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**A5-0122/2003**

24 April 2003

**\*\*\*I**  
**REPORT**

on the proposal for a European Parliament and Council regulation on smoke flavourings used or intended for use in or on foods  
(COM(2002) 400 – C5-0348/2002 – 2002/0163(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Minerva Melpomeni Malliori

***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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## PROCEDURAL PAGE

By letter of 15 July 2002 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, the proposal for a European Parliament and Council regulation on smoke flavourings used or intended for use in or on foods (COM(2002) 400 – 2002/0163(COD)).

At the sitting of 2 September 2002 the President of Parliament announced that he had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Legal Affairs and the Internal Market and the Committee on Industry, External Trade, Research and Energy for their opinions (C5-0348/2002).

The Committee on the Environment, Public Health and Consumer Policy appointed Minerva Melpomeni Malliori rapporteur at its meeting of 2 October 2002.

The committee considered the Commission proposal and draft report at its meetings of 24 March and 24 April 2003.

At the latter meeting it adopted the draft legislative resolution by 43 votes to 1, with 1 abstention.

The following were present for the vote: Caroline F. Jackson, chairman; Alexander de Roo and Guido Sacconi, vice-chairmen; Minerva Melpomeni Malliori, rapporteur; María del Pilar Ayuso González, Jean-Louis Bernié, Hans Blokland, David Robert Bowe, John Bowis, Martin Callanan, Dorette Corbey, Anne Ferreira, Christel Fiebiger (for Pernille Frahm), Marialiese Flemming, Karl-Heinz Florenz, Monica Frassoni (for Inger Schörling, pursuant to Rule 153(2)), Cristina García-Orcoyen Tormo, Laura González Álvarez, Robert Goodwill, Cristina Gutiérrez Cortines, Jutta D. Haug (for Torben Lund), Marie Anne Isler Béguin, Hedwig Keppelhoff-Wiechert (for Raffaele Costa), Christa Klaß, Eija-Riitta Anneli Korhola, Bernd Lange, Peter Liese, Giorgio Lisi (for Avril Doyle), Caroline Lucas (for Hiltrud Breyer), Emilia Franziska Müller, Riitta Myller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Béatrice Patrie, Marit Paulsen, Fernando Pérez Royo (for María Sornosa Martínez), Dagmar Roth-Behrendt, Yvonne Sandberg-Fries, Karin Scheele, Horst Schnellhardt, Bart Staes (for Patricia McKenna), Catherine Stihler, Astrid Thors, Antonios Trakatellis, Elena Valenciano Martínez-Orozco, Kathleen Van Brempt, Peder Wachtmeister and Phillip Whitehead.

The Committee on Legal Affairs and the Internal Market decided on 8 October 2002 not to deliver an opinion. The Committee on Industry, External Trade, Research and Energy decided on 12 November 2002 not to deliver an opinion.

The report was tabled on 24 April 2003.

## DRAFT LEGISLATIVE RESOLUTION

### European Parliament legislative resolution on the proposal for a European Parliament and Council regulation on smoke flavourings used or intended for use in or on foods (COM(2002) 400 – C5-0348/2002 – 2002/0163(COD))

#### (Codecision procedure: first reading)

*The European Parliament,*

- having regard to the Commission proposal to the European Parliament and the Council (COM(2002) 400<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 (C5-0348/2002),
  - having regard to Rule 67 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (A5-0122/2003),
1. Approves the Commission proposal as amended;
  2. Asks to the matter to be referred to it again, should the Commission intend to amend its 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

Amendments by Parliament

#### Amendment 1

##### Recital 18

(18) It is **appropriate** that food business operators using primary smoke condensates or primary tar fractions or derived smoke flavourings be required to establish procedures in accordance with which it is possible, at all stages of placing a primary product or derived smoke flavouring on the market, to verify whether it is authorised by this Regulation and whether the conditions of use are respected.

(18) It is **necessary** that food business operators using primary smoke condensates or primary tar fractions or derived smoke flavourings be required to establish procedures in accordance with which it is possible, at all stages of placing a primary product or derived smoke flavouring on the market, to verify whether it is authorised by this Regulation and whether the conditions of use are respected.

<sup>1</sup> OJ C 262 E, 29.10.2002, p. 523.

*Justification*

*Self-explanatory.*

Amendment 2  
Article 4, paragraph 1, first indent

- it does not present risks to human health;
- it does not present **any** risks to human health;

*Justification*

*The wording must be strengthened in order to guarantee that the authorised products cause no risk to human health.*

Amendment 3  
Article 5, paragraph 1

***1. Only those types of untreated wood listed in Annex I may be used for the production of primary smoke condensates and primary tar fractions.*** ***deleted***

*Justification*

*There should not be a positive list unless it is exhaustive. The list in Annex I is not exhaustive. Types of wood other than those mentioned in the list are regularly used for the production of smoke flavourings.*

Amendment 4  
Article 5, paragraph 2, subparagraph 1

2. The wood ***referred to in paragraph 1*** shall not have been treated, whether intentionally or unintentionally, with chemical substances during the six months immediately preceding felling or subsequent thereto, unless it can be demonstrated that the substance used for the treatment does not give rise to

2. The wood ***used for the production of primary products*** shall not have been treated, whether intentionally or unintentionally, with chemical substances during the six months immediately preceding felling or subsequent thereto, unless it can be demonstrated that the substance used for the treatment does not

potentially toxic substances during combustion.

give rise to potentially toxic substances during combustion.

