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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 4.7.2003
COM(2003) 407 final

2002/0163 (COD)

-

Amended proposal for a

EUROPEAN PARLIAMENT AND COUNCIL REGULATION

on smoke flavourings used or intended for use in or on foods

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

EXPLANATORY MEMORANDUM

1. PROCEDURE

On 15 July 2002, the Commission adopted a proposal for a European Parliament and Council Regulation on smoke flavourings used or intended for use in or on foods^A. The proposal was sent to the European Parliament and the Council on the same day. The Economic and Social Committee issued its opinion supporting the Commission proposal on 11 December 2002.

On 8 May 2003, Coreper agreed unanimously on a revised text.

On 4 June 2003, the European Parliament voted in favour of amendments in line with the revised text resulting from Coreper.

In respect to the the evaluation and authorisation procedure, the European Parliament and Coreper agreed to the same procedure as adopted as Common Position on the Regulation of the European Parliament and the Council on genetically modified food and feed which has been accepted by the Commission.

As there is agreement between the European Parliament and the Council, it is the intention of the Council to adopt the proposal in Coreper as an A point during the Greek presidency.

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The Commission proposal aims at

- to establish Community procedures for the safety assessment and the authorisation of smoke flavourings intended for use in or on foods in order to ensure a high level of protection of human health and protection of consumers' interests, as well as to ensure fair trade practices.
- to establish a positive list of primary products authorised to the exclusion of all others in the Community to be used as such in and on foods or for the production of derived smoke flavourings.
- to ensure a smooth transition from national to Community regulations without disturbing the existing market.

3. COMMISSION OPINION ON THE AMENDMENTS ADOPTED BY THE EUROPEAN PARLIAMENT

The Commission can accept all the amendments adopted by the European Parliament.

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4. CONCLUSION

Having regard to Article 250 paragraph 2 of the EC Treaty, the Commission modifies its proposal as follows:

Amended proposal for a

EUROPEAN PARLIAMENT AND COUNCIL REGULATION

on smoke flavourings used or intended for use in or on foods

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 Commission¹,

Having regard to the opinion of the Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foods and to source materials for their production³, and in particular Article 5 (1) seventh indent thereof, provides for the adoption of appropriate provisions concerning source materials used for the production of smoke flavourings and reaction conditions under which they are prepared.
- (2) 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.
- (3) A high level of protection of human life and health should be assured in the pursuit of Community policies.
- (4) In order to protect human health smoke flavourings should undergo a safety assessment through a Community procedure before being placed on the market or used in or on foods within the Community.
- (5) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of smoke flavourings may hinder their free movement, creating conditions of unequal and unfair competition. An authorisation procedure should therefore be established at Community level.

¹ ~~(...)~~OJ C 262, 29.10.2002, p. 523.

² ~~(...)~~OJ C 85, 8.4.2003, p. 32.

³ OJ L 184, 15.7.1988, p. 61.

