



COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**establishing a common authorisation procedure for food additives, food enzymes and  
food flavourings**

(presented by the Commission)

## EXPLANATORY MEMORANDUM

### 1) CONTEXT OF THE PROPOSAL

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- **Grounds for and objectives of the proposal**

As part of the efforts undertaken to improve Community legislation on the basis of the “farm to table” concept, in the White Paper on Food Safety, the Commission announced its intention to update and complete existing legislation with regard to additives and flavourings and to lay down specific provisions in respect of enzymes. (Actions 11 and 13 of the White Paper).

This proposal aims to ensure the proper functioning of the internal market, while also ensuring a high level of protection of human life and health as regards food additives, food enzymes and food flavourings.

In order to do this, it aims to establish a common authorisation procedure that is centralised, effective, expedient and transparent and that is based on risk assessment carried out by the European Food Safety Authority (hereinafter referred to as “the Authority”) and a risk management system in which the Commission and the Member States take action within the framework of a regulatory committee procedure.

It assigns to the Commission, on the basis of the Authority’s scientific assessments, the task of creating, maintaining and updating a general positive list for each category of substances concerned. The inclusion of a substance on one of these lists means that its use is authorised in general for all operators on the Community market.

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- **General context**

So as to meet the objectives set in the White Paper, and for reasons of efficiency in the areas of food safety, human health protection and the free movement of the products concerned, the Commission has developed, in parallel, three other proposals for Regulations that make the placing on the Community market of these substances subject to compliance with harmonised criteria and the granting of authorisation:

1. Proposal for a Regulation of the European Parliament and of the Council on food additives;
2. Proposal for a Regulation of the European Parliament and of the Council on food enzymes;
3. Proposal for a Regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods.

The new regulatory framework proposed for the substances in question must be completed by the establishment of a common authorisation

procedure, insofar as the existence of different national authorisation procedures could potentially lead to different results and, in consequence, hinder the free movement of the substances concerned and distort free competition.

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- **Existing provisions in the area of the proposal**

1. Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption.

The procedure laid down in the above Directive is close to the procedure established by this proposal in that it provides for the creation of a positive list of authorised additives at Community level.

It differs from the procedure envisaged in this proposal as regards the following aspects in particular:

- the existing procedure is out of date insofar as it does not use the new framework for risk assessment in matters of food safety established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- an additive is included on the positive list following the adoption of a directive under the codecision procedure, rather than by means of a regulation and the comitology procedure as envisaged by this proposal.

2. Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs.

The procedure laid down in the above Regulation is close to the procedure established by this proposal in that it assigns the Commission the task of creating a positive list of flavouring substances and lays down that this list be adopted in accordance with the comitology procedure.

It differs from the procedure envisaged in this proposal on several points, and on the following aspects in particular:

- the existing procedure is out of date insofar as it does not use the new framework for risk assessment in matters of food safety established by Regulation (EC) No 178/2002;
- it is a procedure that is limited to notification of the

Commission by the Member States of all the flavouring substances that may, in accordance with Directive 88/388/EEC, be used in or on foodstuffs marketed in their territory. Unlike the current proposal, it does not make provision for private operators to submit authorisation requests;

- it involves the creation of a positive list of flavouring substances without making provision for the list to be updated;
- the existing procedure lacks clarity in relation to new substances and the deadlines for the various stages of the procedure.

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- **Consistency with the other policies and objectives of the Union**

The proposed Regulation not only falls within the general framework of the Lisbon Strategy but also fulfils the Commission's objectives as regards simplification and "Better Regulation".

## 2) CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

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*Consultation methods, main sectors targeted and general profile of respondents*

The consultation methods and the organisations consulted are described in detail in the explanatory memorandums of the proposals for regulations on additives, enzymes and flavourings.

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*Summary of responses and how they have been taken into account*

The parties consulted welcomed the idea of a simplified, transparent and expedient common authorisation procedure.

The involvement of the Member States in the authorisation procedure as compulsory relays between applicants and the Commission was criticised by the Member States. This "extra-step procedure" seems to be regarded as a bureaucratic complication that needlessly slows down the procedure. In consequence, this proposal abolishes the "letter-box" role of the national authorities in the common procedure.

