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

REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 28 January 2002

laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission[(1)],

Having regard to the opinion of the Economic and Social Committee[(2)],

Having regard to the opinion of the Committee of the Regions[(3)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(4)],

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.

(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 and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.

(4) There are important differences in relation to concepts, principles and procedures between the food laws of 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.

(5) Accordingly, it is necessary to approximate these concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level. It is however necessary to provide for sufficient time for the adaptation of any conflicting provisions in existing legislation, both at national and

Community level, and to provide that, pending such adaptation, the relevant legislation be applied in the light of the principles set out in the present Regulation.

(6) Water is ingested directly or indirectly like other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. However, as the quality of water intended for human consumption is already controlled by Council Directives 80/778/EEC[(5)] and 98/83/EC[(6)], it suffices to consider water after the point of compliance referred to in Article 6 of Directive 98/83/EC.

(7) Within the context of food law it is appropriate to include requirements for feed, including its production and use where that feed is intended for food-producing animals. This is without prejudice to the similar requirements which have been applied so far and which will be applied in the future in feed legislation applicable to all animals, including pets.

(8) 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.

(9) 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.

(10) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not 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. Similar issues relating to feed safety should be addressed.

(11) 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.

(12) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.

(13) Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, 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.

(14) 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.

(15) Networking of laboratories of excellence, at regional and/or interregional level, with the aim of ensuring continuous monitoring of food safety, could play an important role in the prevention of potential health risks for citizens.

(16) Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. 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.

(17) Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components 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.

(18) 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.

(19) 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, traditional, ethical and environmental factors and the feasibility of controls.

(20) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.

(21) 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.

(22) Food safety and the protection of consumer's interests 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.

(23) 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 feed 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 feed and safe, wholesome food in a non-discriminatory manner, following fair and ethical trading practices.

(24) It is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.

(25) It is necessary to establish the general principles upon which food and feed may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.

(26) 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, these 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. Similarly such barriers may arise to trade in feed.

(27) 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.

(28) Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed 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.

(29) It is necessary to ensure that a food or feed business including an importer can identify at least the business from which 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.

(30) 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, it 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.

(31) Similar requirements should apply to feed and feed business operators.

(32) The scientific and technical basis of Community legislation relating to the safety of food and feed 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.

(33) The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of a European Food Safety 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.

(34) Pursuant to the general principles of food law, the Authority should take on the role of an independent scientific point of reference in risk assessment 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 the Community institutions and Member States to take informed risk management decisions necessary to ensure food and feed safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food and feed.

(35) The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; nevertheless, in order to promote coherence between the risk assessment, risk management and risk communication functions, the link between risk assessors and risk managers should be strengthened.

(36) The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supply chains, which implies wide-ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health. However, it is necessary to ensure that the Authority focuses on food safety, so its mission in relation to animal health, animal welfare and plant health issues that are not linked to the safety of the food supply chain should be limited to the provision of scientific opinions. The Authority's mission should also cover scientific advice and scientific and technical support on human nutrition in relation to Community legislation and assistance to the Commission at its request on communication linked to Community health programmes.

(37) Since some products authorised under food law 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 also be assessed by the Authority in accordance with the relevant legislation.

(38) In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC[(7)] and without prejudice to the procedures established therein.

(39) The Authority should contribute through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety standards and trade agreements.

(40) 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 Member States is also indispensable.

(41) To that effect the Management Board should be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise, for instance in management and in public administration, and the broadest possible geographic distribution within the Union. This should be facilitated by a rotation of the different countries of origin of the members of the Management Board without any post being reserved for nationals of any specific Member State.

(42) The Authority should have the means to perform all the tasks required to enable it to carry out its role.

(43) 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.

(44) The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively. An Advisory Forum should be created in order to advise the Executive Director, to constitute a mechanism of exchange of information, and to ensure close cooperation in particular with regard to the networking system. Cooperation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.

(45) 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.

(46) 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.

(47) 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. In order to ensure the manageability and consistency of the process of scientific advice, the Authority should be able to refuse or amend a request providing justification for this and on the basis of predetermined criteria. Steps should also be taken to help avoid diverging scientific opinions and, in the event of diverging scientific opinions between scientific bodies, procedures should be in place to resolve the divergence or provide the risk managers with a transparent basis of scientific information.

(48) 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. It should be done in an open and transparent fashion and the Authority should take into account existing Community expertise and structures.

(49) 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. A review of Community data collection networks already existing in the fields covered by the Authority is called for.