- (6) The chemical composition of smoke is complex and depends among other things on the types of wood used, the method used for developing smoke, the water content of the wood and the temperature and oxygen concentration during smoke generation. Smoked foods in general give rise to health concern, especially with respect to the possible presence of polycyclic aromatic hydrocarbons. Because smoke flavourings are produced from smoke which is subjected to fractionation and purification processes, the use of smoke flavourings is generally considered to be of less health concern than the traditional smoking process. **However, the possibility of wider applications of smoke flavourings in comparison to conventional smoking has to be taken into account in safety assessments.**
- (7) The present Regulation covers smoke flavourings as defined in Article 1 (2) (e) of Directive 88/388/EEC. The production of these smoke flavourings starts with the condensation of smoke. The condensed smoke is normally separated by physical processes into a water-based primary smoke condensate, a water insoluble high density tar phase and a water insoluble oily phase. The water insoluble oily phase is a by-product and unsuitable for the production of smoke flavourings. The primary smoke condensates and fractions of the water insoluble high density tar phase, the so called ‘primary tar fractions’, are purified to remove components of smoke which are most harmful to human health. They may then be suitable for use as such in or on foods or for the production of derived smoke flavourings made by further appropriate physical processing such as extraction procedures, distillation, concentration by evaporation, absorption or membrane separation and the addition of food ingredients, **other flavourings,** food additives or solvents, without prejudice to more specific Community legislation.
- (8) The Scientific Committee on Food concluded that because of the wide physical and chemical differences in smoke flavourings used for flavouring food, it is not possible to design a common approach to their safety assessment and, accordingly, toxicological evaluation should focus on the safety of individual smoke condensates. Following this advice, this Regulation provides for the scientific evaluation of primary smoke condensates and primary tar fractions, **hereinafter referred to as “primary products”**, in terms of the safety of their use as such and/or for the production of derived smoke flavourings intended for use in or on foods.
- (9) As regards conditions of production, this Regulation reflects the findings set out by the Scientific Committee on Food in its report on smoke flavourings of 25 June 1993⁴, in which it ~~provided a non-exhaustive list of types of wood which may be used for the production of smoke flavourings and~~ specified various production conditions and the information necessary to evaluate smoke flavourings used or intended for use in or on foods. That report was based, in turn, on the report of the Council of Europe on “health aspects of using smoke flavours as food ingredients”⁵. **It also contains a non-exhaustive list of types of wood which may be regarded as an indicative list of woods suitable for the production of smoke flavourings.**
- (10) Provision should be made for the establishment, on the basis of the safety assessment, of a list of primary ~~smoke condensates and primary tar fractions~~**products** authorised for use as such in or on foods and/or for the production of smoke flavourings for use in or on foods within the Community. That list should clearly

⁴ Reports of the Scientific Committee for Food, Thirty-fourth series, p. 1 – 7.

⁵ Council of Europe Publishing, 1992, reprinted 1998, ISBN 92-871-2189-3.

describe the primary products, specifying conditions of their uses and the dates from which the authorisations are valid.

- (11) In order to ensure harmonisation, safety assessments should be carried out by the European Food Safety Authority (“the Authority”), 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 safety⁶.
- (12) The safety assessment of a specific primary product should be followed by a risk management decision as to whether the product should be entered on the Community list of authorised primary products; that decision should be adopted in accordance with the regulatory procedure so as to ensure close cooperation between the Commission and the Member States.
- (13) It is appropriate that the person (“the applicant”) who intends to place on the market primary products or derived smoke flavourings should submit all the information necessary for the safety assessment. **The applicant and**—should **also** propose **a** validated methods of sampling and detection **for the primary product** to be used for control of compliance with the provisions of this Regulation; if necessary, the Commission should adopt quality criteria for those analytical methods after having consulted the Authority for scientific and technical assistance.
- (14) Since many smoke flavourings are already on the market in the Member States, provision should be made to ensure that the transition to a Community authorisation procedure is smooth and does not disturb the existing smoke flavourings market. Sufficient time should be allowed for the applicant to make available to the Authority the information necessary for the safety assessment of these products. Therefore, a certain time period, hereinafter referred to as the ‘first phase’, should be fixed during which the information for existing primary products should be submitted by the applicant to the Authority. Applications for authorisation of new primary products may also be submitted during the first phase. The Authority should evaluate without delay all applications for existing as well as new primary ~~smoke condensates or primary tar fractions~~**products** for which sufficient information has been submitted during the first phase.
- (15) The Community positive list should be established by the Commission after the completion of the safety assessment of all primary products for which sufficient information was submitted during the first phase. In order to ensure fair and equal conditions for all applicants, this initial establishment of the list should be done in a single step. After the initial establishment of the list of authorised primary products, it should be possible for additional primary ~~smoke condensates and primary tar fractions~~**products** to be added thereto by decision of the Commission, following the safety assessment by the Authority.
- (16) Whenever the evaluation by the Authority indicates that an existing smoke flavouring already on the market in the Member States constitutes a serious risk to human health, this product should be removed from the market without delay.

⁶ OJ L 31, 1.2.2002, p. 1.

- (17) Articles 53 and 54 of Regulation (EC) No 178/2002 establish procedures for taking emergency measures in relation to food of Community origin or imported from a third country. They allow the Commission to adopt such measures in situations where food is 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.
- (18) It is ~~appropriate~~ necessary that food business operators using primary ~~smoke condensates or primary tar fractions~~ products 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.
- (19) In order to ensure equal access of existing and new primary products to the market, an interim period should be established during which national measures continue to apply in the Member States.
- (20) Provision should be made for the Annexes to this Regulation to be adapted to scientific and technical progress.
- (21) Since those Annexes, which are necessary for the implementation of this Regulation, are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁷, amendments thereto should be adopted by use of the regulatory procedure provided for in Article 5 of that Decision.
- (22) The Commission shall be assisted by the Committee referred to in Article 58 (1) of Regulation (EC) No 178/2002.

