

# EUROPEAN PARLIAMENT

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*Committee on the Environment, Public Health and Food Safety*

PROVISIONAL  
**2006/0143(COD)**

7.2.2007

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## **DRAFT REPORT**

on the 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  
(COM(2006)0423 – C6-0258/2006 – 2006/0143(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Åsa Westlund

### ***Symbols for procedures***

- \* Consultation procedure  
*majority of the votes cast*
- \*\*I Cooperation procedure (first reading)  
*majority of the votes cast*
- \*\*II Cooperation procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\* Assent procedure  
*majority of Parliament's component Members except in cases  
covered by Articles 105, 107, 161 and 300 of the EC Treaty and  
Article 7 of the EU Treaty*
- \*\*\*I Codecision procedure (first reading)  
*majority of the votes cast*
- \*\*\*II Codecision procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\*III Codecision procedure (third reading)  
*majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

### ***Amendments to a legislative text***

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the 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**

**(COM(2006)0423 – C6-0258/2006 – 2006/0143(COD))**

**(Codecision procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2006)0423)<sup>1</sup>,
  - having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0258/2006),
  - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
  - having regard to Rule 51 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A6-0000/2007),
1. Approves the Commission proposal as amended;
  2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
  3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

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Amendments by Parliament

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### Amendment 1

#### Citation 1

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

Having regard to the Treaty establishing the European Community, and in particular Article 95 **and Article 175** thereof,

### *Justification*

*What a person eats does not stay in the human body but is dispersed into the natural environment and becomes part of the natural cycle. Even if a substance does not entail any*

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<sup>1</sup> Not yet published in OJ.

*health risk to the person consuming the product which contains the substance, there may be negative effects on the environment and public health at subsequent stages, which should be taken into consideration when deciding to grant authorisation or not.*

#### Amendment 2

##### Recital 2

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

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

#### Amendment 3

##### Recital 4

(4) Regulation (EC) No XXX/2006 of the European Parliament and of the Council of ... on food additives, Regulation (EC) No YYY/2006 of the European Parliament and of the Council of ... on food enzymes 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 lay down **harmonised** criteria and requirements concerning the assessment and authorisation of these substances.

(4) Regulation (EC) No XXX/2006 of the European Parliament and of the Council of ... on food additives, Regulation (EC) No YYY/2006 of the European Parliament and of the Council of ... on food enzymes 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 lay down criteria and requirements concerning the assessment and authorisation of these substances.

#### *Justification*

*It is not certain that the criteria should be exactly the same for the various substances. One reason why they are dealt with in three different regulations is that there are, nevertheless, various differences to take into account.*

#### Amendment 4

##### Recital 5 a (new)

***(5a) Transparency in the production and handling of food is absolutely crucial to achieve consumer credibility.***

#### *Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of*

*managing food-related issues.*

Amendment 5  
Recital 7 a (new)

***(7a) The criteria laid down for authorisation in the Regulations of the European Parliament and of the Council on food additives, food enzymes and certain food ingredients with flavouring properties for use in and on foods shall also be fulfilled for authorisation pursuant to this Regulation.***

*Justification*

*This is self-evident but is not set out particularly clearly in the Commission's proposal.*

Amendment 6  
Recital 11

(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.

(11) So that both business operators in the sectors concerned and the public are kept informed of the authorisations in force, the authorised substances ***shall*** be included on a Community list created, maintained and published by the Commission.

*Justification*

*Consumers and the industry must be able to assume that substances and uses which are not included on the Community list are unauthorised.*

Amendment 7  
Recital 13

(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.

(13) The common authorisation procedure for the substances ***shall*** fulfil transparency and public information requirements while guaranteeing applicants' right to preserve the confidentiality of certain information.

Amendment 8  
Recital 18 a (new)

***(18a) In particular, the Commission should be empowered to update and modify the Community list of food additives, food enzymes and food flavourings to be established under this Regulation. Since those measures are of general scope and are designed to amend, delete or supplement non-essential elements of this Regulation, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.***

*Justification*

*This amendment is needed in order to align the text to the provisions of the new comitology decision.*

Amendment 9  
Article 1, paragraph 1

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.

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 ***food*** within the Community.

*Justification*

*The primary aim of this legislation is to contribute to the free movement of food within the Community.*

Amendment 10  
Article 2, paragraph 1

1. Under each sectoral food law,

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*.

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 ***in accordance with the procedure referred to in Article 14(2a)***. It shall be published in the *Official Journal of the European Union*.

#### *Justification*

*This amendment is needed in order to align the text to the provisions of the new comitology decision.*

#### Amendment 11

##### Article 3, paragraph 4, subparagraph 2

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.

In such cases, the Commission shall ***make public its decision and*** inform the applicant directly, indicating in its letter the reasons for the update not being considered justified.

#### *Justification*

*Decisions not to take decisions must also be made public. Transparency is a crucial factor if consumers are to have confidence in the EU's way of managing food-related issues.*

#### Amendment 12

##### Article 3, paragraph 3a (new)

***All authorisations for use of food additives, food enzymes and food flavourings shall be reviewed on a regular basis.***

#### *Justification*

*It is important that the use of substances in food is consistent with the latest scientific research. Moreover, it is important for certain groups of consumers that substances which are not used are deleted from the list, along with uses which are no longer current.*

Amendment 13  
Article 4, paragraph 1, subparagraph 2

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

The application shall be made available to the Member States by the Commission **and it shall be made public.**

*Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of managing food-related issues.*

Amendment 14  
Article 4, paragraph 2

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.

