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

PROVISIONAL  
**2006/0145(COD)**

8.2.2007

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## **DRAFT REPORT**

on the proposal for a regulation of the European Parliament and of the Council  
on food additives  
(COM(2006)0428 – C6-0260/2006 – 2006/0145(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 on food additives

(COM(2006)0428 – C6-0260/2006 – 2006/0145(COD))

(Codecision procedure: first reading)

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2006)0428)<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 (C6-0260/2006),
  - having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,
  - having regard to Rules 51 and 36 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*

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

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

*entail any 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 account when deciding to grant authorisation or not. A sound environment must therefore also be one of the aims of the Regulation.*

Amendment 2  
Recital 3

(3) This Regulation replaces previous Directives and Decisions concerning food additives permitted for use in foods with a view to ensuring the effective functioning of the internal market and a high level of protection of human health and the interests of consumers via comprehensive and streamlined procedures.

(3) This Regulation replaces previous Directives and Decisions concerning food additives permitted for use in foods with a view to ensuring the effective functioning of the internal market and a high level of protection of human health **and of the environment**, and the interests of consumers, **including those consumers who are allergic to certain substances**, via comprehensive and streamlined procedures.

*Justification*

*In accordance with the Cardiff Process, environmental aspects must be integrated into all EU legislation. 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 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 account when deciding to grant authorisation or not. A sound environment must therefore also be one of the aims of the Regulation. It is important to stress that the Regulation must also take account of vulnerable groups of consumers, such as allergy sufferers.*

Amendment 3  
Recital 6

(6) Substances not consumed as food itself but used intentionally in the processing of foods, which **only** remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation.

(6) Substances not consumed as food itself but used intentionally in the processing of foods, which **do not** remain as residues in the final food and do not have a technological effect in the final product (processing aids), should not be covered by this Regulation.

### *Justification*

*It is of no significance to consumer health whether a substance has been used as a processing aid or an additive. The decisive factor is whether it remains in the final product or not. Naturally, a long transitional period is required before processing aids and additives, as defined at the present time, will need to be authorised in accordance with this Regulation.*

### Amendment 4 Recital 14

(14) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information.

(14) Food additives should be kept under continuous observation and must be re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. ***Special evaluation programmes shall be adopted to review authorisations granted.***

### *Justification*

*Authorisation for the use of additives must be reviewed continually. Additives should be ranked in order of priority according to the urgency of reviewing their use. This priority ranking should be drawn up by means of an evaluation programme so that it is clear to all parties involved. This does not prevent the Commission and/or EFSA, however, from taking the initiative to review certain substances more promptly.*

### Amendment 5 Recital 16 a (new)

***(16a) Since there is no significance from a consumer perspective whether a food ingredient is present as a processing aid or food additive, processing aids (with the exception of enzymes governed by the regulation on food enzymes) which remain in the final product should be treated as food additives. That requires a long transitional period, however.***

### *Justification*

*It is of no significance to consumer health whether a substance has been used as a processing aid or an additive. The decisive factor is whether it remains in the final product or not. Naturally, a long transitional period is required before processing aids and additives, as defined at the present time, will need to be authorised in accordance with this Regulation.*

Amendment 6  
Recital 17 a (new)

***(17a) In particular, the Commission should be empowered to update and modify the Community list of food additives 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 7  
Recital 21

(21) Following the adoption of this Regulation the Commission assisted by the Standing Committee on Food Chain and Animal Health should review all the existing authorisations ***for criteria, other than safety, such as intake, technological need and the potential to mislead the consumer.*** All food additives that are to continue to be authorised in the Community should be transferred to the Community lists in Annexes II and III to this Regulation. Annex III to this Regulation should be completed with the other food additives used in food additives and enzymes and their conditions of use in accordance with Regulation (EC) No [...] establishing a common authorisation procedure for food additives, food enzymes and food flavourings. To allow a suitable transition period, the provisions in Annex

(21) Following the adoption of this Regulation the Commission assisted by the Standing Committee on Food Chain and Animal Health should review all the existing authorisations ***on the basis of the conditions for authorisation laid down in this Regulation.*** All food additives that are to continue to be authorised in the Community should be transferred to the Community lists in Annexes II and III to this Regulation. Annex III to this Regulation should be completed with the other food additives used in food additives and enzymes and their conditions of use in accordance with Regulation (EC) No [...] establishing a common authorisation procedure for food additives, food enzymes and food flavourings. To allow a suitable transition period, the provisions in Annex III, other than the provisions concerning

III, other than the provisions concerning carriers for food additives, should not apply until [1.1.2011].

carriers for food additives, should not apply until [1.1.2011].