HAVE ADOPTED THIS REGULATION:

Article 1
Subject matter

1. This Regulation seeks to ensure the effective functioning of the internal market in relation to smoke flavourings used or intended for use in or on foods, whilst providing the basis for securing a high level of protection for human health and the interests of consumers.
2. To this end, this Regulation lays down
 - a Community procedure for the evaluation and authorisation of primary smoke condensates and primary tar fractions for use as such in or on foods or in the production of derived smoke flavourings for use in or on foods;
 - a Community procedure for the establishment of a list of primary smoke condensates and primary tar fractions authorised to the exclusion of all others in the Community and their conditions of use in or on foods.

⁷ O.J. L 184, 17.7.1999, p. 23.

Article 2
Scope

This Regulation shall apply to:

- smoke flavourings used or intended for use in or on foods;
- source materials for the production of smoke flavourings;
- the reaction conditions under which smoke flavourings are prepared;
- foods in or on which smoke flavourings are present.

Article 3
Definitions

For the purposes of this Regulation, the definitions laid down in Directive 88/388/EEC and Regulation (EC) No 178/2002 shall apply.

The following definitions shall also apply:

1. “*primary smoke condensates*” ~~and “*primary tar fractions*”~~ shall refer to **the purified water-based part of condensed smoke and shall fall within the definition of ‘smoke flavourings’.**
2. ~~“*primary tar fraction*” shall refer to the purified fraction of the water insoluble high density tar phase of condensed smoke and shall fall within the definition of ‘smoke flavourings’.~~ ~~primary smoke condensates and primary tar fractions used or intended to be used as such in or on foods in order to impart smoke flavour to those foods; it shall also refer to primary smoke condensates and primary tar fractions used for the production of derived smoke flavourings used or intended to be used in or on foods.~~
3. “*primary products*” shall refer to primary smoke condensates and primary tar fractions.
4. “*derived smoke flavourings*” shall refer to flavourings produced as a result of the further processing of primary **smoke condensates and primary tar fractions** ~~products~~ and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods.

Article 4
General use and safety requirements

1. The use of smoke flavourings in or on foods shall only be authorised if it is sufficiently demonstrated that
 - it does not present risks to human health;
 - it does not mislead consumers.

Each authorisation may be subject to specific conditions of use.

2. No person shall place on the market a smoke flavouring or any food in or on which such a smoke flavouring is present if the smoke flavouring is not a primary product authorised in accordance with Article 6, or if it is not derived therefrom, and if the conditions of use laid down in the authorisation in accordance with this Regulation are not adhered to.

Article 5
Conditions of production

~~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.~~

1. The wood ~~referred to in paragraph 1~~ 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 give rise to potentially toxic substances during combustion.

The person who places on the market primary products ~~smoke condensates and primary tar fractions or derived smoke flavourings or food containing smoke flavourings~~ must be able to demonstrate by appropriate certification or documentation that the requirements laid down in the first paragraph have been met.

2. The conditions for the production of primary ~~smoke condensates and primary tar fractions~~ products are laid down in Annex ~~II~~ III. The water insoluble oily phase which is a by-product of the process shall not be used for the production of smoke flavourings.
3. Without prejudice to other Community legislation, primary ~~smoke condensates and primary tar fractions~~ products may be further processed by appropriate physical processes for the production of derived smoke flavourings. Where opinions differ as to whether a particular physical process is appropriate, a decision may be reached in accordance with the procedure referred to in Article ~~1819~~ 1819 (2).

Article 6
Community list of authorised products

1. A list of the primary ~~smoke condensates and primary tar fractions~~ products authorised to the exclusion of all others in the Community for use as such in or on foods and/or for the production of derived smoke flavourings shall be established in accordance with the procedure referred to in Article ~~1819~~ 1819 (2).
2. In respect of each authorised product, the list referred to in paragraph 1 shall give a unique code for that product, the name of the primary product, the name and address of the authorisation holder, a clear description and characterisation of the primary product, the conditions of its use in or on specific foods or food categories and the date from which the product is authorised.