Some consumer organisations expressed the fear that replacing codecision with the comitology procedure in the authorisation procedure for additives would reduce the current transparency. Nevertheless, use of the comitology procedure is desirable, as it establishes a common procedure for the three types of substance. Moreover, the codecision procedure currently applicable in relation to additives is an isolated case in food legislation as a whole, despite its use not being justified by a

higher level of risk posed by additives.

- **Collection and use of expertise**

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No recourse to external expertise was necessary.

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- **Impact assessment**

This proposal and the options considered have no environmental impact.

1. No action

Economic impact

The current authorisation mechanisms for additives and flavourings are slow and outdated. The lack of clarity and the shortcomings in the current legislation create a situation of legal uncertainty that could hinder industrial innovation and new technological developments.

Social impact

The different national approaches to assessing the safety of the substances concerned could lead to different levels of protection. This situation is liable to create confusion among consumers and undermine their confidence in the public authorities, the internal market and the scientific basis of food legislation.

2. No legislative action

The nature of the action to be taken in this area is subject to and connected with the nature of the action taken in the sectors concerned. Given that the principle of general Community-level authorisation of the substances is accepted, legislative action is needed to ensure that there is an effective and fast common procedure.

Economic impact

A coordination-based solution (possible adoption of guidelines for the parties concerned in relation to the procedure to follow or a Community code) would not offer the protection and legal certainty that the industry requires. Furthermore, it would contradict the legislative approach followed for the authorisation of other food substances. This situation could have a negative economic impact insofar as it could discourage industrial innovation.

Social impact

Legal uncertainty as regards the procedures to be followed could

compromise the effectiveness of scientific assessments and the level of human health protection. This situation could undermine consumer confidence.

### 3. Deregulation

#### Economic impact

Deregulation would lead to the introduction of different national authorisation procedures that could create additional administrative burdens for the competent authorities of the Member States. Furthermore, the operators concerned would have to submit separate authorisation applications to each Member State in which they wanted to market their product.

#### Social impact

The existence of different procedures for assessing the safety of substances would lead to there being different levels of protection. This could create confusion among consumers and undermine their confidence.

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The Commission has carried out an impact assessment under its Legislative and Work Programme, and the report is available at: [http://ec.europa.eu/food/food/chemicalsafety/additives/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/additives/index_en.htm).

## 3) LEGAL ELEMENTS OF THE PROPOSAL

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- **Summary of the proposed action**

This proposal establishes an effective, expedient and transparent common authorisation procedure for food additives, food enzymes and food flavourings (in the form of a list of substances that is kept up to date). Community authorisation will be granted in a transparent, centralised manner on the basis of the scientific opinion of the Authority, provided that the authorisation criteria set out in the sectoral food laws are met. Such authorisation will take the form of a regulation to be adopted according to the comitology rules.

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- **Legal basis**

Article 95 of the EC Treaty

This proposal aims to improve the conditions for the functioning of the internal market, since it will be possible for products authorised in accordance with the proposed procedure to be used throughout the Community. The Regulation envisaged will lead to the Member States' legal provisions concerning the use of food additives, food enzymes and food flavourings being harmonised in the form of a positive list of authorised substances to be created by the Commission pursuant to the Regulation.

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- **Subsidiarity principle**

The principle of subsidiarity applies insofar as the proposal does not concern an area in which the Community has exclusive competence.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reasons.

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This proposal aims to establish a centralised authorisation procedure at Community level. It would not be possible for this to be achieved by national legislators, even if they simultaneously adopted national provisions with the same content as the proposed Regulation.

A Community measure on the authorisation procedure complements the other three harmonisation measures proposed in this area.

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Putting in place authorisation procedures separately in each Member State would make the authorisation mechanisms considerably more unwieldy and would create needless additional administrative burdens for the competent authorities of the Member States and for operators.

The objectives of the proposal can be better achieved by Community action for the following reasons.

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Community action in relation to the authorisation procedure for the substances in question is more effective than action taken by the Member States insofar as it will fully benefit all operators that market the products concerned on the Community market as well as consumers, who will be able to enjoy the same level of protection in all Member States.