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

*Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of managing food-related issues.*

Amendment 15  
Article 5, paragraph 1

1. The Authority shall give its opinion within **six** months of receipt of a valid application.

1. The Authority shall give its opinion within **nine** months of receipt of a valid application.

*Justification*

*Given the resources at the EFSA's disposal and the quality standards required of the EFSA's opinion, the Commission's proposal for such a short period of time is not reasonable.*

Amendment 16  
Article 5, paragraph 2

2. The Authority shall forward its opinion to the Commission, the Member States and, **where appropriate**, the applicant.

2. The Authority shall forward its opinion to the Commission, the Member States and the applicant. **The opinion shall also be made public.**

*Justification*

*The applicant must ALWAYS be informed and the EFSA's opinion must be made public.*

Amendment 17  
Article 6, paragraph 3

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.

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, ***unless there are special reasons for extending the period of time.***

*Justification*

*There must not be any incentives for the applicant to submit additional information once the deadline has expired. Without the above addendum, there would unfortunately be such a negative incentive.*

Amendment 18  
Article 7, paragraph 1 a (new)

***The Commission shall justify its proposal and explain the considerations on which its decision is based.***

*Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of managing food-related issues. The Commission should be able to explain, without difficulty, the considerations on which its decision is based. A transparent explanation of this nature would benefit consumers, the industry and the Member States' authorities.*

Amendment 19  
Article 7, paragraph 2

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

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

### *Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of managing food-related issues. The Commission should be able to explain, without difficulty, the considerations on which its decision is based. A transparent explanation of this nature would benefit consumers, the industry and the Member States' authorities.*

### Amendment 20 Article 7, paragraph 3

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

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

### *Justification*

*This amendment is needed in order to align the text to the provisions of the new comitology decision.*

### Amendment 21 Article 7, paragraph 3 a (new)

***(3a) If the final decision differs from the Commission's original proposal to the committee, the Commission shall set out the reasons therefor.***

### *Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of handling food-related issues. The Commission should be able to explain, without difficulty, the considerations on which its decision is based. A transparent explanation of this nature would benefit consumers, the industry and the Member States' authorities.*

### Amendment 22 Article 10

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

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 8(1). In such cases, the Commission shall inform the applicant of the extension and the reasons for it.

*Justification*

*The applicant must always be informed.*

Amendment 23  
Article 11, paragraph 1 a (new)

***The Commission shall ensure the transparency of the authorisation procedure by making public all applications and by making all relevant material in the matter available to the public.***

*Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of handling food-related issues.*

Amendment 24  
Article 12, paragraph 1, subparagraph 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*** provided by applicants ***may be given*** confidential treatment ***only where the disclosure thereof*** might significantly harm their competitive position.

*Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of handling food-related issues. There may sometimes be grounds, however, for treating information confidentially.*

Amendment 25  
Article 12, paragraph 1, subparagraph 2, introduction

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

Information relating to the following ***may never***, in any case, be considered confidential:

*Justification*

*Transparency is a crucial factor if consumers are to have confidence in the EU's way of handling food-related issues. There may sometimes be grounds, however, for treating information confidentially.*

Amendment 26  
Article 14, paragraph 2 a (new)

***2a. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having due regard to the provisions of Article 8 thereof.***

*Justification*

*This amendment is needed in order to align the text to the provisions of the new comitology decision.*

## **EXPLANATORY STATEMENT**

### **Environmental considerations**

In accordance with the Cardiff process, environmental aspects must be integrated into all EU legislation.

It is particularly relevant in this legislation since what a person eats does not stay in the human body but is dispersed into the natural environment and becomes part of the natural cycle. Negative environmental effects should therefore be taken into consideration when deciding to grant authorisation or not. Article 175 of the Treaty establishing the European Communities should therefore also form the basis for the regulation.

### **Transparency**

Transparency is a crucial factor if consumers are to feel confident in the EU's way of managing food-related issues. The Commission must, therefore, ensure the transparency of the authorisation procedure by making public all applications and making all relevant material in the matter available to the public. Producers applying for authorisation must always be informed directly on matters concerning their application.

The Commission should be able, without difficulty, to explain the considerations on which its decision is based. A transparent explanation of this nature would benefit consumers, industry and the Member States' authorities. The Commission should, therefore, always make public its proposals for decisions, justify its proposal and explain the considerations on which its decision is based. Decisions not to take decisions must also be made public.

Where the adopted regulation departs from the Commission's original proposal to the Committee on the Food Chain and Animal Health, the Commission shall also explain the background to the final decision.

### **Food safety**

Given the resources at the EFSA's disposal and the quality standards required of the EFSA's opinion, six months, as the Commission has proposed, is not a reasonable period within which to produce an opinion on an application. Having regard to food safety, therefore, it is proposed that this time period be extended so that the EFSA has nine months in which to present an opinion.

It is important that the use of substances in food is consistent with the latest scientific research. It is also important for certain groups of consumers that substances and uses which are no longer current are removed from the list. All authorisations for use of food additives, food enzymes and food flavourings must therefore be reviewed on a regular basis.

### **The new comitology procedure**

In the light of the new comitology procedure, a number of amendments are proposed to the Commission's proposal.