3. Following the establishment of the list referred to in paragraph 1, primary ~~smoke condensates or primary tar fractions~~**products** may be added to that list in accordance with the procedure referred to in Article ~~18~~**19** (2).

Article 7
Application for authorisation

1. To obtain the authorisation referred to in Article 6(1), an application shall be submitted in accordance with the following provisions.

2. The application shall be sent to the national competent authority of a Member State.

(a) The national competent authority:

(i) shall acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) shall inform without delay the European Food Safety Authority (hereinafter referred to as the "Authority"); and

(iii) shall make the application and any supplementary information supplied by the applicant available to the Authority.

(b) The Authority shall inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them.

~~1. To obtain the authorisation referred to in Article 6 (1), a written application shall be submitted to the European Food Safety Authority, hereinafter referred to as "the Authority".~~

~~2. The Authority shall acknowledge in writing receipt of the application to the applicant within fifteen working days of its receipt. The acknowledgement shall state the date of receipt of the application.~~

3. The application shall be accompanied by the following:

- the name and address of the applicant;
- the information listed in Annex ~~III~~**III**;
- a reasoned statement affirming that the product complies with Article 4 (1), first indent;
- a summary of the dossier.

4. The Authority shall publish detailed guidance concerning the preparation and the submission of the application. Pending such publication, applicants shall consult the “Guidance on submissions for food additive evaluations” drawn up by the “Scientific Committee on Food”⁸.

Article 8
Opinion of the Authority

1. The Authority shall give an opinion within six months of the receipt of a valid application as to whether the product and its intended use complies with Article 4 (1). The Authority may extend the said period. In such a case it shall **provide an explanation for the delay to inform** the applicant, the Commission and the Member States.
2. The Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a time limit specified by the Authority which in no event shall exceed **6-12** months. Where the Authority requests supplementary information, the time limit laid down in paragraph 1 shall be suspended until such time that this information has been provided. Likewise, this time limit shall be suspended for the time allowed to the applicant to prepare oral or written explanations.
3. In order to prepare its opinion, the Authority shall:
 - (a) verify that the particulars and documents submitted by the applicant are in accordance with Article 7 (3) in which case the application shall be regarded as valid;
 - ~~(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) inform the applicant, the Commission and the Member States if an application is not valid.
4. In the event of an opinion in favour of authorising the evaluated product, the opinion shall include
 - ~~where appropriate,~~ any conditions or restrictions which should be attached to the use of the evaluated primary ~~smoke condensate or primary tar fraction~~**product** either as such and/or as derived smoke flavourings in or on specific foods or food categories;
 - an assessment as to whether the analytical method proposed in accordance with point 3 of Annex ~~III~~**II** is appropriate for the intended control purposes.

⁸ Until publication, applicants shall follow the “Guidance on submissions for food additive evaluations” by the Scientific Committee on Food, of 11 July 2001 or its latest update: http://europa.eu.int/comm/food/fs/sc/scf/out98_en.pdf

5. The Authority shall forward its opinion to the Commission, the Member States and the applicant.
6. The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article ~~14~~15.

Article 9
Community authorisation

1. Within three months of receiving the opinion of the Authority, the Commission shall prepare a draft of the measure to be taken in respect of the application for inclusion of a substance in the list referred to in Article 6 (1), taking into account the requirements of Article 4 (1), Community law and other legitimate factors relevant to the matter under consideration. Where the draft measure is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the reasons for the differences.

The measure referred to in paragraph 1 shall be

- a draft regulation amending the list referred to in Article 6 (1), by including the primary product on the list of authorised products, in accordance with the requirements under Article 6 (2) or
 - a draft decision, addressed to the applicant, refusing authorisation.
2. The measure shall be adopted in accordance with the procedure laid down in Article ~~18~~19 (2). The Commission shall inform the applicant of its adoption without delay.
 3. Without prejudice to Article 11, the authorisation granted in accordance with the procedure laid down in this Regulation shall be valid throughout the Community for ten years and shall be renewable in accordance with Article 12.
 4. After an authorisation has been issued in accordance with this Regulation, the authorisation holder or any other food business operator using the authorised primary product or derived smoke flavourings shall comply with any condition or restriction attached to such authorisation.
 5. The authorisation holder shall inform the Commission ~~and the Authority~~ immediately of any new scientific or technical information which might affect the assessment of the safety of the authorised primary product or derived smoke flavourings in relation to human health. If necessary, the Authority shall then review the assessment.
 6. The granting of an authorisation shall not diminish the general civil and criminal liability of any food business operator in respect to the authorised primary ~~smoke condensate, primary tar fraction~~product, derived smoke flavouring or food containing the authorised primary product or derived smoke flavouring.