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Community action in the area envisaged brings added value as regards legal certainty and efficiency for operators in the sector, administrative simplification, the functioning of the internal market and consumer protection.

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The proposal relates exclusively to the intrinsic elements of a centralised authorisation procedure.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

The proposal complies with the principle of proportionality for the following reasons.

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The proposed measure is procedural in nature and follows from the principle of pre-marketing authorisation that is established in the sectors concerned. A coordination-based solution would make the authorisation procedure for the substances concerned considerably more unwieldy. The proposed act does not exceed the limits of what is appropriate and

necessary in order to achieve the legitimate objective of the legislation in question, namely the proper functioning of the internal market and human health protection.

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The procedures put in place by the proposed measure streamline the processing of authorisation files, the majority of which (except for enzymes) have already been scientifically assessed by the Authority and processed by the Commission. Therefore, this has an impact on the procedures currently used by the Commission and the Authority, but one which remains limited. Nevertheless, the proposed measure will considerably reduce the administrative burdens on the Member States by allowing them to devote their resources particularly to implementing the legislation and to control activities. The new rules will enable operators to avail of a clear, transparent, effective and fast procedure by submitting a single authorisation application. The creation and updating of a Community list of authorised substances should also facilitate the movement of the products concerned and increase the level of information in this area.

- **Choice of instruments**

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Proposed instrument(s): Regulation.

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Other means would not be adequate for the following reasons.

The nature of the proposed measure is subject to and connected with the nature of the action taken in the sectors concerned. A different solution (directive, code of conduct, guidelines) would make the authorisation procedure for the substances concerned considerably more unwieldy and would not offer the necessary legal certainty.

#### 4) **BUDGETARY IMPLICATION**

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The proposal has no implication for the Community budget.

#### 5) **ADDITIONAL INFORMATION**

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- **Simplification**

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The proposal simplifies the legislative framework, the administrative procedures applicable to (national or European) public authorities and the administrative procedures applicable to bodies and private individuals.

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A single regulation will set out the applicable procedure for the authorisation of additives, enzymes and flavourings.

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The competent authorities of the Member States will be able to follow all the stages of the authorisation procedure without being burdened with needless administrative tasks.

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The operators concerned will benefit fully from the advantages of a

centralised, transparent, time-limited procedure. The granting of authorisation by means of a regulation updating a Community list will significantly speed up the authorisation procedure.

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The proposal is included in the Commission's programme for updating and simplifying the Community *acquis* and in its Work and Legislative Programme under the reference 2005/SANCO/034.

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- **European Economic Area**

This draft act concerns an area covered by the EEA Agreement and must therefore be extended to the European Economic Area.

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- **Detailed explanation of the proposal by chapter or by article**

Chapter I: General principles

A common procedure is established for assessing and authorising additives, enzymes and flavourings. This procedure has been designed to be simple, fast and effective, while respecting the principles of good administration and legal certainty. It is centred around the updating, on the basis of the criteria laid down in the sectoral laws, of a list of authorised substances that must be created and maintained by the Commission.

Chapter II: Common procedure

Under the proposed procedure, requests for updates must be addressed to the Commission, without first going through a national authority.

The Commission shall send the request file to the Authority and to the Member States and shall seek the opinion of the Authority, which must issue such opinion within six months.

So as to ensure the binding effect of the updating measures, the proposal provides for their adoption to take the legal form of a regulation adopted in accordance with the comitology procedure.

When the list is being updated within the framework of this proposal for a Regulation, any other relevant legitimate factors must be taken into account. Thus, when initiating the decision-making process, the Commission, as risk manager, may propose a measure that is not in line with the outcome of the risk assessment carried out under the responsibility of the Authority. In such cases, the Commission must explain its reasons for such a departure. This is in line with the Codex Alimentarius General Principles on Risk Analysis.

Chapter III: Miscellaneous provisions

So as to take account of the specific characteristics of each sectoral food law, this proposal gives the Commission the power, following consultation of the Authority, to take decisions on various details of the

procedure and provides for a certain degree of flexibility as regards complex and sensitive cases.

