COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 7.8.2001
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2000/0286 (COD)

Amended 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 safety

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

EXPLANATORY MEMORANDUM

1. PROCEDURE

– Adoption of the proposal by the Commission: 8 November 2000[1]

– Opinion of the Economic and Social Committee: 28 March 2001[2]

– Opinion of the Committee of the Regions: 14 June 2001[3]

– Opinion of the European Parliament at first reading:12 June 2001[4]

– Date of political agreement in Council: 28 June 2001(unanimity without the Commission's support)

2. COUNCIL POLITICAL AGREEMENT

Main changes approved by the Commission

Chapters I and II General food law:

The main thrust of the original proposal on Chapters I and II remains unchanged although the text has been significantly re-ordered with some articles placed into a more logical order with principles separated from requirements. The definitions, particularly the definitions of food, food law, traceability and primary production have been clarified. The definition of stages of production, processing and distribution has been significantly redrafted so that the scope of Chapter II which covers these stages is clearer. An additional definition "final consumer" is included, and the definition of 'official control' deleted for inclusion in a more specific text on controls.

Article 4 includes now an obligation to adapt existing food law principles and procedures before a specific date, which previously was covered by Article 64 of the original proposal and consequently this is deleted. These new arrangements for the application of various articles were designed in common agreement between the Council and Commission Legal Services.

Article 5 is in principle the same although there is some change in emphasis in relation to fair trade practices. After Article 6 the text is significantly re-ordered. Articles 6 to 10 reflect the substance of the original proposal. There are some minor changes in emphasis in relation to the import and export of food in Articles 11 and 12 and importantly food that may be injurious to health or unsafe feed shall not be exported from the Community.

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1 COM(2000) 716 Final of 8.11.00.
2 OJ C 155 of 29.05.2001 p. 32.
3 13/06/2001 not yet published in OJ.
4 A5-0198/2001 final of 12.06.01.

The Articles on food and feed safety requirement (14 and 15) are now better aligned with the general product safety directive with the addition of a paragraph which enables products to be withdrawn or otherwise controlled even though they are in conformity with specific requirements of food law but are found to be unsafe.

A requirement for food and feed businesses to enable employees to co-operate with the competent authorities to prevent, reduce or avoid risk has been added in Articles 19 and 20.

Chapter III European Food Authority:

Article 22 (mission of the Authority) has been amended to ensure that while retaining a wide scope, the Authority's mission will remain focussed on food and feed safety. Therefore the mission of the Authority in relation to animal health, animal welfare and plant health issues **that are not linked** to food and feed safety, is now limited to scientific opinions. The scope on nutrition is maintained with some slight changes concerning the communication on nutrition linked to Community health programmes.

The new wording of Article 22 (5) underlines that co-operation between the Authority, the Commission and the Member States is needed to ensure the coherence between risk assessment, risk management and risk communication functions.

The management of the rapid alert system will remain in the Commission (deletion of this task in Articles 22 and 23 and new wording in Articles 35 and 50). However the Authority will be a member of this network.

The role of the Advisory Forum (Article 27) has been specified more completely, since this body of the Authority will ensure the functional link with the Member States similar bodies.

The conditions of referral to the Authority of a request for scientific opinions have been completed and the situations in which a request may be amended or refused specified (Article 29).

Several new provisions in relation to transparency have been added in particular in Articles 32, 36 and 38.

Chapter IV (rapid Alert, crisis management and crisis situations)

This chapter has been amended in relation to rapid alert (see above), to extend the emergency procedure to feed (Article 53 and 54) and to align this emergency procedure with the Directive on official inspections in the field of animal nutrition[5].

Chapter V Procedures and final provisions

There are few major changes with the exception of the deletion of the Article on the seat, which the Commission did not agree to, and the transfer of the provision of Article 64 of the original proposal to Article 4. The date of the commencement of the Authority has been fixed by the Council as the 1 January 2002.

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5 adopted 19.06.2001 not yet published in the OJ.

Changes not agreed by the Commission

Council reached a unanimous political agreement on 28 June 2001. However, the Commission was unable to support this agreement primarily due to its position in relation to the composition of the Management Board, which differs from the orientation taken by the Council.

In addition, the Article relating to the procedure to establish the seat was deleted and some of the amendments accepted by the Commission in the European Parliament were not taken up by the Council. The Commission does not agree to the date proposed by the Council of January 2005 for the application of Articles 11, 12, 14 to 20 and would prefer an earlier date of January 2004.

3. COMMENTS ON THE AMENDMENTS ADOPTED BY THE EUROPEAN PARLIAMENT (FIRST READING)

The European Parliament adopted 189 amendments. The Commission accepted in full 43 amendments, in part or in principle 55 amendments and could not accept 88 amendments. (186 as some were merged)

The legal basis for this proposal, which fully engages Parliament in the co-decision procedure, has received the full support in Council. Hence the Commission cannot accept Amendments 4 or 209 changing or expanding the legal basis.

Chapters I and II

Amendments 12 and 81 which refer to food hygiene were not accepted in this broad, horizontal context, which covers not just hygiene, but also contaminants, additives, materials in contact with food and much more. Similarly, Amendments 59 and 72 were too detailed for a horizontal text. The Commission did not accept Amendment 202 on concessions for SMEs, as consumers should enjoy the same protection regardless of the size or type of the business. Nor could the Commission accept Amendments 26, 40, and 50, which extend the scope of the Regulation to food quality as this Regulation is not the correct legal instrument and other work is being undertaken in this regard.

A number of amendments (3, 6, 7, 8) in relation to the Recitals were fully accepted since they are in line with overall concept of this proposal to cover the whole food chain.

