite such information, the consumer has chosen to ignore such instructions or other information concerning that food or categories of foods.

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 of 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 of food law shall be deemed to be safe in so far as the aspects covered by the specific Community provisions are concerned.

8. 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 in circulation, such provisions being drawn up and applied without prejudice to the Treaty, and in particular Articles 28 and 30 thereof.

Article 13

Feed safety requirements

1. No feed shall be placed on the market or fed to any food-producing animal unless it satisfies the feed safety requirements.

2. A feed does not satisfy the feed safety requirement if it:

— has a detrimental effect on human or animal health;

— makes the food derived from the food-producing animal to which it is fed or to which it may be expected to be fed, unsafe for human consumption;

— harms the consumer by impairing the distinctive features of the animal products.

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 in so far as the aspects covered by the specific Community provisions are concerned.

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

*Article 14***Responsibilities for food safety: food businesses**

1. Food business operators shall ensure that all stages of production and distribution under their control are carried out in such a manner that food complies with the relevant provisions of food law, and in particular, food safety.

2. A food business operator shall immediately inform the competent authorities if he considers or suspects that a food which it has placed on the market may be potentially injurious to human health. The operators shall inform the competent authorities of the action taken to prevent risks to the final consumer.

In cases where the food business operator considers or suspects that a food may present a serious risk to human health he shall notify the competent authority thereof.

3. Food business operators shall collaborate with the competent authorities according to the requests of the latter, on action taken to avoid risks posed by a food which they supply or have supplied.

4. If a food business operator considers or suspects that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall initiate procedures to withdraw the food in question from the market. The operator shall adequately and effectively 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.

5. A food business operator responsible for import, retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall act with due care to help ensure compliance with the food safety requirements.

Within the limits of their respective activities, such food business operators shall 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.

*Article 15***Responsibilities for food safety: feed businesses**

1. Feed business operators shall ensure that all stages of production and distribution under their control are carried

out in such a manner that the feed they produce or handle complies with the relevant provisions of food law, and in particular that the feed satisfies the feed safety requirements.

2. A feed business operator shall immediately inform the competent authorities if it considers or suspects 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.

In cases where the feed business operator considers or suspects that the use of the feed would present a serious risk to human health he shall notify the competent authority thereof.

3. Feed business operators shall collaborate with the competent authorities according to the requests of the latter, on action taken to avoid risks posed by a feed which they supply or have supplied.

4. If a feed business operator considers or suspects that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall initiate procedures to withdraw the feed in question from the market. The operator shall adequately and effectively 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.

5. A feed business operator responsible for import, retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed, shall act with due care to help ensure compliance with the feed safety requirements.

Within the limits of their respective activities, such operators shall 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.

Section 3***Principles of food trade****Article 16***Food imported into the Community**

1. Food imported into the Community shall comply with the relevant requirements of food law or, where specific agreements exist, with requirements which are at least equivalent.

2. By way of derogation from paragraph 1, food which is not intended to be placed on the market in the Community by reason of its being in transit from one third country to another, or intended to be processed for immediate exportation, may be allowed on to the territory of the Community provided that such food or its derivatives do not enter the Community market.

3. Feed imported into the Community shall comply with the relevant requirements of food law, or, where specific agreements exist, with requirements which are at least equivalent. Paragraph 2 shall apply to feed similarly.

Article 17

Food exported from the Community

1. Food exported from the Community shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or stated by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

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 exported from the Community to that third country shall comply with the said provisions.

3. Food exported from the Community shall not be unsafe, or labelled or presented in a manner that is false, misleading or deceptive.

4. Food which has been found to be injurious to health, or labelled or presented in a manner that is false, misleading or deceptive in the Community, or has been otherwise denied access to the Community market shall not be exported or re-exported from the Community, unless the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances under which, the concerned food could not be placed on the market in the Community.

5. Paragraphs 1 to 4 shall apply similarly to feed.

Article 18

International food standards

Without prejudice to its rights and obligations, the Community 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.