(50) 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 and providing evaluation of and information on emerging risks with a view to their prevention.

(51) 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.

(52) It is necessary to ensure that a balance is struck between the need to use national organisations to carry 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. 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 with the objective of taking into account the establishment of the Authority and the new facilities it offers, the evaluation procedures remaining at least as stringent as before.

(53) The Commission remains fully responsible for communicating risk management measures. The appropriate information should therefore be exchanged between the Authority and the Commission. Close cooperation between the Authority, the Commission and the Member States is also necessary to ensure the coherence of the global communication process.

(54) 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.

(55) Appropriate cooperation with the Member States and other interested parties is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.

(56) 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.

(57) The Authority should be financed by the general budget of the European Union. 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 following the entry into force of this Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors.

(58) It is necessary to allow for the participation of 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.

(59) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety[(8)]. 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 managed by the Commission and include as members of the network the Member States, the Commission and the Authority. The system should not cover the Community arrangements for the early exchange of information in the event of a radiological emergency as defined in Council Decision 87/600/Euratom[(9)].

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

(61) Recent food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crisis 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 form of advice in the event of a food crisis.

(62) In order to ensure a more effective, comprehensive approach to the food chain, a Committee on the Food Chain and Animal Health should be established to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs and the Standing Committee for Feedingstuffs. Accordingly, Council Decisions 68/361/EEC[(10)], 69/414/EEC[(11)], and 70/372/EEC[(12)], should be repealed. For the same reason the Committee on the Food Chain and Animal Health should also replace the Standing Committee on Plant Health in relation to its competence (for Directives 76/895/EEC[(13)], 86/362/EEC[(14)], 86/363/EEC[(15)], 90/642/EEC[(16)] and 91/414/EEC[(17)]) on plant protection products and the setting of maximum residue levels.

(63) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(18)].

(64) It is necessary that operators should have sufficient time to adapt to some of the requirements established by the present Regulation and that the European Food Safety Authority should commence its operations on 1 January 2002.

(65) It is important to avoid confusion between the missions of the Authority and the European Agency for the Evaluation of Medicinal Products (EMEA) established by Council Regulation (EEC) No 2309/93[(19)]. Consequently, it is necessary to establish that this Regulation is without prejudice to the competence conferred on the EMEA 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[(20)].

(66) It is necessary and appropriate for the achievement of the basic objectives of this Regulation to provide for the approximation of the concepts, principles and procedures forming a common basis for food law in the Community and to establish a European Food Safety Authority. In accordance with the principle of proportionality as set out in Article 5 of the Treaty, this Regulation does not go beyond what is necessary in order to achieve the objectives pursued,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 96 E, 27.3.2001, p. 247.

(**2**) OJ C 155, 29.5.2001, p. 32.

(**3**) Opinion delivered on 14 June 2001 (not yet published in the Official Journal).

(**4**) Opinion of the European Parliament of 12 June 2001 (not yet published in the Official Journal), Council Common Position of 17 September 2001 (not yet published in the Official Journal) and Decision of the European Parliament of 11 December 2001 (not yet published in the Official Journal). Council Decision of 21 January 2002.

(**5**) OJ L 229, 30.8.1980, p. 11. Directive repealed by Directive 98/83/EC.

(**6**) OJ L 330, 5.12.1998, p. 32.

(**7**) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

(**8**) OJ L 228, 11.8.1992, p. 24.

(**9**) OJ L 371, 30.12.1987, p. 76.

(**10**) OJ L 255, 18.10.1968, p. 23.

(**11**) OJ L 291, 19.11.1969, p. 9.

(**12**) OJ L 170, 3.8.1970, p. 1.

(**13**) OJ L 340, 9.12.1976, p. 26. Directive as last amended by Commission Directive 2000/57/EC (OJ L 244, 29.9.2000, p. 76).

(**14**) OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2001/57/EC (OJ L 208, 1.8.2001, p. 36).

(**15**) OJ L 221, 7.8.1986, p. 43. Directive as last amended by Commission Directive 2001/57/EC.

(**16**) OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2001/57/EC.

(**17**) OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2001/49/EC (OJ L 176, 29.6.2001, p. 61).

(**18**) OJ L 184, 17.7.1999, p. 23.

(**19**) OJ L 214, 24.8.1993, p. 1. Regulation amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

(**20**) OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1553/2001 (OJ L 205, 31.7.2001, p. 16).

Status:
Point in time view as at 28/04/2006.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 178/2002 of the European Parliament and of the Council, Introductory Text.