The scope of the Regulation covers misleading and deceptive practices but not financial fraud between traders. Hence Amendment 49 was only accepted in part. Food safety requirements have been kept apart from other consumer interests. Therefore Amendment 57 has been only acceptable in part/in principle, - not in Article 8 on consumer interests, but in Article 14, which covers the food safety requirement.

A range of Amendments: 28, 29, 32, 33, 34, 36, 37, 39, 41, 43, 44, 46 which refer to the definitions used in this text were not acceptable. In these amendments, either the horizontal nature of the text would be compromised; the change in the amendment becomes redundant or inaccurate in relation to the usage of the term, or is already contained in another definition or could lead to confusion. For example, the reference to food supplements in Amendment 28 is redundant as these are already covered by the definition of food in the proposal. It is not appropriate to deal with the interface between medicines and foods in this text as this is defined in the Medicinal Products Directive and therefore Amendment 29 is not acceptable. The term ingredient no longer appears in the proposal therefore Amendment 33 is not taken. Amendments on retail – 36 and 37 are not appropriate in this text but are for a more vertical text as is the case with Amendment 51 on the objectives of food law. The definition of 'official control' is now deleted and will be included on a more specific proposal from the Commission on controls therefore Amendment 39 is not accepted.

Part of Amendment 38 introducing distribution is acceptable, but not the part on placing in circulation. Amendment 45 on the change to the definition of primary production is acceptable but has been subject to editorial changes.

Amendment 30 introducing the definition of "final consumer" has been fully accepted. Amendment 35 that clarifies the definition of feed business has been accepted in part. Some of the details of this Amendment however are dealt with in Recital 13. Amendment 42 on the definition of stages of production, processing and distribution has a significant impact on clarifying the scope of Chapter II.

There are a number of Amendments which could prove detrimental to the Community's ability to negotiate in Codex Alimentarius or cannot be aligned with international agreements to which the Community is already committed. This is the case particularly with those Amendments which attempt to rewrite internationally accepted definitions which the Community has fought to have accepted (for example Amendment 40 on risk management), or where changes are not in line with the Commission's Communication on the precautionary principle, as endorsed by the Council and Parliament. For example, Amendment 53 attempts to rewrite what exists in WTO agreements for those situations where a full risk analysis is warranted. Amendment 54 which would oblige the Community to accept other legitimate factors which are internationally agreed is not acceptable since there are no such factors at this time. Amendment 52 is also unacceptable, owing to its impact on the Community's international obligations; it is contrary to WTO rights and obligations. Although the concept in Amendment 84, is acceptable this is already covered in Article 5.

Similar problems are raised by Amendments 55 and 56 on the precautionary principle. Amendment 55, is not acceptable as it is appropriate to retain some discretion, without there being a mandatory requirement to act and, perhaps, for no measures to be adopted. This is a satisfactory risk management action, and this was included in the Commission's Communication, as endorsed by Parliament and Council, and therefore contradicts positions adopted previously. Although many of the points in Amendment 56 reflect these positions, the text is too detailed and this could cause problems in a legally binding regulation. Amendment 63, which requires food control work and surveillance to be kept confidential, cannot be accepted. Any necessary confidentiality will be covered in the horizontal control text to be proposed in the near future. However Amendment 8 on the non-discriminatory application of the principle to food regardless of its origin is acceptable in principle.

There are several other Amendments relating to general food law which are acceptable in principle and have been aligned with the general principles and orientation of the text. The first part of Amendment 61 is acceptable, which makes the legal responsibilities of feed businesses more precise. In Amendment 69 only the reference to transport is acceptable which is dealt with in Article 3 in the enhanced definition of stages of production, processing and distribution.. The concept in Amendment 80 and 178 that dangerous foods and feeds should not be exported has been included in principle in this amended proposal. This concept is also found in Amendment 82, but the part of this amendment which refers to the supplier taking products back, is not acceptable as this confuses the legal meanings of import and export. In addition a number of Amendments (64, 65, 66, 70, 71, 79) were fully acceptable since they were in line with the text and providing useful additions for instance in relation to the extension to feed (79).

Amendments 74 and 77 are not acceptable since they are linked to liability provisions covered by other Community legislation. This proposal is specifically "without prejudice of liability law.

Amendments 70 and 75 are acceptable in principle and are included in amendments to articles 18 and 19.

Amendments 48 and 189 are not acceptable, as these are inappropriate for the date of application of different parts of the text. As regards Amendment 185, it would not be possible to have a report on the application of the principles of food law, as these will not have an impact for a significant period of time.

Amendment 47 is acceptable in principle and has been accepted by extending the definition of the stages of production and distribution covered by Chapter II of the Regulation. Also acceptable in principle is Amendment 207 on transparency, but the text has been fully aligned with the Amsterdam Treaty Protocol on subsidiarity and proportionality.

Several other Amendments have been accepted in principle but brought in line with the general principles and orientation of the text. These are Amendments 2, 5, 10, 16, 27, 35, 42, 60 and 62. The first part of Amendment 67 has been dealt with in recital 18 and the second as a paragraph in article 14.

Chapter III

A number of Amendments (14, 16, 20, 22, 25) in relation to the recitals have been included in the modified proposal**.** Amendment 19 and the part of Amendment 20 which relates to a recital use the word 'authorised' and are not acceptable since this wording is not in line with the corresponding Article. Amendment 13 also relates to a recital and is unacceptable, since a request for a scientific opinion during the legislative process should be limited to justified cases - new scientific information - for example - in order to avoid repeated requests on the same topic.