Section 4

Principles of transparency

Article 19

Public consultation

Wherever circumstances allow there shall be effective public consultation, directly or through representative bodies, at an appropriate stage, during the preparation of food law.

Article 20

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 may present a risk for human, animal or plant 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 type of food, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

CHAPTER III

EUROPEAN FOOD AUTHORITY

Section 1

Mission and tasks

Article 21

Mission of the Authority

1. A European Food Authority is hereby established, hereinafter referred to as the 'Authority'.
2. The mission of the Authority shall be to contribute to a high level of protection of human life and health, protection of animal health and welfare, protection of plant life, protection of the environment and protection of the health of workers, while facilitating the functioning of the internal market, by setting up an integrated, coherent system of scientific and technical support for the Community's legislation and policies and by the provision of independent information and risk communication.

That mission shall cover:

- (a) all fields having a direct or indirect impact on the safety of the food;
- (b) animal health and welfare, plant health;
- (c) nutrition;
- (d) any matter relating to genetically modified organisms within the meaning of Directive 90/220/EC.

As regards genetically modified organisms that are not food or feed, the mission of the Authority shall be limited to the provision of scientific opinions.

The mission of the Authority shall include the operation of the rapid alert system for food and feed.

3. The Authority shall provide opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.

4. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation and its diligence in performing the tasks assigned to it.

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks.

5. The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.

Article 22

Tasks of the Authority

The tasks of the Authority shall be the following:

- (a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;
- (b) to promote and coordinate the harmonisation of risk assessment methodologies in the fields falling within its mission;
- (c) to provide scientific and technical support to the Commission in the areas within its mission;
- (d) to commission scientific studies necessary for the accomplishment of its mission;
- (e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;
- (f) to undertake action to identify and characterise emerging risks with a view to reducing or preventing them, in the fields within its mission;

- (g) to establish a system of networks of organisations operating in the fields within its mission and shall be responsible for their operation;
- (h) to be responsible for the operation of the rapid alert system for food and feed established by this Regulation;
- (i) to provide scientific and technical assistance when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;
- (j) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, European Union applicant countries, international organisations and third countries, in the fields within its mission;
- (k) to provide, when requested to do so by the Commission, assistance concerning communication on health-policy-related nutritional issues;
- (l) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;
- (m) to express its own conclusions and orientations on matters within its mission;
- (n) to undertake any other task assigned to it by the Commission within its mission.

Section 2

Organisation

Article 23

Bodies of the Authority

The Authority shall comprise:

- (a) a Management Board;
- (b) an Executive Director and his staff;
- (c) an Advisory Forum;
- (d) a Scientific Committee and Scientific Panels.

Article 24

Management Board

1. The Management Board shall be composed of four representatives appointed by the European Parliament, four representatives appointed by the Council, four representatives appointed by the Commission and four representatives of consumers and industry designated by the Commission.

2. Representatives may be replaced by alternates, appointed at the same time. Their term of office shall be four years, and may be renewed once.

3. The Management Board shall elect its Chairperson from among its members for a two-year period, which shall be renewable.

4. The Management Board shall adopt its rules of procedure.

Unless otherwise provided, the Management Board shall act by a majority of its members.

5. The Management Board shall meet at the Chairperson's invitation or at the request of at least a third of its members.

6. The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

7. Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Commission's legislative and policy priorities in the area of food safety.

Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.

The Executive Director shall forward the programmes and report to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

8. The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director.

9. The Management Board, having received the Commission's approval and the opinion of the Court of Auditors, shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the financial regulation applicable to the European Union's general budget.

10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat.

Article 25

Executive Director

1. The Executive Director shall be appointed by the Management Board, on the basis of a proposal by the Commission, for a period of five years which shall be renewable. He may be removed from office by the Management Board.

2. The Executive Director shall be the legal representative of the Authority. He shall be responsible:

(a) for the day-to-day administration of the Authority;

(b) for drawing up the Authority's work programmes in agreement with the Commission;

(c) for implementing the work programmes and the decisions adopted by the Management Board;

(d) for ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;

(e) for ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;

(f) for the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;

(g) for all staff matters.