*Justification*

*The choice of wood should not be limited to the list in Annex I.*

Amendment 5  
Article 8, paragraph 3, point b

(b) make available to the Member States and to the Commission ***a summary of each application, and, at the request of a Member State or of the Commission, transmit*** the full application dossier and any supplementary information supplied by the applicant;

(b) make available to the Member States and to the Commission the full application dossier and any supplementary information supplied by the applicant;

*Justification*

*Without prejudice to Article 14 on confidentiality, the preparation of the EFSA opinion should take place as transparently as possible. This is important because the final decision on the authorisation is done behind closed doors through comitology.*

Amendment 6  
Article 8, paragraph 4, first indent

- ***where appropriate***, any conditions or restrictions which should be attached to the use of the evaluated primary smoke condensate or primary tar fraction either as such and/or as derived smoke flavourings in or on specific foods or food categories;

- any conditions or restrictions which should be attached to the use of the evaluated primary smoke condensate or primary tar fraction either as such and/or as derived smoke flavourings in or on specific foods or food categories;

*Justification*

*Self-explanatory.*

Amendment 7  
Article 13a (new)

**Article 13 a**

**Public access**

***The application for authorisation, supplementary information from applicant and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Article 38, 39 and 41 in Regulation (EC) No 178/2002.***

***The Authority shall apply the principles of 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 when handling applications for access to documents held by the Authority.***

***Member States shall handle applications for access to documents received under this regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.***

*Justification*

*The general provisions on transparency (Regulation 1049/2001) and the provisions on the European Food Safety Authority (Regulation 178/2002) should be applied also to the evaluation of the applications for authorisation of smoke flavourings.*

Amendment 8  
Annex I

***This Annex deleted.***

*Justification*

*The use of a non-exhaustive positive list will only cause confusion.*



Amendment 9  
Annex II, point 1

1. Smoke is generated from wood *species listed in Annex I*. Herbs, spices, twigs of juniper and twigs, needles and cones of picea may be added if they are free of residues of intentional or unintentional chemical treatment or if they comply with more specific Community legislation. The source material is subjected to controlled burning, dry distillation or treatment with superheated steam in a controlled oxygen environment with a maximum temperature of 600°C.

1. Smoke is generated from wood **as referred to in Article 5**. Herbs, spices, twigs of juniper and twigs, needles and cones of picea may be added if they are free of residues of intentional or unintentional chemical treatment or if they comply with more specific Community legislation. The source material is subjected to controlled burning, dry distillation or treatment with superheated steam in a controlled oxygen environment with a maximum temperature of 600°C.

*Justification*

*As there should not be an Annex I, Annex II should be modified accordingly.*

Amendment 10  
Annex III, point -1 (new)

***-1. The type of wood used for the production of the primary product.***

*Justification*

*The choice of wood for the production of primary products should not be limited. The applicant must, however, state the type of wood used in the production.*

## EXPLANATORY STATEMENT

The objective of the proposal is to establish common procedures for the safety assessment and the authorisation of smoke flavouring used in or on foods. It will set up common rules for the industry and enhance the protection of human health and consumers' interests. At present, the rules for the authorisation of smoke flavourings are diverse in different Member States.

Smoke flavourings are produced from condensed smoke, which is fractionated and purified. The purification process decreases health risks related to the traditional smoking. The number of commercially available smoke condensates used for the production of smoke flavourings is fairly small. The Commission suggests that the toxicological evaluation should therefore focus on the smoke condensates (primary products) rather than all smoke flavourings. After a safety assessment and an authorisation procedure, primary smoke condensates and primary tar fractions for which no health concern is revealed will be included in a positive list of products authorised in the Community. According to the Commission, not more than 20 products need to be evaluated. The authorisation will be restricted to a period of 10 years. Products must be re-evaluated according to the latest scientific and technical knowledge before the authorisation can be renewed.

The European Food Safety Authority (EFSA) will be responsible for the evaluation of the authorisation applications. The final decision on the inclusion of products in the positive list will be done through a comitology procedure. The proposal contains transitional arrangements for the authorisation of existing products.

### Remarks

The rapporteur welcomes the proposal and supports its overall goals. It is important that the production of smoke flavourings is regulated in a uniform manner throughout the Community. The authorisation procedure must guarantee that the smoke flavourings used in foodstuffs do not present any risk to human health.

The Commission suggests that only wood that have been listed in Annex I may be used for the production of primary smoke condensates and primary tar fractions. The list of different types of wood is not, however, exhaustive. The major question is whether it is even possible to create an exhaustive list of wood that can be used for this purpose. As the traditional smoking methods and the natural reserves of wood vary between Member States, the presentation of a positive list in a regulation based on 10 year old findings is not recommended. The more important thing is to guarantee that the wood used in the production is non-treated and that the strict conditions for the production are met.

The draft regulation gives the European Food Safety Authority a key role in the authorisation procedure. It will receive the applications, request supplementary information, if needed, and prepare an opinion on each application. The formal decision on the authorisation, i.e. the composition of the positive list, will be done through comitology. Therefore it is vitally important to add explicit provisions on public access to documents.