Article 10

Initial establishment of the Community list of authorised smoke flavourings

1. During the 18 months following the entry into force of this Regulation, business operators shall submit an application in accordance with Article 7 in view of the establishment of an initial Community list of authorised primary products. Without prejudice to Article 9 (1), this initial list shall be established after the Authority has issued an opinion on each primary product for which a valid application has been submitted during this period.

Applications for which the Authority could not issue an opinion owing to the applicant's failure to comply with the time limits specified for submission of supplementary information in accordance with Article 8 (2) shall be excluded from consideration for inclusion in the initial Community list.

2. Within three months of receiving all the opinions referred to in paragraph 1, the Commission shall prepare a draft regulation for the initial establishment of the list referred to in Article 6 (1), having regard to the requirements of Article 6 (2).
3. The list referred to in Article 6 (1) shall be established in accordance with the procedure referred to in Article ~~1819~~ (2).

Article 11

Modification, suspension and revocation of authorisations

1. The authorisation holder may, in accordance with the procedure laid down in Article 7, apply for a modification of the existing authorisation.
2. ~~Where, o~~**On** its own initiative or following a request from ~~the authorisation holder,~~ a Member State or the Commission, the Authority ~~has reviewed the assessment of a primary product authorised in accordance with this Regulation, it~~ shall deliver ~~its an~~ **opinion on whether an authorisation is still in accordance with this Regulation**, following the procedure laid down in Article 8, where applicable.
3. The Commission shall examine the opinion of the Authority without delay and prepare a draft of the decision to be taken.
4. A draft ~~decision-measure~~ modifying an authorisation shall specify any necessary changes in the conditions of use and, if any, in the restrictions attaching to that authorisation.
5. ~~A~~**The final decision-measure, i.e. on** the modification, suspension or revocation of the authorisation, shall be adopted in accordance with the procedure referred to in Article ~~1819~~ (2).
6. The Commission shall without delay inform the authorisation holder of the ~~decision~~ **measure** taken.

Article 12
Renewal of authorisations

1. **Without prejudice to Article 11, a** Authorisations under this Regulation shall be renewable for ten-year periods on application to the **Authority-Commission** by the authorisation holder, at the latest 18 months before the expiry date of the authorisation.
- ~~2. The Authority shall acknowledge in writing receipt of the application for renewal to the authorisation holder within 15 working days of its receipt. The acknowledgement shall state the date of receipt of the application.~~
2. The application shall be accompanied by the following particulars and documents:
 - (a) a reference to the original authorisation;
 - (b) any available information concerning the points listed in Annex ~~III~~ which supplements the information already provided to the Authority in the course of the previous evaluation(s) and updates this in the light of the most recent scientific and technical developments;
 - (c) a reasoned statement affirming that the product complies with Article 4 (1), first indent.
3. Articles 7 to 9 shall apply ~~in a like manner~~ **mutatis mutandis**.
4. Where, for reasons beyond the control of the authorisation holder, no decision is taken on the renewal of an authorisation **until one month** before its expiry date, the period of authorisation of the product shall automatically be extended **by 6 months** ~~until the Commission takes a decision~~. The Commission shall inform the authorisation holder **and the Member States** about the delay.

Article 13
Traceability

1. At the first stage of the placing on the market of an authorised primary **smoke condensate or primary tar fraction product** or smoke flavouring derived from the authorised products specified in the list referred to in Article 6 (1), food business operators shall ensure that the following information is transmitted to the food business operator receiving the product:
 - (a) the code of the authorised product as given in the list referred to in Article 6 (1);
 - (b) the conditions of use of the authorised product as set out in the list referred to in Article 6 (1);
 - (c) in the case of a derived smoke flavouring, the quantitative relation to the primary product; this shall be expressed in clear and easily understandable terms so that the receiving food business operator can use the derived smoke flavouring in compliance with the conditions of use set out in the list referred to in Article 6 (1).