In relation to the Authority’s scope, Amendment 87 and related Amendments 88 and 187 are not acceptable, because they reduce its remit to fields to known to have an impact on food safety. A wide remit is necessary in order not to repeat the failure to identify BSE as a risk for humans at an early stage. However, Amendment 86, which makes it clear that the primary mission of the Authority is food safety, is acceptable. Amendment 1 which proposes to include the word 'safety' in the title of the Authority is not acceptable since it could lead to the reduction of the Authority's remit.

Amendment 91 is not acceptable. The Authority will be able to provide scientific opinions at the request of the European Parliament according to Article 29 but it would dilute its mission and risk the duplication of work of other bodies if the Authority were to provide permanent scientific support to the European Parliament. Amendment 90 is covered in Article 23(a) since the Parliament is a Community institution and more specifically in Article 29 (1).

The Commission now considers that it should remain fully responsible for operation of the rapid alert system, with the Authority acting as a member of the network, so Amendments 15, 89, 94, 158, 159, 161, 162, 163 and 169 are not acceptable. Amendments 160, 164 and 166 have been accepted and included in the text since they were in line with the management of this network by the Commission. Amendment 131 is covered by Article 35 since the initial wording of this Article has been changed.

Amendments 17, 18, and 213 are in favour of a Management Board composed of members selected on the basis of an open process and with practical experience of agriculture, the food industry, small firms and consumer groups. They are not acceptable. The main objective of the Commission remains to have a small, functional Board which, through the balance of its membership (4 representatives of Council, 4 of European Parliament, 4 of Commission, 4 of industry and consumers) can be seen to be independent, yet accountable to the Community institutions. The Commission's original proposal is therefore maintained.

Amendment 102 in relation to the composition of the Management Board is not acceptable as this removes the possibility of alternate Board members. Neither is Amendment 143, which insists that the Management Board shall meet only in public, since this should be left to the Board's own discretion.

Amendments 103 (consistency of the work program with the Community's priorities instead of Commission's priorities) and 105 (publicity of the Authority’s internal rules) are acceptable, as is Amendment 106, which enables the chair of the Scientific Committee to attend the Board meetings at the invitation of the Board. They are included in Article 25.

Amendments 107 and 220 on the open and transparent appointment of the Executive Director by the Management Board with a hearing in Parliament, are acceptable in principle and are included in Article 26 of the modified proposal. The candidate selected by the Management Board will be appointed after a hearing in the European Parliament.

Amendment 108, accepted in principle, on the drawing up of the work program by the Executive Director is covered in Article 26 (2) h) and in Article 27(3). Amendment 109 on contact and dialogue between the Executive Director and the European Parliament is also included in Article 26 (2) h). The inclusion of Amendment 109 covers the last part of Amendment 111 concerning the dialogue with the European Parliament.

In addition, a number of Amendments are included since they were mostly editorial or relating to the transfer of provisions from one Article or paragraph to an another one: 104, 110, 111, 127 and 128.

In relation to the Advisory Forum, Amendment 112 on the role of the Forum as a mechanism for exchange of information and pooling of knowledge, is included in Article 27. Amendment 114 is included in the text since representatives of the European Parliament and other relevant bodies may be invited to attend the meetings of this Forum. Amendment 113 is acceptable but the Advisory Forum shall not be compelled to meet 6 times per year so this part was not included in Article 27.

Amendment 115 on the possibility to organise public hearings of the Scientific Committee and Panels is included in Article 28 (9).

Amendment 118 is not acceptable, as it removes the possibility for the Authority to refuse or modify requests for scientific opinions. Such flexibility is a critical operational requirement of the Authority. Amendment 119 replacing "conflicting" by "diverging" is included in Article 30.

Amendments 121, 122 and 123 are not acceptable. They remove the procedure applied in the event of a divergence between the Authority's scientific opinions and those of a national scientific body, thereby making the Authority the final arbitrator in science. This is not appropriate. In any event, the Article 29 procedure is designed to achieve a result through transparency, and the decision is the risk manager's. Subsequent failure by Member States to comply with any measure brought forward by the risk manager or the legislative authority will lead to infringement proceedings. That provides the degree of clarity and sureness that Parliament requires.

Risk managers need to be clearly responsible for taking decisions and risk assessors for assessing the risks. For these reasons, Amendments 21 and 212 are not acceptable. Amendment 92 has been accepted in principle, included in Article 23 (c) and aligned to ensure that there is no confusion between the Authority’s risk assessment responsibility and the risk managers' responsibility.

Amendment 93 has been acceptable in principle and included in Recital 51 with some deletions to ensure that the Authority will not be involved in risk management activities. Amendment 98 is acceptable, in so far as it makes it clear that the Authority can express 'independently' its own conclusions and orientations. Amendment 97 is not acceptable, since it would have involved the Authority in risk management.

Amendment 132 was accepted in principle. It is covered by Article 33, which refers to networking with all organisations, and more specific reference is made to these organisations in the corresponding Recital 50.

Only the part of Amendment 134 that makes public the list of scientific bodies competent to help the Authority in its work is acceptable and included in Article 36, although the suggested deletion that requires the Member States to designate these bodies is not. The rest of Amendment 134, which deals with EEA/EFTA countries has been accepted in principle, but under Article 49 on the participation of third countries.

Amendment 125, which removes the ability of the Authority to collect food consumption data could not be accepted since this is a basic requirement, enabling scientists to assess the exposure of consumers to substances through their diet. Amendment 126 is acceptable in principle, since the new wording of Article 22(2) specifies that the Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.

Amendment 130 adding the word "evaluation" improves the meaning of Article 34 and has been included. Amendment 152 makes Article 42 more specific without changing its meaning and has been included.