3. Each year, the Executive Director shall submit to the Management Board for approval:

(a) a draft report covering all the activities of the Authority in the previous year;

(b) draft programmes of work;

(c) the draft annual accounts for the previous year;

(d) the draft budget for the coming year.

4. The Executive Director shall approve all financial expenditure of the Authority and report on the Authority's activities to the Management Board.

Article 26

Advisory Forum

1. The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State.

2. Members of the Advisory Forum may not be members of the Management Board.

3. The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation and shall ensure close cooperation between the Authority and the competent bodies in the Member States which undertake tasks similar to those of the Authority.

4. The Advisory Forum shall be chaired by the Executive Director, who shall convene its meetings. Its operational procedures shall be specified in the Authority's internal rules.

5. The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the secretariat of its meetings.

6. Representatives of the Commission's departments shall be entitled to take part in the work of the Advisory Forum.

Article 27

Scientific Committee and Scientific Panels

1. The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence.

2. The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on multisectoral issues falling within the competence of several Scientific Panels, and on issues which do not fall within the competence of any of the Scientific Panels.

3. The Scientific Committee shall be composed of the chairpersons of the Scientific Panels and 6 independent scientific experts who do not belong to any of the Scientific Panels.

4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:

- (a) the Panel on food additives, flavourings, processing aids and materials in contact with food;
- (b) the Panel on additives and products or substances used in animal feed;
- (c) the Panel on plant protection products and their residues;
- (d) the Panel on genetically modified organisms;
- (e) the Panel on dietetic products, nutrition and allergies;
- (f) the Panel on biological hazards;
- (g) the Panel on contaminants in the food chain;
- (h) the Panel on animal health and welfare.

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request, in accordance with the procedure referred to in Article 57(2).

5. The members of the Scientific Committee that are not members of Scientific Panel and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, which shall be renewable, following publication in the *Official Journal of the European Communities* of a call for expressions of interest.

6. The Scientific Committee and the Scientific Panels shall each choose a Chairperson and two Vice-Chairpersons from among their members.

7. The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.

8. The representatives of the Commission's services shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.

9. The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules.

These procedures shall relate in particular to:

- (a) the number of times that a Member can serve consecutively on a Scientific Committee or Scientific Panel;
- (b) the number of members in each Scientific Panel;
- (c) the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;
- (d) the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;
- (e) the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups.

Section 3

Operation

Article 28

Scientific opinions

1. The Authority shall issue a scientific opinion:
 - (a) at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;
 - (b) at the request of the European Parliament or a Member State or a national competent body as mentioned in Article 21(4), in respect of any matter within its mission, where Community legislation makes no specific provision for the Authority to be consulted on such a matter;
 - (c) on its own initiative, on matters falling within its mission.

2. Where Community legislation does not already specify a time-limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time-limit specified in the requests for opinions, except in duly justified circumstances.

3. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure referred to in Article 57(2). These rules shall specify:

(a) the procedure to be applied by the Authority to the requests referred to it, laying down in particular the circumstances in which it may refuse or modify a request for an opinion;

(b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

4. The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

Article 29

Conflicting scientific opinions

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of conflict between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of conflict, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.

3. Where a substantive conflict over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to cooperate with a view to either resolving the conflict or presenting a joint document to the Commission clarifying the contentious scientific issues.

4. Where a substantive conflict over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate, in consultation with the Advisory Forum, with a view to either resolving the conflict or presenting a joint document clarifying the contentious scientific issues.

Article 30

Scientific and technical assistance

1. The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which do not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular the establishment or evaluation of technical criteria, the development of technical guidelines or guides as to good practice.

2. Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time-limit within which the task must be completed.

Article 31

Scientific studies

1. The Authority shall commission scientific studies necessary for the performance of its mission. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

Article 32

Collection of data

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

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

(b) incidence and prevalence of biological risk;

(c) contaminants in food intended for human and animal consumption, including residues.

2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from European Union applicant countries, third countries or international bodies.