2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, food business operators shall ensure that the information received in accordance with paragraph 1 is transmitted to the food business operators receiving the products.
3. Food business operators shall have in place systems and procedures in accordance to which it is possible to identify the person from whom and to whom the products mentioned in paragraph 1 have been made available.
4. Paragraphs 1 to 3 are without prejudice to other specific requirements under Community legislation.

Article 14
Public access

- 1. The application for authorisation, supplementary information from the 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.**
- 2. 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.**
- 3. Member States shall handle applications for access to documents received under this regulation in accordance with Article 5 of Regulation (EC) No 1049/2001.**

Article 15
Confidentiality

1. The applicant may indicate which information submitted under Article 7 should be treated as confidential because disclosure may significantly harm his competitive position. Verifiable justification must be given in such cases.
2. Without prejudice to paragraph 3, the ~~Authority~~ **Commission** shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant **and the Authority** of its decision.
3. Without prejudice to Article 39 (3) of Regulation (EC) No 178/2002, information relating to the following shall not be considered confidential:
 - (a) the name and address of the applicant and the name of the product;
 - (b) in the case of an opinion in favour of authorising the evaluated product, the particulars mentioned in Article 6 (2);
 - (c) information of direct relevance to the assessment of the safety of the product;
 - (d) the analytical method referred to in Annex II (4).**

4. Notwithstanding paragraph 2, the Authority shall on request supply the Commission and the Member States with all information in its possession.
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 the present Regulation except for information which must be made public if circumstances so require**~~keep confidential all the information identified as confidential under paragraph 2, except in cases where certain information must be made public~~ in order to protect human health.
6. If an applicant withdraws or has withdrawn an application, the Authority, the Commission and the Member States shall respect the confidentiality of the commercial and industrial information provided, including research and development information as well as information on which the ~~Authority~~ **Commission** and the applicant disagree as to its confidentiality.

Article 16
Data protection

The information in the application submitted according to Article 7 may not be used for the benefit of another applicant, unless the other applicant has agreed with the authorisation holder that such information may be used.

Article 17
Inspection and control measures

1. Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation.
2. Where necessary and on the request of the Commission, the Authority shall assist in developing technical guidance on sampling and testing to facilitate a co-ordinated approach for the implementation of paragraph 1.
3. If necessary, the Commission shall, after having requested scientific and technical assistance from the Authority, adopt quality criteria for validated analytical methods proposed in accordance with point 4 of Annex ~~III~~, including substances to be measured, in accordance with the procedure referred to in Article ~~18~~**19** (2).

Article 18
Amendments

Amendments to the Annexes to this Regulation and to the list referred to in Article 6 (1) shall be adopted in accordance with the procedure referred to in Article ~~18~~**19** (2), after having consulted the Authority for scientific and/or technical assistance.

Article 19
Implementing powers of the Commission

1. The Commission shall be assisted by the Committee referred to in Article 58 (1) of Regulation (EC) No 178/2002.

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 and Article 8 thereof.
3. The period provided for in Article 5 (6) of Decision 1999/468/EC shall be three months.

Article 20
Transitional measures

Without prejudice to Article 4 (2), trade in and use of the following primary products and derived smoke flavourings, as well as foods containing any of those products, already on the market on the date of entry into force of this Regulation, shall be permitted for the following periods:

- (a) primary products for which a valid application is submitted in accordance with Article 7 and Article 8 (3) before [*18 months after the date of entry into force of this Regulation*] and derived smoke flavourings: until the establishment of the list referred to in Article 10 (1);
- (b) foods containing primary products for which a valid application is submitted in accordance with Article 7 and Article 8 (3) before [*18 months after the date of entry into force of this Regulation*] and/or containing derived smoke flavourings: until 12 months after the establishment of the list referred to in Article 10 (1);
- (c) foods containing primary products for which a valid application is not submitted in accordance with Article 7 and Article 8 (3) before [*18 months from the date of entry into force of this Regulation*] and/or derived smoke flavourings: until [*30 months after the date of entry into force of this Regulation*];

Products and f Foods that have been lawfully **put-placed** on the market before the end of the periods referred to in ~~(ba)~~ **to-and** (c) may be marketed until stocks are exhausted.