Amendments 116, 124, 135 to 142, and 144, which improve the transparency of the Authority are acceptable and included mostly in Article 38 but also in other Articles in particular 26 and 28. However, Amendment 145 is not acceptable. The text deleted by this amendment requires the Authority to not keep confidential any conclusions of scientific opinions where foreseeable health effects have been identified. The deletion of this text from the original proposal would reduce transparency and the publication of health related information might not therefore always take place.

Amendments 149 and 150, accepted in principle, are covered by Article 38 on transparency since the opinions of the Scientific Committee and panels and therefore the conclusions of these opinions, are immediately published after adoption. In addition, the conclusions of the scientific opinions in relation to the foreseeable health effects shall not on any account be kept confidential in accordance with Article 39.

Amendments 23, 153 and 157 are not acceptable, because they remove the possibility for the Authority to receive fees. The Commission wants to review this within three years of operation, even though it agrees that it is inappropriate for the Authority to charge fees at present.

Other amendments are not acceptable, because they are incompatible with existing Community procedures or important legal aspects, or because they are covered by other legal provisions either in this text or in other Community texts. For these reasons, only paragraphs 6a and 6b in Amendment 154 were included in Article 43. Amendment 155 is included in Article 44 in relation to 'the recommendation from the Council', but not in relation to the discharge given to the Management Board. Amendment 156 on OLAF has been included in Article 25(9) but it was considered inappropriate to repeat existing legislative provisions in the modified proposal.

Chapters IV and V

Amendment 24 on the emergency procedure is not acceptable, as a 'serious risk' is the precondition for emergency measures in all existing Community legislation. However, Amendment 177 that extends the emergency procedure to feed is included in Article 53.

Amendment 174 is not acceptable, since the crisis unit will not be a permanent structure. Amendment 176 makes the information role of the Crisis Unit clearer and has been included in Article 57(3).

Amendments 172 and 173 propose involving Parliament in practical crisis management. This is not compatible with its institutional role of control and supervision.

Amendments 175, 179, 180, 181 and 182 are not in line with existing comitology procedure and therefore not acceptable.

Amendment 183 been accepted in part and included in Article 61 to make clear that an independent evaluation, taking into account the views of the stakeholders, should be carried out by the Authority at regular interval. But the evaluation commissioned by the Authority cannot address the whole Regulation, as it can only be relevant to the Authority. Amendment 186 on transparency has been included in Article 61(3).

Amendment 205 is not acceptable, since it is already clear that the Authority has the right to change its own internal rules. Amendment 191 is not acceptable, as the delay that this may cause would be impractical and may have a detrimental effect on the start date. Amendment 192 is not acceptable, as the Food Authority does not affect the ceiling for heading three of the financial perspective.

Amendment 188 is acceptable in part, as the location of the European Food Authority should be based on operational criteria only. The other criteria are not acceptable. Neither is the part of this amendment relating to the procedures for choosing the location acceptable. The accepted part of this amendment is included in Article 64

4. CONCLUSION

This amended proposal is based on the political agreement achieved in Council except for the following Recitals and Articles:

- Recital 19 which relates to Amendment 8 on the precautionary principle and its application in a non-discriminatory manner,

- Recital 31, Articles 18 (3) and 19 (3) which relate to Amendments 10, 70 and 75 which requires food and feed business operators to not prevent or discourage any person from co-operating with the competent authorities, where this may prevent reduce or avoid a risk to health,

- Recital 50 in relation to Amendment 132 which specifies that consumers and other stakeholders organisations could co-operate with the Authority,

- Recital 56 in relation to Amendment 96 which emphasises the need for communication from the Authority on nutrition should take account of the dietary habits within the European Union,

- Article 23 (c) this indent includes Amendment 92. This amendment was accepted in principle provided that a rewording made it clear that the Authority, which is responsible for risk assessment would not be involved in risk management activities. Therefore it is only at the request of the Commission that the Authority can assist the risk manager in the interpretation and consideration of the scientific opinions.

- Article 25 (Management Board). Paragraphs 1 and 2 are based on the Commission's initial proposal. However the Council concluded that it would prefer 16 Members selected on the basis of competence, relevant experience and geographical distribution plus one representative of the Commission rather than representation from all three Community institutions with 4 representatives of stakeholder organisations which was the basis of the Commission's original proposal.

- Article 25 (10): this paragraph is completed to include Amendment 106 which was accepted in principle by the Commission. It provides the possibility for the Chairperson of the Scientific Committee to be invited to attend Management Board meetings.

- Article 26 (1) this paragraph is completed to include a part of Amendment 107 which is not accepted in the Council political agreement relating to a preliminary hearing in the European Parliament of the Executive Director before the final appointment by the Management Board.

- Article 27(5) this paragraph is completed to include Amendment 113 which was accepted in principle/in part by the Commission and not retained in the Council political agreement. This modification provides for regular meeting of the Advisory Forum at the Chairperson's invitation or at the request of at least a third of its members.

- Article 64 retains the Commission's original proposal for the Seat to be decided by the competent authorities based on a proposal from the Commission and includes also certain selection criteria from Amendment 188.

- Article 66 where the Council is proposing a date of 1 January 2005 for the application of Articles 11, 12 and 14 to 20, and the Commission wants these provisions which refer to basic food safety requirements and traceability to be in place by 1 January 2004.

Amendments of the European Parliament, which were accepted by the Commission and the Council shown in ***bold, underlined and italics***. Amendments of the European Parliament that the Commission accepted but were rejected in the Council are shown in **bold and underlined**.