All non-confidential data should be made available to the public.

If the Member States or the Commission consider that a substance that has been authorised in accordance with this proposal poses serious risks to human health, animal health or the environment, emergency measures must be adopted.

F-11958

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**establishing a common authorisation procedure for food additives, food enzymes and food flavourings**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission<sup>1</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

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) So as to protect human health, the safety of additives, enzymes and flavourings for use in foodstuffs for human consumption must be assessed before they are placed on the Community market.
- (4) Regulation (EC) No XXX/2006 of the European Parliament and of the Council of ... on food additives<sup>3</sup>, Regulation (EC) No YYY/2006 of the European Parliament and of the Council of ... on food enzymes<sup>4</sup> and Regulation (EC) No ZZZ/2006 of the European Parliament and of the Council of ... on food flavourings and certain food ingredients with flavouring properties<sup>5</sup> lay down harmonised criteria and requirements concerning the assessment and authorisation of these substances.

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<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> OJ C [...], [...], p. [...].

<sup>3</sup> OJ L [...], [...], p. [...].

<sup>4</sup> OJ L [...], [...], p. [...].

<sup>5</sup> OJ L [...], [...], p. [...].

- (5) It is envisaged, in particular, that food additives, food enzymes and food flavourings, to the extent that the safety of the latter must be assessed in accordance with Regulation (EC) No ZZZ/2006, must not be placed on the market or used in foodstuffs for human consumption, in accordance with the conditions laid down in each sectoral food law, unless they are included on the Community list.
- (6) In this context, it appears appropriate to establish a common Community assessment and authorisation procedure for these three categories of substances that is effective, time-limited and transparent, so as to contribute to their free movement within the Community market.
- (7) This common procedure must be founded on the principles of good administration and legal certainty and must be implemented in compliance with these principles.
- (8) This Regulation will thus complete the regulatory framework concerning the authorisation of the substances by laying down the various stages of the procedure, the deadlines for these stages, the role of the parties involved and the principles that apply. Nevertheless, for some aspects of the procedure, it is necessary to take the specific characteristics of each sectoral food law into consideration.
- (9) In accordance with the framework for risk assessment in matters of food safety established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>6</sup>, the placing of substances on the market must be authorised only after a scientific assessment, of the highest possible standard, of the risks that they pose to human health. This assessment, which must be carried out under the responsibility of the European Food Safety Authority (hereinafter referred to as “the Authority”), must be followed by a risk management decision taken by the Commission under a regulatory procedure that ensures close cooperation between the Commission and the Member States.
- (10) It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.
- (11) So that both business operators in the sectors concerned and the public are kept informed of the authorisations in force, the authorised substances should be included on a Community list created, maintained and published by the Commission.
- (12) Networking between the Authority and the Member States’ organisations operating in the fields within the Authority’s mission is one of the basic principles of the Authority’s operation. In consequence, in preparing its opinion, the Authority may use the network made available to it by Article 36 of Regulation (EC) No 178/2002 and by Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of Regulation (EC) No 178/2002 with regard to the network of

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<sup>6</sup> OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

organisations operating in the fields within the European Food Safety Authority's mission<sup>7</sup>.

- (13) The common authorisation procedure for the substances must fulfil transparency and public information requirements while guaranteeing applicants' right to preserve the confidentiality of certain information.
- (14) Pursuant to Article 41 of Regulation (EC) No 178/2002, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents<sup>8</sup> applies to documents held by the Authority.
- (15) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to foodstuffs of Community origin or imported from third countries. They authorise the Commission to adopt such measures in situations where foodstuffs are likely to constitute a serious risk to human health, animal health or the environment and where such risk cannot be contained satisfactorily by measures taken by the Member State(s) concerned.
- (16) In the interests of efficiency and legislative simplification, there should be a medium-term examination as to whether to extend the scope of the common procedure to other legislation in the area of food.
- (17) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States on account of differences between national laws and provisions and can therefore be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve these objectives.
- (18) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>9</sup>,

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<sup>7</sup> OJ L 379, 24.12.2004, p. 64.

<sup>8</sup> OJ L 145, 31.5.2001, p. 43.