*Justification*

*There is no need to list here the criteria for authorisation pursuant to this Regulation.*

Amendment 8  
Article 1, introductory part

This Regulation lays down rules on food additives used in foods to ensure the effective functioning of the internal market and a high level of human health protection **and consumer protection.**

This Regulation lays down rules on food additives used in foods to ensure the effective functioning of the internal market and a high level of human health protection, **and consumer and environmental protection.**

*Justification*

*In accordance with the Cardiff Process, environmental aspects must be integrated into all EU legislation. 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 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 account when deciding to grant authorisation or not. A sound environment must therefore also be one of the aims of the Regulation.*

Amendment 9  
Article 2, point (a)

(a) processing aids;

(a) processing aids, **unless they remain in the final product;**

*Justification*

*It is of no significance to consumer health whether a substance has been used as a processing aid or an additive. The decisive factor is whether it remains in the final product or not. Naturally, a long transitional period is required before processing aids and additives, as defined at the present time, will need to be authorised in accordance with this Regulation.*

Amendment 10  
Article 3, paragraph 2, point (b), point (iii)

(iii) **may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product;**

(iii) **does not remain in** the final product;

*Justification*

*It is of no significance to consumer health whether a substance has been used as a processing aid or an additive. The decisive factor is whether it remains in the final product or not. Naturally, a long transitional period is required before processing aids and additives, as defined at the present time, will need to be authorised in accordance with this Regulation.*

Amendment 11

Article 5, paragraph 1, point (a a) (new)

**(aa) It does not, on the basis of the scientific evidence available, adversely affect public health or the health of vulnerable groups during any part of its life cycle.**

*Justification*

*Even if a substance does not entail any 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 account when deciding to grant authorisation or not. The use of antibiotics in food and its implications for the development of resistance is one example.*

Amendment 12

Article 5, paragraph 1, point (b)

(b) there is a reasonable technological need that cannot be achieved by other economically and technologically practicable means;

(b) there is a reasonable technological need that cannot be achieved **better** by other economically and technologically **reasonable and** practicable means;

*Justification*

*If there are alternatives which entail less of a risk to human health and freedom of choice, and to the environment, these should be used in the first instance.*

Amendment 13  
Article 5, paragraph 1, point (c a) (new)

***(ca) It will not contribute to reducing the range of food available to allergy sufferers.***

*Justification*

*Particular consideration should be given to vulnerable groups and allergy sufferers. The majority should be able to eat food sold in normal shops without being referred to special dietary food. One of the criteria for authorisation under this Regulation should therefore be that the substance or its use does not reduce the range of foods available to allergy sufferers.*

Amendment 14  
Article 5, paragraph 1, point (c b) (new)

***(cb) It does not, on the basis of the scientific evidence available, entail any adverse environmental effect during any part of its life cycle.***

*Justification*

*According to the Cardiff process, environmental aspects must be integrated into all EU legislation. 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.*

Amendment 15  
Article 5, paragraph 1 a (new)

***1a. Even if an additive may affect health in accordance with 1(aa), the environment in accordance with 1(cb) or the range of products available to allergy sufferers in accordance with 1(ca), it may be authorised if the advantages to consumers in accordance with paragraph 2 outweigh those disadvantages.***

*Justification*

*An additive or a use of an additive may have both advantages and disadvantages according to the above criteria. Ultimately, therefore, the various pros and cons must be weighed against each other.*

Amendment 16  
Article 5, paragraph 3, point (a)

***(a) the food does not constitute a significant component of a normal diet;*** ***deleted***  
***or***

*Justification*

*Lowering the quality of a food can never be to the benefit of consumers, except in the case of point (b).*

Amendment 17  
Article 7, subparagraph 2 (new)

***There must, however, be no risk of the additive misleading consumers into believing that the food contains ingredients other than those actually present.***

*Justification*

*Consumers are sometimes misled by the use of additives despite the fact that one of the criteria for authorisation under previous legislation is that consumers must not be misled. For example, consumers are sometimes duped into believing that a product contains a certain fruit through the use of a particular colour for the product. Consumer protection must therefore be strengthened in this regard.*

Amendment 18  
Article 8, paragraph 2

2. Where necessary, as a result of scientific progress or technological development, additional functional classes may be added to Annex I in accordance with the procedure referred to in Article **28(2)**.

