

# EUROPEAN PARLIAMENT

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

**2006/0143(COD)**

9.4.2008

## **AMENDMENTS 13 - 21**

**Draft recommendation for second reading**  
**Åsa Westlund**  
(PE404.468v01-00)

on the Council common position for adopting a regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings

Council common position  
(16673/2/2007 – C6-0138/2008 – 2006/0143(COD))



## Amendment 13

Åsa Westlund

### Council common position

#### Recital 11 a (new)

*Council common position*

*Amendment*

***(11a) The criteria laid down for authorisation under Regulations (EC) No XXX/2006, (EC) No YYY/2006 and (EC) No ZZZ/2006 should be fulfilled for authorisation to be granted pursuant to this Regulation.***

Or. en

## Amendment 14

Horst Schnellhardt

### Council common position

#### Article 2 – paragraph 1

*Council common position*

*Amendment*

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.

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 authorised on the Community list may be used by all food business operators subject to the conditions applicable to them, provided their use is not restricted under Article 12a.***

Or. de

### *Justification*

*The actual objective is not data protection itself, but, rather, authorisation of the substance in question, for the applicant's benefit, for a limited period. In connection with the authorisation of substances, therefore, an appropriate reference is needed.*

#### **Amendment 15**

**Françoise Grossetête and Pilar Ayuso**

#### **Council common position**

**Article 2 – paragraph 1 a new**

*Council common position*

*Amendment*

***1a. Substances included on the Community list may be used by all food business operators subject to the conditions applicable to them, provided their use is not restricted under Article 12(6a).***

Or. fr

### *Justification*

*Amendment 14 adopted by Parliament at first reading has been retabled. Assessment of the safety of a substance calls for large-scale studies. Logically, the benefit of that investment should go to the first applicant in order to support lasting innovation in the European Union. This mechanism, by protecting these data, gives the first applicant an incentive to innovate.*

#### **Amendment 16**

**Åsa Westlund**

#### **Council common position**

**Article 4 – paragraph 1 – subparagraph 1 point b and subparagraph 2**

*Council common position*

*Amendment*

***(b) where applicable, shall as soon as possible*** notify the Authority of the application and request its opinion in accordance with Article 3(2).

***(b)*** shall notify the Authority of the application and request its opinion in accordance with Article 3(2).

The application shall be made available to

The application shall be made available to

the Member States *by the Commission*.

the Member States *and be made public in accordance with Regulation (EC) 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents*.

Or. en

## **Amendment 17**

**Carl Schlyter and Bart Staes**

### **Council common position**

#### **Article 6 – paragraph 1**

##### *Council common position*

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 shall 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. The Commission shall inform the Member States of the extension.

##### *Amendment*

1. 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.

Or. en

## **Amendment 18**

**Horst Schnellhardt**

### **Council common position**

#### **Article 7 – paragraph 1**

*Council common position*

1. 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. In those cases where an opinion of the Authority has not been requested, the **nine-month** period shall start from the date the Commission receives a valid application.

*Amendment*

1. Within **six** 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. In those cases where an opinion of the Authority has not been requested, the **six-month** period shall start from the date the Commission receives a valid application.

Or. de

*Justification*

*To date, the Commission has failed to justify the longer examination period. Six months should be enough for an appropriate response to the EFSA findings. An extension, in some instances, would still be possible. First-reading amendment.*

**Amendment 19**  
**Horst Schnellhardt**

**Council common position**  
**Article 8 – paragraph 1**

*Council common position*

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 that information can be provided. In such cases, the period referred to in Article 7 may be extended accordingly. The Commission shall inform the Member States of the extension and shall make the additional information available to the Member States once it has been provided.

*Amendment*

1. **In duly justified cases**, the Commission **may request additional information from applicants on matters concerning risk management. In those instances**, it shall determine, together with the applicant, a period within which that information can be provided. In such cases, the period referred to in Article 7 may be extended accordingly. The Commission shall inform the Member States of the extension and shall make the additional information available to the Member States once it has

been provided.

Or. de

*Justification*

*There are no understandable reasons why the EFSA can invoke an extension only in justified cases, while this requirement to give reasons is waived for the Commission. Accordingly, the same wording is proposed for both the EFSA and the Commission.*

**Amendment 20**

**Françoise Grossetête and Pilar Ayuso**

**Council common position**

**Article 12 – paragraph 6 a (new)**

*Council common position*

*Amendment*

***6a. Scientific data and other information provided by applicants may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used and costs are shared accordingly, where:***

- a) the scientific data and other information were designated as proprietary by the prior applicant at the time the prior application was made; and***
- b) the prior applicant had exclusive rights of reference to the proprietary data at the time the prior application was made; and***
- c) the substance could not have been authorised without the submission of the proprietary data by the prior applicant.***

Or. fr

*Justification*

*Parliament's first-reading Amendment 33 has been retabled. Assessment of the safety of a*

*substance calls for large-scale studies. This mechanism, by protecting these data, gives the first applicant an incentive to innovate. Data protection must be temporary, however, since the unwarranted repetition of identical studies on the effects on humans and animals should be reduced. For that reason, it is proposed that this innovation incentive be limited to a five-year period.*

**Amendment 21**  
**Horst Schnellhardt**

**Council common position**  
**Article 12 a (new)**

*Council common position*

*Amendment*

**Article 12a**

***Scientific data and other information provided by applicants may not be used for the benefit of a subsequent applicant for a period of five years from the date of authorisation, unless the subsequent applicant has agreed with the prior applicant that such data and information may be used, where:***

- a) the scientific data and other information were designated as proprietary by the prior applicant at the time the prior application was made; and***
- b) the prior applicant had exclusive rights of reference to the proprietary data at the time the prior application was made; and***
- c) the food additive, food enzyme or food flavouring could not have been authorised without the submission of the proprietary data by the prior applicant.***

Or. de

*Justification*

*Data protection must be fully guaranteed. Without adequate protection, there is no incentive for manufacturers to invest in innovation. That view was backed by Parliament at first reading. First-reading amendment.*