3. The Member States shall take the necessary measures to enable the data collected in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.

5. Within one year from the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the scope of the Authority.

The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:

- (a) for each system, the role which should be assigned to the Authority, and any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States;
- (b) the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its scope.

6. The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

Article 33

Identification of emerging risks

1. The Authority shall search for, collect, collate, analyse and summarise all information and data enabling it to identify emerging risks in the fields within its mission.
2. Where the Authority has information leading to the suspicion of a serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as quickly as possible and forward any relevant information in their possession.
3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.
4. The Authority shall forward the information collected on emerging risks to the European Parliament, the Commission and the Member States.

Article 34

Rapid alert system

1. The Authority shall be responsible for the operation of the rapid alert system for food and feed established in Article 49.
2. The Authority, in consultation with the Member States and the Commission, shall set up the facilities necessary for the

rapid transmission of information required for the operation of the rapid alert system.

Article 35

Networking of organisations operating in the fields within the Authority's mission

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.
2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list of competent and independent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular, preparatory work for scientific opinions, scientific and technical assistance, scientific studies, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.
3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 57(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent and independent organisations designated by the Member States, modalities setting out harmonised quality requirements and the financial rules governing any financial support.
4. Within one year from the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States.

Section 4

Independence, transparency and communication

Article 36

Independence

1. The members of the Management Board and the members of the Advisory Forum shall undertake to act independently in the public interest.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

2. The members of the Scientific Committee and the Scientific Panels, shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the lack of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

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

Article 37

Transparency

1. The Authority shall ensure that it carries out its activities with a high level of transparency. It shall make public:

- (a) the opinions of the Scientific Committee and the Scientific Panels as soon as possible after adoption, minority opinions always being included;
- (b) the annual declarations of interest made by members of the Management Board, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings;
- (c) the results of its scientific studies;
- (d) its annual report of its activities.

2. The Management Board, acting on a proposal from the Executive Director, may decide to hold some of its meetings in public and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.

3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

Article 38

Confidentiality

1. By way of derogation from Article 37, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made

public if circumstances so require, in order to protect human health.

2. Members of the Management Board, the executive director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, are subject to the requirements of confidentiality pursuant to Article 287 of the EC Treaty.

3. The conclusions of the scientific opinions delivered by the Authority in relation with foreseeable health effects shall not on any account be kept confidential.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

Article 39

Communication

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk-management decisions.

2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily understandable information, in particular with regard to the results of its work. To facilitate the public's understanding of its work, it shall develop and disseminate information material for the general public.

3. The Commission and the Authority shall ensure appropriate exchange of information on matters relating to their respective competence in the field of risk communication.

4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

Article 40

Access to documents

1. The Authority shall ensure wide access to the documents which it possesses.

2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1, taking into full account the general principles and conditions governing the right of access to the Community institutions' documents.

Article 41

Consumers and other interested parties

The Authority shall develop appropriate contacts with consumer representatives and any other interested parties.

Section 5

Financial provisions

Article 42

Adoption of the Authority's budget

1. The revenues of the Authority shall consist of a contribution from the Community and, in addition, any fees received by the Authority in payment for the services it provides.
2. The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 35.
3. By 31 March each year at the latest, the Executive Director shall draw up an estimate of the Authority's revenue and expenditure for the coming financial year, and shall forward it to the Management Board, accompanied by a list of posts.
4. Revenue and expenditure shall be in balance.
5. The Management Board shall, by 31 March at the latest, adopt the draft budget and forward it to the Commission which on that basis shall enter the relevant estimates in the preliminary draft general budget of the European Communities, which it shall put before the Council pursuant to Article 272 of the Treaty
6. The Management Board shall adopt the Authority's budget, adjusting it where necessary to the Community's contribution.

Article 43

Implementation of the Authority's budget

1. The Executive Director shall implement the Authority's budget.
2. Control of commitment and payment of all expenditure, and control of the existence and recovery of all the Authority's revenue shall be carried out by the Commission's financial controller.
3. By 31 March each year at the latest, the Executive Director shall forward to the Commission, the Management Board and the Court of Auditors the detailed accounts for all the revenue and expenditure in respect of the previous financial year.