Article 21
Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European ~~Communities~~ Union*.

Article 4 (2) shall apply from [*18 months from the date of entry into force of this Regulation*]. Until this date, national provisions in force concerning smoke flavourings and their use in and on foods continue to apply in the Member States.

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

ANNEX I

List of untreated wood which may be used for the production of primary smoke condensates or primary tar fractions

Latin name	Common name
Acer negundo L.	Maple tree
Betula pendula Roth. (with ssp. B. alba L. and B. verrucosa Ehrh.)	White birch
Betula pubescens Ehrh.	European birch
Carpinus betulus L.	Hornbeam
Carya ovata (Mill.) Koch	Hickory
Castanea sativa Mill.	Chestnut tree
Eucalyptus sp.	Eucalyptus
Fagus grandifolia Ehrh.	Beech
Fagus silvatica L.	Beech
Fraxinus excelsior L.	Common ash
Juglans regia L.	Walnut tree
Malus pumila Mill.	Apple
Prosopis juliflora DC.	Mesquite wood
Prunus avium L.	Cherry tree
Quercus alba L.	White oak
Quercus ilex L.	Holm oak
Quercus robur L.	Common red oak
Rhamnus frangula L.	Alder Buckthorn
Robinia pseudoacacia	Black locust
Ulmus fulva Michx.	Sweet elm
Ulmus rubra Mühlenb.	Elm

ANNEX II

Conditions for the production of primary smoke condensates and primary tar fractions/products

1. Smoke is generated from wood ~~species listed in Annex I~~ as referred to in Article 5 (1). 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.
2. The smoke is condensed. Water and/or, without prejudice to other Community legislation, solvents may be added to achieve phase separation. Physical processes may be used for isolation, fractionation and/or purification to obtain the following phases:
 - (a) a water-based “primary smoke condensate” mainly containing carboxylic acids, carbonylic and phenolic compounds, having a maximum content of
 - ~~benzo[a]pyrene~~3,4 benzopyrene 10 µg / kg
 - ~~1,2-benz[a]anthracene~~ 20 µg / kg
 - (b) a water insoluble high density tar phase which during the phase separation will precipitate, and which cannot be used as such for the production of smoke flavourings but only after appropriate physical processing to obtain fractions from this water insoluble tar phase which are low in polycyclic aromatic hydrocarbons, already defined as “primary tar fractions”, having a maximum content of
 - ~~3,4 benzopyrene~~benzo[a]pyrene 10 µg / kg
 - ~~1,2-benz[a]anthracene~~ 20 µg / kg
 - (c) a “water insoluble oily phase”.

If no phase separation has occurred during or after the condensation, the smoke condensate obtained must be regarded as a water insoluble high density tar phase, and must be processed by appropriate physical processing to obtain primary tar fractions which stay within the specified limits.

ANNEX III

Information necessary for the scientific evaluation of primary ~~smoke condensates and primary tar fractions~~ products

The information should be compiled in accordance with the guidelines referred to in Article 7 (4) and should be submitted as described therein. Without prejudice to Article 8 (2), the following information should be included in the application for authorisation referred to in Article 7:

1. The type of wood used for the production of the primary product.
2. Detailed information on the production methods of the primary ~~smoke condensates or primary tar fractions~~ products and the further processing in the production of derived smoke flavourings.
3. The qualitative and quantitative chemical composition of the primary product and the characterisation of the portion which has not been identified. Of major importance are the chemical specifications of the primary product and information on the stability and the degree of variability of the chemical composition. The portions which have not been identified, i.e. the amount of substances whose chemical structure is not known, should be as small as possible and should be characterised by appropriate ~~validated~~—analytical methods, e.g. chromatographic ~~or~~ physico-chemical methods.
4. A validated analytical method(s) for sampling, identification and characterisation of the primary product ~~and of derived smoke flavourings~~.
5. Information on the intended use levels in or on specific food or food categories.
6. Toxicological data following the advice of the Scientific Committee on Food given in its report on smoke flavourings of 25 June 1993 or its latest update.