Article 25 (1) and (2) maintain the Commission original proposal on the composition of the Management Board. The first sentence of Article 64 maintains the wording of the Commission original proposal on the procedure to determine the seat. These paragraphs of the modified proposal are shown in *italics*.

The Commission would welcome a smooth adoption of this Regulation in order to ensure that the European Food Authority is able to commence its operations in early 2002, in line with the Resolution of the Nice summit.

2000/0286 (COD)

Amended 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 safety

(Text with EEA relevance)

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 152(4)(b) thereof,

Having regard to the proposal from the Commission,[6]

Having regard to the opinion of the Economic and Social Committee,[7]

Having regard to the opinion of the Committee of the Regions[8],

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

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,

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6 COM(2000) 716 Final of 8.11.00.
7 OJ C 155 of 29.05.2001 p. 32.
8 13/06/2001 not yet published in OJ.

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 water intended for human consumption is already controlled by Council Directives 80/778/EEC[9] and 98/83/EC[10], it suffices to consider water after the point of compliance as defined in Article 6 of Council 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, 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.

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9 OJ L 229, 30.8.1980, p. 11.

10 OJ L 330, 5.12.1998, p.32.

(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) 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.

(16) 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.

(17) 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.

(18) 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.

(19) 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. **A measure based on the precautionary principle should not discriminate or provide disguised restriction on the ground of the origin of the food or feed.**

(20) 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.

(21) 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

(22) 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 and wholesome foods in a non-discriminatory manner, following fair and ethical trading practices.

(23) 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 provided that the importing country has expressly agreed; however it is necessary to ensure that even where there is an agreement of the importing country, food injurious to health or unsafe feeds are not exported or re-exported;

(24) 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.

(25) 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. Similarly such barriers may arise for the trade of feed.

(26) 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

(27) 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 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.

(28) 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.

(29) 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.

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

(31) Experience has shown that employees in food or feed businesses who by virtue of their professional activities become aware that an unsafe feed or a food with the potential to be injurious to health has been placed on the market, can contribute significantly to the reduction or prevention of that risk.

(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 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 supply chain and feed, 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, 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 in accordance with the relevant legislation.

(38) In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms, the Authority should also provide scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC[11] of the European Parliament and Council 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' roles 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

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11 OJ L 106, 17.04.01, p. 1.

independence, high scientific quality, transparency and efficiency; co-operation with the Member States is also indispensable.

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

(42) 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.

(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) 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.*

(45) The Authority should co-operate 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 co-operation in particular with regard to the networking system; ***co-operation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.***

(46) 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.

(47) 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.

(48) 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 several scientific bodies, procedures should be in place to solve the divergence or provide the risk managers with a transparent basis of scientific information.

(49) The Authority should also be able to commission in an open and transparent fashion 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.

(50) 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 co-ordinated by the Authority **with all relevant organisations including where appropriate, consumers and other stakeholders' scientific organisations.** A review of the Community data collection networks in the fields covered by the Authority is called for.

(51) 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.***

(52) The establishment of the Authority should enable Member States to become more closely involved in scientific procedures; there should therefore be close co-operation 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.

(53) 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 ***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***.

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

(55) 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.

(56) 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; **communication on the health implications of nutrition should take into account the diversity of dietary habits within the European Union.**

(57) 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.

(58) 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.

(59) 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.

(60) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety[12]. 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 early exchange of information in the event of a radiological emergency established in Council Decision 87/600/Euratom[13].

(61) 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.

(62) 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 co-ordination 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.

(63) 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[14], 69/414/EEC[15], 70/372/EEC[16] and 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[17],

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12 OJ L 228, 11.8.1992, p. 24.
13 OJ L 371, 30.12.1987, p.76.
14 OJ L 255, 18.10.1968, p. 23.
15 OJ L 291, 19.11.1969, p. 9.
16 OJ L 170, 3.8.1970, p. 1.
17 OJ L 341, 9.12.1976, p. 26. Directive as last amended 96/32/EC (OJ L 144, 18.6.1996, p. 12).

86/362/EEC[18], 86/363/EEC[19], 90/642/EEC[20] and 91/414/EEC[21]) on plant protection products and the setting of maximum residue levels.

(64) The measures necessary for the implementation of this regulation should be adopted in accordance with Council Decision 1999/468/EC[22] of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

(65) It is necessary to give operators sufficient time to adapt to some of the requirements established by the present regulation and to foresee that the European Food Authority commences its operations on 1 January 2002.

(66) It is important to avoid confusion between the missions of the Authority and the European Medicinal Evaluation Agency (EMEA) established by Council Regulation (EEC) No 2309/93[23]. 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[24].

(67) 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 the approximation of the concepts, principles and procedures forming a common basis for food law 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.

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18 OJ L 221, 7.8.1986, p. 37.

19 OJ L 221, 7.8.1986, p. 43.

20 OJ L 350, 14.12.90, p. 71.

21 OJ L 230, 19.8.1991, p. 1.

22 OJ L 184, 17.7.1999, p. 23.

23 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).

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

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 and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

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

   It establishes the European Food Authority.

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

3. This Regulation shall apply to all stages of production, ***processing*** 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 private domestic consumption.

Article 2
Definition of "food"

For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. It includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directive 80/778/EEC and 98/83/EC.

It shall not include:

(a) feed;

(b) live animals unless they are prepared for placing on the market for human consumption;

(c) plants prior to harvesting;

(d) medicinal products within the meaning of Council Directive 65/65/EEC[25] and 92/73/EEC[26];

(e) cosmetics within the meaning of Council Directive 76/768/EEC[27];

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC[28];

(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;

(h) residues and contaminants.