2. Where necessary, as a result of scientific progress or technological development, additional functional classes may be added to Annex I in accordance with the procedure referred to in Article **28(2a)**.

*Justification*

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

Amendment 19  
Article 10, paragraph 1 a (new)

***1a. If the use of nanotechnology is authorised, separate limit values for that purpose shall be laid down in accordance with paragraph 1(a).***

*Justification*

*There is currently little known about the health risks of nanotechnology. It is not certain that the limit value for traditional use of an additive and the limit value for nanoparticles of an additive should be the same.*

Amendment 20  
Article 28, 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 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.*

Amendment 21  
Article 30, paragraph 1 a (new)

***1a. Additives previously classified as processing aids but which, in future, are to be classified as food additives pursuant to this Regulation, may continue to be used as processing aids for a transitional period of 8 years. Thereafter, their use must be approved in accordance with this Regulation in order to be authorised.***

*Justification*

*It is of no significance to consumer health whether a substance has been used as a processing aid or an additive. The decisive factor is whether it remains in the final product or not. Naturally, a long transitional period is required before processing aids and additives, as*

*defined at the present time, will need to be authorised in accordance with this Regulation.*

Amendment 22  
Article 31, paragraph 2

***2. The authority's risk evaluation shall form part of the review to be carried out by the Commission, assisted by the committee, of all food additives which were approved prior to the entry into force of this Regulation. This review shall be conducted on the basis of the conditions of authorisation laid down in this Regulation, and on the basis of an assessment of intake and risk management.***

***All food additives that are to continue to be authorised in the Community shall be transferred to the Community lists in Annexes II and III to this Regulation. Annex III to this Regulation should be completed with the other food additives used in food additives and enzymes and their conditions of use in accordance with the Regulation (EC) No [...] establishing a common authorisation procedure for food additives, food enzymes and food flavourings. To allow a suitable transition period, the provisions in Annex III, other than the provisions concerning carriers for food additives, should not apply until [1.1.2011].***

***2. After consultation of the Authority, an evaluation programme for those additives shall be adopted*** within one year after the date of entry into force of this Regulation, in accordance with the procedure laid down in Article 28(2). The evaluation programme shall be published in the *Official Journal of the European Union*.

***The review shall be conducted on the basis of an evaluation programme which shall be adopted, after consultation of the Authority, within one year after the date of entry into force of this Regulation, in accordance with the procedure laid down in Article 28(2)(a). The evaluation programme shall be published in the Official Journal of the European Union.***

*Justification*

*It is important that the review is conducted on the basis of the new criteria. It is also important that all authorised substances are included on the Community list. The procedure*

*should also be laid down in an Article.*

Amendment 23  
Article 31, paragraph 2 a (new)

***2a. After the evaluation programme in paragraph 2 has been carried out, and after consultation of the Authority, a new evaluation programme shall be adopted for authorisations pursuant to this Regulation. This new evaluation programme shall be adopted in accordance with the procedure laid down in Article 28(2)(a) and shall be published in the Official Journal of the European Union.***

*Justification*

*There should also be a rolling review in the future. It is important that this is put on a formal footing at the same time as giving the EFSA scope to rank food additives according to the urgency of reviewing their use.*

Amendment 24  
Article 31, paragraph 2 b (new)

***2b. Food additives and uses which are no longer current shall be removed from the Annexes when the authorisation is reviewed.***

*Justification*

*This is required so that the Community list is up to date and provides correct information to consumers.*

Amendment 25  
Annex III

Community list of food additives approved for use in food additives **and** food enzymes, and conditions of use.