The Court of Auditors shall examine the accounts in accordance with Article 248 of the Treaty. It shall publish each year a report on the Authority's activities.

4. The European Parliament, acting on a recommendation from the Management Board, shall give a discharge to the

Authority's Executive Director in respect of the implementation of the Budget.

Article 44

Fees received by the Authority

Within three years from the date of entry into force of this Regulation, the Commission shall publish, after consulting the Authority, the Member States and the interested parties, a report on the feasibility and advisability of introducing fees payable by undertakings for obtaining a Community authorisation and for other services provided by the Authority.

Section 6

General provisions

Article 45

Legal personality and privileges

1. The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.
2. The Protocol on the privileges and immunities of the European Communities shall apply to the Authority.

Article 46

Liability

1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.
2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.
3. The personal liability of its servants towards the Authority shall be governed by the relevant conditions applying to the staff of the Authority.

Article 47

Staff

1. The staff of the Authority shall be subject to the rules and regulations applicable to officials and other staff of the European Communities.
2. In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.

Article 48

Participation of third countries

1. The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.

2. Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to financial contributions and staff.

CHAPTER IV

RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES

Section 1

Rapid alert system

Article 49

Rapid alert system

1. A rapid alert system for food and feed shall be established as a network. It shall involve the Member States, the Commission and the Authority, which is responsible for its operation. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network.

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Authority under the rapid alert system. The Authority shall establish whether, on the basis of the notification, the product in question presents a serious risk to human health, necessitating rapid action. If this is the case, it shall transmit this information immediately via the rapid alert system. It may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate action by the Member States.

3. Where a national competent authority is notified by a food business operator pursuant to Article 14(2) or by a feed business operator pursuant to Article 15(2), it shall, after verification, inform the Authority via the rapid alert system. The Authority shall thereafter act as laid down in paragraph 2.

4. Without prejudice to other Community legislation, the Member States shall immediately notify the Authority under the rapid alert system of:

- (a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;
- (b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;
- (c) any rejection of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Authority shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.

Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Authority shall immediately notify all the border posts within the European Union, as well as the third country of origin.

5. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Authority shall provide the latter with the appropriate information.

6. The Member States shall immediately inform the Authority of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system.

7. The Authority shall draw up a summary report of the information transmitted under the rapid alert system at sufficiently regular intervals to keep members of the rapid alert system well-informed, and shall forward it to those members.

8. Participation in the rapid alert system may be opened up to European Union applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

*Article 50***Implementing measures**

The measures for implementing Article 49 shall be adopted by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 57(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information and the specific rules applicable to information transmitted by business operators.

*Article 51***Confidentiality rules for the rapid alert system**

1. Information available to the members of the network relating to risk to human health posed by food and feed shall in general be available to the public. In general the public shall have access to information on product identification, the nature of the risk and the measure taken.

However, the members of the network shall take steps necessary to ensure that the members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public if circumstances so require, in order to protect human health.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

*Section 2***Crisis management***Article 52***General plan for crisis management**

1. The Commission shall draw up, in close cooperation with the Authority and where appropriate with the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as 'the general plan').

2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 55 and 56.

The general plan shall also specify the practical and operational procedures necessary to manage a crisis, including the principles of transparency to be applied.

*Article 53***Crisis unit**

1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 55 and 56, it shall immediately notify the Member States and the Authority.

2. The Commission shall set up a crisis unit immediately, in which the Authority shall be involved and provide scientific and technical assistance if necessary.

*Article 54***Tasks of the Crisis Unit**

1. The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.

2. The crisis unit may call upon the assistance of any public or private person whose expertise is necessary to manage the crisis effectively.