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, ***whether at Community or national level***; it covers any stage of production, ***processing*** and distribution of food, and also feed for food-producing animals;

(2) 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;

(3) 'food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

(4) 'feed' (or 'feedingstuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to 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, ***transport*** or distribution of feed including ***any producer producing***, processing or storing feed for feeding to animals on his own holding;

(6) 'feed business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;

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25 OJ B 22, 9.2.1965, p. 369.
26 OJ L 297, 13.10.1992, p. 8.
27 OJ L 262, 27.9.1976, p. 169.
28 OJ L 359, 8.12.1989, p. 1.

(7) ‘retail’ means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution 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, and the sale, ***distribution*** and other forms of transfer themselves;

(9) ‘risk’ means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;

(10) ‘risk analysis’ means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

(11) ‘risk assessment’ means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;

(12) ‘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;

(13) ‘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;

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

(15) ‘traceability’ means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, ***processing*** and distribution;

(16) ‘stages of production, ***processing*** and distribution’ means any stage, including ***import,*** from and including the primary production of a food, up to and ***including its storage, transport,*** sale or supply to the final consumer and, where relevant, the ***importation***, production, manufacture, ***storage, transport*** distribution, sale and supply of feed;

(17) ‘primary production’ means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing ***and the harvesting of wild products;***

(18) ***'final consumer' means the ultimate consumer of a foodstuff who will not use the food as part of any food business operation or activity***.

Chapter II
General Food Law

Article 4
Scope

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

2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.

3. Existing food law principles and procedures shall be adapted as soon as possible and by 1st January 2007 at the latest in order to comply with Articles 5 to 10.

4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.

SECTION 1
GENERAL PRINCIPLES OF FOOD LAW

Article 5
General objectives

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health, ***the protection of consumers' interests, including fair practices*** in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law***, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or 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
Risk analysis

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

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

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

Article 7
Precautionary principle

1. In circumstances where, following an assessment of available information, the possibility of harmful effects on health has been 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

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.

SECTION 2
PRINCIPLES OF TRANSPARENCY

Article 9
Public consultation

There shall be public consultation, directly or through representative bodies, at an appropriate stage, during the preparation of food law, ***except where the urgency of the matter does not allow it.***

Article 10
Public information

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

SECTION 3
GENERAL OBLIGATIONS OF FOOD TRADE

Article 11
Food and feed imported into the Community

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

Article 12
*Food and **feed** exported from the Community*

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

   In other circumstances***, except in the case where foods are injurious to health or feeds unsafe,*** food ***and feed*** can only be exported or re-exported provided that 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 or feed could not be placed on the market in the Community.

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

Article 13
International standards

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

(a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;

(b) promote the co-ordination 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
GENERAL REQUIREMENTS OF FOOD LAW

Article 14
Food safety requirements

1. ***Food shall not be placed on the market if it is unsafe***.

2. Food shall be deemed to be unsafe if it is considered to be:

   (a) injurious to health;

   (b) unfit for human consumption.

3. In determining whether any food is unsafe, regard shall be had:

   (a) to the normal conditions of use of the food by the consumer and at each stage of production, ***processing*** and distribution, and

   (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

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

   (a) not only to the probable immediate and/or short term and/or long term effects of that food on the health of a person consuming it, but also on subsequent generations.

   (b) to the probable cumulative toxic effects.

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

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

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all 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 ***governing food safety*** shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. ***Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that despite such conformity, the food is unsafe.***

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

Article 15
Feed safety requirements

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

2. Feed shall be deemed to be unsafe for its intended use if it is considered to:

– have an adverse effect on human or animal health;

– make the food derived from food-producing animals unsafe for human consumption.

3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

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

5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that despite such conformity, the feed is unsafe.

6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law 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 16
Presentation

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

Article 17
Responsibilities

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

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

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities ***covering all stages of production, processing and distribution***.

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

Article 18
Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be incorporated into a food or feed shall be established at all stages of production, ***processing*** and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

   To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the 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, ***through relevant documentation or information,*** in accordance with the relevant requirements of more specific provisions.

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

Article 19
Responsibilities for food: food business operators

1. 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 immediately initiate procedures to withdraw the food in question from the market and inform the competent authorities thereof. Where the product may have reached the consumer the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

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

3. A food business operator shall immediately inform the competent authorities if it considers or suspects that a food which it has placed on the market may be injurious to human health. The operators shall inform the competent authorities of the action taken to prevent risks to the final consumer **and shall not prevent or discourage any person from co-operating with the competent authorities, where this may prevent, reduce or avoid a risk arising from a food.**

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

Article 20
Responsibilities for feed: feed business operators

1. If a feed business operator considers or suspects that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

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

3. A feed business operator shall immediately inform the competent authorities if it considers or 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 **and shall not prevent or discourage any person from co-operating with the competent authorities, where this may prevent, reduce or avoid a risk arising from a feed.**

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

Article 21
Liability

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC[29] concerning liability for defective products, ***as amended by Directive 1999/34/EC[30].***

[29] OJ L 210, 7.8.1985, p. 29.
[30] OJ L 141, 4.6.1999, p. 20.

Chapter III
European Food Authority

SECTION 1
MISSION AND TASKS

Article 22
Mission of the Authority

1. A European Food Authority is hereby established, hereinafter referred to as the "Authority".

2. ***The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks.***

   The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market.

   The Authority shall collect and analyse ***data*** to allow the characterisation and monitoring of risks which have a direct or indirect ***impact on food and feed safety***.