<sup>9</sup> OJ L 184, 17.7.1999, p. 23.

HAVE ADOPTED THIS REGULATION:

## **CHAPTER I GENERAL PRINCIPLES**

### *Article 1*

#### *Subject matter and scope*

1. This Regulation lays down a common assessment and authorisation procedure (hereinafter referred to as the “common procedure”) for food additives, food enzymes, food flavourings and sources of food flavourings used or intended for use in or on foodstuffs (hereinafter referred to as the “substances”), which contributes to the free movement of these substances within the Community.
2. The common procedure shall set the procedural arrangements for updating the lists of substances the marketing of which is authorised in the Community pursuant to Regulation (EC) No XXX/2006, Regulation (EC) No YYY/2006 and Regulation (EC) No ZZZ/2006 (hereinafter referred to as the “sectoral food laws”).
3. The criteria according to which substances can be included on the Community list provided for in Article 2, the content of the Regulation referred to in Article 7 and, where applicable, the transitional provisions concerning ongoing procedures are laid down in each sectoral food law.

### *Article 2*

#### *Community list of substances*

1. Under each sectoral food law, substances that have been authorised to be placed on the Community market shall be included on a list the content of which is determined by the said law (hereinafter referred to as the “Community list”). The Community list shall be updated by the Commission. It shall be published in the *Official Journal of the European Union*.
2. “Updating the Community list” means:
  - a) adding a substance to the Community list;
  - b) removing a substance from the Community list;
  - c) adding or changing conditions, specifications or restrictions associated with the presence of a substance on the Community list.

## **CHAPTER II**

### **COMMON PROCEDURE**

#### *Article 3*

##### *Main stages of the common procedure*

1. The common procedure for updating the Community list may be initiated either on the initiative of the Commission or following an application. Applications may be made by a Member State or by an interested party, who may represent several interested parties, according to the conditions provided for by the implementing measures referred to in Article 9(1)(a) (hereinafter referred to as “the applicant”).
2. The Commission shall seek the opinion of the European Food Safety Authority (hereinafter referred to as “the Authority”) in advance, in accordance with Article 5.

However, for the updates referred to in Article 2(2)(b) and (c), the Commission shall seek the opinion of the Authority only if these updates are liable to have an effect on public health.

3. The common procedure shall end with the adoption by the Commission of a regulation implementing the update, in accordance with Article 7.
4. By way of derogation from paragraph 3, the Commission may end the common procedure and decide not to proceed with a planned update, at any stage of the procedure, if it judges that such an update is not justified. Where applicable, it shall take account of the opinion of the Authority, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.

In such cases, where applicable, the Commission shall inform the applicant directly, indicating in its letter the reasons for the update not being considered justified.

#### *Article 4*

##### *Initiating the procedure*

1. On receipt of an application to update the Community list, the Commission:
  - a) shall acknowledge receipt of the application in writing to the applicant within 14 working days of receiving it;
  - b) where applicable, notify the Authority of the application and request its opinion.

The application shall be made available to the Member States by the Commission.

2. Where it initiates the procedure on its own initiative, the Commission shall inform the Member States and, where applicable, request the opinion of the Authority.

*Article 5*  
*Opinion of the Authority*

1. The Authority shall give its opinion within six months of receipt of a valid application.
2. The Authority shall forward its opinion to the Commission, the Member States and, where appropriate, the applicant.

*Article 6*  
*Additional information concerning risk assessment*

1. In duly justified cases where the Authority requests additional information from applicants, the period referred to in Article 5(1) may be extended. After consulting the applicant, the Authority shall lay down a period within which this information can be provided and inform the Commission of the additional period needed. If the Commission does not object within eight working days of being informed by the Authority, the period referred to in Article 5(1) shall be automatically extended by the additional period.
2. If the additional information is not sent within the additional period referred to in paragraph 1, the Authority shall finalise its opinion on the basis of the information already provided.
3. Where applicants submit additional information on their own initiative, they shall send it to the Authority and to the Commission. In such cases, the Authority shall give its opinion within the original period.
4. The additional information shall be made available to the Member States by the Authority.