Part 1 Carriers in food additives

Community list of food additives approved for use in food additives, food enzymes **and food flavourings**, and conditions of use.

Part 1 Carriers in food additives, **food**

Part 2 Additives other than carriers in food additives

*enzymes and food flavourings*

Part 2 Additives other than carriers in food additives, *food enzymes and food flavourings*

*Part 3 Additives in food enzymes*

*Justification*

*To be consistent with Article 16, Annex III must include both authorised carriers and authorised other additives in food additives, food enzymes and food flavourings.*

## EXPLANATORY STATEMENT

The Commission has proposed that, in future, decisions on authorisation of food additives should be taken by way of the comitology procedure. Your rapporteur can see advantages in this respect but only if the considerations which the European Parliament has often raised over the years is clearly reflected in the new Regulation on food additives and the new Regulation on a common authorisation procedure for food additives, food enzymes and food flavourings. These considerations primarily relate to the environment, public health and allergy sufferers.

The new Regulation on food additives should also be strengthened in terms of the requirements relating to procedural transparency, the review of authorisations for food additives and clarification of what might be misleading to consumers. In addition, there should be a redefinition of what constitutes a food additive or a processing aid, and the use of nanotechnology should be regulated.

### **Considerations relating to the environment, public health and the range of products available to allergy sufferers**

In accordance with the Cardiff Process, environmental aspects must be integrated into all EU legislation. This is particularly relevant in this legislation as 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 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 account when deciding to grant authorisation or not. The use of antibiotics in food and its implications for the development of resistance to antibiotics is one example of what may have damaging effects on public health. When an additive is considered for authorisation, the criteria must include that it does not have negative effects on either public health or the environment. A sound environment should also be one of the aims of the Regulation.

Allergy sufferers are greatly helped by the fact that products containing common allergenic substances must be labelled, though this does not go far enough. Vulnerable groups and allergy sufferers should be given particular consideration. The majority should be able to eat food sold in normal shops without being referred to special dietary food. One of the criteria for authorisation under this Regulation should, therefore, be that the substance or its use does not reduce the range of foods available to allergy sufferers.

Your rapporteur proposes, however, that even where an additive may adversely affect public health, the environment or the range of products available to allergy sufferers adversely, it should be possible to authorise it, if the advantages to consumers obviously outweigh the disadvantages.

If, on the basis of the criteria laid down in Article 5, there are better alternatives to the additive and it is economically reasonable to use the alternative, then the use of the additive in question should not be authorised. It may be a question, for example, of using a different production method which does not require the use of additives or there may be already authorised additives which are better within the terms of the criteria laid down in Article 5.

## **Transparency and review**

Authorisations for use of additives must be subject to rolling review. Your rapporteur proposes that all current authorisations should be reviewed on the basis of the new criteria before they are transferred to the new Community list. Thereafter, the rolling review of authorisations should continue by way of a transparent procedure in accordance with an evaluation programme to be adopted by comitology procedure. The evaluation programme should be based on a priority system whereby additives are ranked according to the urgency of reviewing their use. This priority ranking should be drawn up by means of an evaluation programme so that it is clear to all parties involved. The evaluation programme must not however prevent the Commission and/or the EFSA from taking initiatives to review certain authorisations more promptly.

## **Consumer considerations**

One of the already existing criteria for authorisation of additives in current legislation is that consumers must not be misled. Nevertheless, colourings are sometimes used in a way which creates the impression that a certain type of fruit is present in the food even though that is not the case. Consumer protection must therefore be strengthened in this respect.

## **Consumer considerations and definitions**

It is of no significance to consumer health at all, whether a substance has been used as a processing agent or additive. The decisive factor is whether it remains in the final product or not. Traditionally, however, there have been differences of opinion over what constitutes a processing aid or an additive. For that reason, a long transitional period is required before what is currently defined as a processing aid but which remains in the final product will need to be approved in accordance with this Regulation.

## **Nanotechnology**

Little is currently known about the health risks of nanotechnology. It is not certain that the limit value for the traditional use of an additive and the limit value for nanoparticles of an additive should be the same. It is therefore proposed that the use of nanoparticles should be regulated separately in the Community list.

## **The new comitology procedure**

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