   The mission of the Authority shall also include the provision of:

   (a) scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication within the framework of the Community health programme;

   (b) scientific opinions on other matters relating to animal health and welfare and plant health;

   (c) scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.

3. The Authority shall provide scientific 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 co-operation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.

5 The Authority, Commission and Member States shall co-operate to promote the necessary coherence between risk assessment, risk management and risk communication functions.

6. The Member States shall co-operate with the Authority to ensure the accomplishment of its mission.

Article 23
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 co-ordinate the development of uniform 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 **and when so requested, in the interpretation and consideration of risk assessment opinions;**

(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, 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 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;

(i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving co-operation between the Community, European Union applicant countries, international organisations and third countries, in the fields within its mission;

(j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

(k) to express ***independently*** its own conclusions and orientations on matters within its mission;

(m) to undertake any other task assigned to it by the Commission within its mission.

SECTION 2
ORGANISATION

Article 24
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 25
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 adopt the Authority's internal rules on the basis of a proposal by the Executive Director. ***These rules shall be made public.***

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

5. The Management Board shall adopt its rules of procedure. Unless otherwise provided, the Management Board shall act by a majority of its members.

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

7. 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.

8. 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 ***Community'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.

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 ***and with the requirements related to the European Anti-fraud Office.***

10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. **The Management Board may invite the chairperson of the Scientific Committee to attend its meetings.**

Article 26
Executive Director

1. The Executive Director shall be appointed by the Management Board, on the basis of ***a list of candidates*** proposed by the Commission ***after an open competition, following publication in the Official Journal of the European Communities and elsewhere of a call for expressions of interest,*** **and after a hearing of the candidate selected by the Management Board in the European Parliament**, 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 a proposal for the Authority's work programmes in consultation 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;

(h) ***for developing and maintaining contact with the European Parliament and for ensuring a regular dialogue with its relevant committees.***

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

(a) a draft ***general*** 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;

The Executive Director shall, ***following adoption by the Management Board, forward the programmes and report to the European Parliament, Council, Commission and the Member States, and shall have them published***.

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

Article 27
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. Representatives may be replaced by alternates, appointed at the same time.

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, ***in particular in drawing up a proposal for the Authority's work programme***. The Executive Director may also request the Advisory Forum for advice on the prioritisation of requests for scientific opinions.

4. ***The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge.*** It shall ensure close co-operation between the Authority and the competent bodies in the Member States in particular on the following items:

(a) avoidance of duplication of the Authority's scientific studies with Member States in accordance with Article 32;

(b) in those circumstances identified in Article 30, paragraph 4, where the Authority and a national body shall be obliged to co-operate;

(c) in the promoting of the European networking of organisations operating within the fields of the Authority's mission, in accordance with Article 36, paragraph 1;

(d) where the Authority or a Member State identifies an emerging risk.

5. The Advisory Forum shall be chaired by the Executive Director. **It shall meet regularly at the Chairperson's invitation or at the request of at least a third of its members**. Its operational procedures shall be specified in the Authority's internal rules ***and shall be made public.***

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

7. Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Executive Director may invite ***representatives of the European Parliament*** and from other relevant bodies to take part.

Where the Advisory Forum discusses the matters referred to in Article 22(2)(b), representatives from competent bodies in the Member States which undertake tasks similar to those referred to in Article 22(2)(b) may participate in the work of the Advisory Forum, on the basis of one representative designated by each Member State.

Article 28
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 co-ordination 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.

Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions.

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 health, 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 58(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, **relevant leading scientific publications and the Authority's home page*** 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 co-operation 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;

(f) the possibility of observers being invited to meetings of the Scientific Committee and Panels;

(g) the possibility to organise public hearings.

SECTION 3
OPERATION

Article 29
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) on its own initiative, on matters falling within its mission.

The European Parliament or a Member State may request the Authority to issue a scientific opinion on matters falling within its mission.

2. Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.

3. 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.

4. Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Authority may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

5. Where the Authority has already delivered a scientific opinion on the specific topic in a request, the Authority may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure provided for in Article 58(2). These rules shall specify in particular:

(a) the procedure to be applied by the Authority to the requests referred to it;

(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.

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

Article 30
Diverging *scientific opinions*

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence 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 divergence, 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 divergence 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 co-operate with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues. This document shall be made public.

4. Where a substantive divergence 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 co-operate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

Article 31
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 assistance to the Commission for the establishment or evaluation of technical criteria and also assistance to the Commission in the development of technical guidelines.

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 32
Scientific studies

1. ***Using the best independent scientific resources available***, the Authority shall commission scientific studies necessary for the performance of its mission***. Such studies shall be commissioned in an open and transparent fashion***. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster co-operation through appropriate co-ordination.

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

Article 33
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 and feed***;

   (d) ***residues***.

2. For the purposes of paragraph 1, the Authority shall work in close co-operation 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 they collect 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 technical 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 co-operation 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 34
Identification of emerging risks

1. The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of 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 a matter of urgency*** 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 ***evaluation and*** information collected on emerging risks to the European Parliament, the Commission and the Member States.

Article 35
Rapid alert system

To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Authority shall be the recipient of any messages forwarded via the rapid alert network. It shall analyse the content of such messages with a view to providing the Commission and the Member States with any information required for the purposes of risk assessment.

Article 36
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 a scientific co-operation framework by the co-ordination 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 ***which shall be made public*** of competent 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, 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 58(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent 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 co-operation with the Member States.

SECTION 4
INDEPENDENCE, TRANSPARENCY AND COMMUNICATION

Article 37
Independence

1. The members of the Management Board, the members of the Advisory Forum ***and the Executive Director*** 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 Executive Director,*** 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 interests which might be considered prejudicial to their independence in relation to the items on the agenda.