3. The crisis unit shall take any measures necessary to inform the public.

*Section 3***Emergencies***Article 55***Emergency measures for food of Community origin or imported from a third country**

1. Where it is evident that food originating in the Community or imported from a third country is likely to constitute a serious risk to human health, the Commission, acting on its own initiative or at the request of a Member State, may immediately adopt one or more of the following interim measures, depending on the gravity of the situation:

(a) in the case of food of Community origin:

(i) suspension of the placing on the market of the food in question;

- (ii) laying down special conditions for the food in question;
- (iii) any other appropriate interim measure;
- (b) in the case of food imported from a third country:
- (i) suspension of imports of the food in question from all or part of the third country concerned and, where applicable, from the third country of transit;
- (ii) laying down special conditions for the food in question from all or part of the third country concerned;
- (iii) any other appropriate interim measure.

Within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 57(2).

2. Where a Member State officially informs the Commission of the need to take emergency measures with regard to food or establishments in another Member State, or with regard to a third country or a food from a third country or an establishment in a third country, and the Commission has not applied the provisions in paragraph 1, the Member State may take interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

Within 10 working days, the Commission shall put the matter before the Committee set up in Article 57(1) in accordance with the procedure provided for in Article 57(2) with a view to the extension, amendment or abrogation of the national interim protective measures.

The Member State may maintain its national interim protective measures until the Community measures have been adopted.

Article 56

Other measures

Where it is evident that food originating in the Community or imported from a third country is likely to constitute a serious risk to human health and the Commission does not consider it appropriate to adopt an emergency measure pursuant to Article 55, the Commission may examine the situation as soon as possible within the Committee set up in Article 57 and adopt the necessary measures in accordance with the procedure referred to in Article 57(2). It shall follow the development of the situation and, if necessary, it shall amend or revoke, in accordance with the procedure referred to in Article 57(2), the measures taken.

CHAPTER V

PROCEDURES AND FINAL PROVISIONS

Section 1

Committee and mediation procedures

Article 57

Committee

1. The Commission shall be assisted by a Committee on Food Safety and Animal Health, hereinafter referred to as the 'Committee', composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 58

Functions assigned to the Committee

The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairperson or at the written request of one of its members.

Article 59

Mediation procedure

1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.

2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on the contentious scientific issue from the Authority. The terms of that request and the time-limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.

Section 2

Final provisions

Article 60

Review clause

1. Within three years of the date established in Article 65, the Authority, in collaboration with the Commission, shall carry out an independent evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices of the Authority and the impact of the Authority, acting as such.

The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary, regarding changes in the Authority and its working practices. The evaluation and the recommendations shall be made public.

2. Within three years from the date established in Article 65, the Commission shall publish a report on the experience acquired from implementing Sections 1 and 2 of Chapter IV.

Article 61

References to the European Food Authority and to the Committee on Food Safety and Animal Health

1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Authority.

2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs, the Standing Veterinary Committee and the Standing Committee on Plant Health shall be replaced by a reference to the Committee on Food Safety and Animal Health.

3. For the purpose of paragraphs 1 and 2, 'Community legislation' shall mean all Community regulations, directives and decisions.

4. Decisions 68/361/EEC, 69/414/EEC, 70/372/EEC and 76/894/EEC are hereby repealed.

Article 62

Competence of the European Medicines Evaluation Agency

This Regulation shall be without prejudice to the competence conferred on the European Agency for the Evaluation of Medicinal Products by Regulation (EEC) No 2309/93, Regulation (EEC) No 2377/90, Council Directive 75/319/EEC⁽¹⁾ and Council Directive 81/851/EEC⁽²⁾.

Article 63

Seat

The seat of the Authority shall be decided by the competent authorities, on the basis of a proposal of the Commission.

Article 64

Relationship between this Regulation and existing food law

Existing food law shall continue to apply until amended to ensure conformity with the provisions laid down in Chapters I and II.

Article 65

Commencement of the Authority's operation

The Authority shall take up its responsibilities on [...].

Article 66

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Articles 49, 51, 52, 53, 54, 59 and 61(1) shall apply from the date provided for in Article 65.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

⁽¹⁾ OJ L 147, 9.6.1975, p. 13.

⁽²⁾ OJ L 317, 6.11.1981, p. 1.