*Article 7*  
*Updating the Community list*

Within nine months of the Authority giving its opinion, the Commission shall submit to the Committee referred to in Article 14(1) a draft regulation updating the Community list, taking account of the opinion of the Authority, any relevant provisions of Community law and any other legitimate factors relevant to the matter under consideration.

Where the draft regulation is not in accordance with the opinion of the Authority, the Commission shall explain the difference.

The regulation shall be adopted in accordance with the procedure referred to in Article 14(2).

*Article 8*  
*Additional information concerning risk management*

1. Where the Commission requests additional information from applicants on matters concerning risk management, it shall determine, together with the applicant, a period within which this information can be provided. In such cases, the period referred to in Article 7 may be extended accordingly.
2. If the additional information is not sent within the additional period referred to in paragraph 1, the Commission shall act on the basis of the information already provided.

**CHAPTER III**  
**MISCELLANEOUS PROVISIONS**

*Article 9*  
*Implementing measures*

1. In accordance with the procedure referred to in Article 14(2), within a period of no longer than 24 months from the adoption of each sectoral food law, the implementing measures for this Regulation shall be adopted, and shall concern in particular:
  - a) the content, drafting and presentation of the application referred to in Article 4(1);
  - b) the arrangements for checking the validity of applications;
  - c) the type of information that must be included in the opinion of the Authority referred to in Article 5.
2. With a view to the adoption of the implementing measures referred to in paragraph 1(a), the Commission shall consult the Authority, which, within six months of the date of entry into force of this Regulation, shall present it with a proposal concerning the data required for risk assessment of the substances concerned.

*Article 10*  
*Extension of time periods*

The periods referred to in Article 5(1) and Article 7 may be extended by the Commission on its own initiative or, where applicable, at the Authority's request, if the nature of the matter in question so justifies, without prejudice to Article 6(1) and Article 8(1). In such cases, where appropriate, the Commission shall inform the applicant of the extension and the reasons for it.

*Article 11*  
*Transparency*

The Authority shall ensure the transparency of its activities in accordance with Article 38 of Regulation (EC) No 178/2002. In particular, it shall make its opinions public without delay. It shall also make public any request for its opinion as well as any time period extension pursuant to Article 6(1).

*Article 12*  
*Confidentiality*

1. Among the information provided by applicants, confidential treatment may be given to information the disclosure of which might significantly harm their competitive position.

Information relating to the following shall not, in any case, be considered confidential:

- a) the name and address of the applicant and the name of the substance;
  - b) a clear description of the substance and the conditions for its use in or on specific foodstuffs or food categories;
  - c) information that is relevant to the assessment of the safety of the substances;
  - d) where applicable, the analysis method(s).
2. So that paragraph 1 can be implemented, applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.
  3. The Commission shall decide which information can remain confidential and notify applicants accordingly.
  4. After being made aware of the Commission's position, applicants shall have three weeks in which to withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality is preserved until this period expires.
  5. The Commission, the Authority and the Member States shall take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

6. If an applicant withdraws, or has withdrawn, its application, the Authority, the Commission and the Member States shall respect the confidentiality of commercial and industrial information, including research and development information, as well as information the confidentiality of which is the subject of disagreement between the Commission and the applicant.
7. The implementation of paragraphs 1 to 6 shall not affect the circulation of information between the Commission, the Member States and the Authority.

*Article 13  
Emergencies*

In the event of an emergency concerning a substance on the Community list, particularly in the light of an opinion of the Authority, measures shall be adopted in accordance with the procedures referred to in Articles 53 and 54 of Regulation (EC) No 178/2002.

*Article 14  
Committee*

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58 of Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having due regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

*Article 15  
Competent authorities of the Member States*

Not later than six months after the entry into force of this Regulation, the Member States shall forward to the Commission and to the Authority, in relation to each sectoral food law, the name and address of the national competent authority for the purposes of the common procedure, as well as a contact point therein.

## **CHAPTER IV**

### **FINAL PROVISION**

#### *Article 16* *Entry into force*

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

For each sectoral food law, it shall apply from the date of application of the measures referred to in Article 9(1).

Article 9 shall apply from the date of entry into force of this Regulation.

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

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*