Article 38
Transparency

1. The Authority shall ensure that it carries out its activities with a high level of transparency. It shall make public, ***without delay***:

(a) ***agendas and minutes of the Scientific Committee and the Scientific Panels;***

(b) the opinions of the Scientific Committee and the Scientific Panels ***immediately*** after adoption, minority opinions always being included;

(c) ***without prejudice to Articles 39 and 41, the information on which its opinions are based;***

(d) the annual declarations of interest made by members of the Management Board, the ***Executive Director***, 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;

(e) the results of its scientific studies;

(f) the annual report of its activities;

(g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

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 39
Confidentiality

1. By way of derogation from Article 38, 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 public 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 40
Communications from the Authority

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 accessible information, in particular with regard to the results of its work. In order to achieve these objectives the Authority shall develop and disseminate information material for the general public.

3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.

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

Article 41
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 42
*Consumers, **producers,** and other interested parties*

The Authority shall develop ***effective*** contacts with consumer representatives***, producer representatives, processors*** and any other interested parties.

SECTION 5
FINANCIAL PROVISIONS

Article 43
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 36.

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 ***estimates including the provisional establishment plan accompanied by the preliminary work program*** 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. ***After the adoption of the general Budget by the budgetary authority,*** **t**he Management Board shall adopt the Authority's ***final*** budget ***and work program***, adjusting ***them*** where necessary to the Community's contribution. ***It forwards them without delay to the Commission and the budgetary authority.***

Article 44
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 Council,*** shall give a discharge to the Authority's Executive Director in respect of the implementation of the Budget.

Article 45
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 46
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 47
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 judgement 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 48
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 49
Participation of third countries

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.

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 ***participation in the networks operated by the Authority, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Authority***, financial contributions and staff.

Chapter IV
Rapid Alert System, Crisis Management and Emergencies

SECTION 1
RAPID ALERT SYSTEM

Article 50
Rapid alert system

1. ***A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. 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 Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.

   The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.

3. Without prejudice to other Community legislation, the Member States shall immediately notify ***the Commission*** 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, related to a direct or indirect risk to human health, 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 Commission 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 Commission 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 Commission shall provide the latter with the appropriate information.

6. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the Members of the network.

7. 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 51
Implementing measures

The measures for implementing Article 50 shall be adopted by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 58(2)**.** These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

Article 52
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 accordance with the information principle provided for in Article 10***. 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
EMERGENCIES

Article 53
*Emergency measures for **food and feed** of Community origin or imported from a third country*

1. Where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 58(2) on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

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

   i. suspension of the placing on the market of the food in question;

ii. suspension of the placing on the market or use of the feed in question;

iii. laying down special conditions for the food or feed in question,

iv. any other appropriate interim measure;

(b) in the case of food or feed imported from a third country:

i. suspension of imports of the food or feed 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 or feed in question from all or part of the third country concerned;

iii. any other appropriate interim measure.

2. However, in emergencies, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 58(2).

Article 54
Other Emergency Measures

Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt 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 58(1) in accordance with the procedure provided for in Article 58(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.

SECTION 3
CRISIS MANAGEMENT

Article 55
General plan for crisis management

1. The Commission shall draw up, in close co-operation with the Authority and 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 53 and 54.

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

Article 56
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 53 and 54, 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 participate and provide scientific and technical assistance if necessary.

Article 57
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 request the assistance of any public or private person whose expertise it deems necessary to manage the crisis effectively.

3. The crisis unit shall ***keep the public informed on the risks involved and the measures taken***.

Chapter V
Procedures and Final Provisions

SECTION 1
COMMITTEE AND MEDIATION PROCEDURES

Article 58
Committee

1. The Commission shall be assisted by a Standing Committee on the Food Chain and Animal Health, hereinafter referred to as the "Committee", composed of representatives of the Member States and chaired by the representative of the Commission. The Committee shall be organised in sections to deal with all relevant matters.

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 59
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 Chairman or at the written request of one of its members.

Article 60
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 61
Review clause

1. Within three years of the date established in Article 65, ***and every six years thereafter,*** the Authority, in collaboration with the Commission, shall ***commission*** an independent ***external*** 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 evaluation will take into account the views of the stakeholders, both at European and national level.***

   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.

3. ***The reports and recommendations referred to in paragraphs 1 and 2 shall be forwarded to the Council and the European Parliament.***

Article 62
References to the European Food Authority and to the Standing Committee on the Food Chain 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 and the Standing Veterinary Committee shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

Every reference to the Standing Committee on Plant Health in Community legislation based upon and including Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC and 91/414/EEC relating to plant protection products and the setting of maximum residue levels shall be replaced by a reference to the Standing Committee on the Food Chain 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 and 70/372/EEC are hereby repealed.

Article 63
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 and Council Directive 81/851/EEC.

Article 64
Seat

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

The location of the Authority should meet the following criteria:

i. It should be easily accessible in terms of communications and have good and rapid transport connections;

ii. It should enable the Authority to work closely and efficiently with those Commission services which deal with public health and consumer protection issues;

iii. It should be cost-effective and enable the Authority to start its work immediately;

iv. It should provide for the necessary infrastructure for the personnel of the Authority.

Article 65
Commencement of the Authority's operation

The Authority shall commence its operations on 1st January 2002.

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 29, 56, 57, 60 and 62(1) shall apply as from the date of appointment of the scientific committee and scientific panels which shall be announced by means of a notice in the 'C' series of the *Official Journal of the European Communities.*

Articles 11, 12 and 14 to 20 shall apply from 1 January 2004.

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*