Proposal for a European Parliament and Council Regulation on smoke flavourings used or intended for use in or on foods

(2002/C 262 E/38)

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(Submitted by the Commission on 15 July 2002)

EXPLANATORY MEMORANDUM

Smoke flavourings fall within the scope of Council Directive 88/388/EEC on flavourings. Article 5 of this Directive 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. As part of the framework to improve Community legislation in the area of foods, the Commission announced in the White Paper on Food Safety a proposal for a European Parliament and Council Regulation on smoke flavourings used or intended for use in or on foods.

The current situation in the Member States concerning the authorisation of smoke flavourings is diverse. Some Member States have a very strict authorisation procedure, others have none at all. Thus, there is a need for harmonisation at Community level.

The objective of the present proposal is 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.

Smoke flavourings are produced from condensed smoke. The chemical composition of smoke is complex depending among other things on the species 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. The condensed smoke is however fractionated and purified during the production of smoke flavourings. Because of this purification process, the use of smoke flavourings is generally considered to be of less health concern than the traditional smoking process.

A wide range of different smoke flavourings is produced from the purified primary smoke condensates. The Scientific Committee on Food (SCF) concluded in its report of 25 June 1993 that the existing multitude of smoke flavourings is based on only a limited number of commercially available smoke condensates and that, therefore, the toxicological evaluation should focus on the limited number of individual smoke condensates rather than on the multitude of derived smoke flavourings.

The present draft proposes to establish a safety assessment and authorisation procedure for primary smoke condensates and primary tar fractions which can be used as such in and on foods and/or for the production of derived smoke flavourings. The primary products for which no health concern is revealed during evaluation and their conditions of use will be included in a positive list of products authorised to the exclusion of all others in the Community.

Smoke flavourings for the Community market are produced by few companies inside and outside of the EU. Each of these companies has a very limited number of primary products. It is estimated that not more than 20 products need to be evaluated.

It is proposed to restrict the authorisations to a period of ten years after which the authorisations will need to be renewed. This provision ensures that products are regularly re-evaluated according to the latest scientific and technical knowledge and ensures also that authorised products which are no longer used will disappear from the Community positive list.

For an application for authorisation of a primary product, detailed information on the production method of this product as well as on the further steps in the production of derived smoke flavourings, the intended uses in or on specific food or food categories, chemical specifications, toxicological studies and validated methods for sampling and detection of the primary product and derived smoke flavourings have to be provided by the applicant. The evaluation will be done by the European Food Safety Authority according

to a defined time limited and transparent procedure. The Authority has to inform the Commission and the Member States about the receipt of an application and has to provide a summary thereof or the whole dossier. Confidentiality for sensitive data is provided if requested by the applicant, except for information of direct relevance to the assessment of the safety of the product.

After the European Food Safety Authority has completed its scientific evaluation, the Commission will propose a risk management decision to be adopted by the regulatory procedure laid down by Council Decision 1999/468/EC.

Since many smoke flavourings are already on the market in the Community, the transition to a Community positive list should be smooth and should not lead to unfair conditions for smoke flavouring producers. Therefore, the proposal foresees an initial period of eighteen months during which applications for existing and new products can be submitted to the European Food Safety Authority. The establishment of the Community list will take place in a single step procedure after the European Food Safety Authority has expressed opinions on all products for which applications have been submitted during the 18-month period. This procedure will ensure that all companies are subject to the same conditions. After the initial establishment new products may be added following evaluation by the European Food Safety Authority.

The Scientific Committee on Food in its report on smoke flavourings of 25 June 1993, provided a non-exhaustive list of types of wood which may be used for the production of smoke flavourings. This list is annexed to the present Regulation. Additional species of wood, not present in the list, may be included after primary products produced from those species have received a favourable opinion from the European Food Safety Authority.

This Proposal intends to ensure a high level of protection of human health and the protection of consumers' interests with respect to smoke flavourings intended for use in or on foods and to ensure market unity while abiding by the principle of proportionality.

This Proposal has no financial implications for the budget of the European Community.

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 Commission,

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

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 production [1], 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.

(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.

[1] OJ L 184, 15.7.1988, p. 61.

(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, 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 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 1993 [1], 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' [2].

(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 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 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 safety [3].

(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 and should propose validated methods of sampling and detection 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 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 to be added thereto by decision of the Commission, following the safety assessment by the Authority.

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[1] Reports of the Scientific Committee for Food, Thirty-fourth series, pp. 1-7.

[2] Council of Europe Publishing, 1992, reprinted 1998, ISBN 92-871-2189-3.

[3] OJ L 31, 1.2.2002, p. 1.

(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.

(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 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.

(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 Commission [1], 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.

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 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.

2. 'primary products' shall refer to primary smoke condensates and primary tar fractions.

3. 'derived smoke flavourings' shall refer to flavourings produced as a result of the further processing of primary smoke condensates and primary tar fractions 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.

[1] OJ L 184, 17.7.1999, p. 23.

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 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.

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 potentially toxic substances during combustion.

The person who places on the market primary 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.

3. The conditions for the production of primary smoke condensates and primary tar fractions are laid down in Annex II. The water insoluble oily phase which is a by-product of the process shall not be used for the production of smoke flavourings.

4. Without prejudice to other Community legislation, primary smoke condensates and primary tar fractions 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 18(2).

Article 6

Community list of authorised products

1. A list of the primary smoke condensates and primary tar fractions 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 18(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 may be added to that list in accordance with the procedure referred to in Article 18(2).

Article 7

Application for authorisation

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;

— 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' ([1]).

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 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 six 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;

([1]) 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

(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;

(c) 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 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 is appropriate for the intended control purposes.

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.

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(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, 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 eighteen 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 18(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, 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 opinion 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 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 final decision on the modification, suspension or revocation of the authorisation shall be adopted in accordance with the procedure referred to in Article 18(2).

6. The Commission shall without delay inform the authorisation holder of the decision taken.

Article 12

Renewal of authorisations

1. Authorisations under this Regulation shall be renewable for ten-year periods on application to the Authority by the authorisation holder, at the latest eighteen 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 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 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.

4. Articles 7 to 9 shall apply in a like manner.

5. Where, for reasons beyond the control of the authorisation holder, no decision is taken on the renewal of an authorisation before its expiry date, the period of authorisation of the product shall automatically be extended until the Commission takes a decision. The Commission shall inform the authorisation holder 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 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

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 shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant 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.

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 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 and the applicant disagree as to its confidentiality.

Article 15

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 16

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 coordinated 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 3 of Annex III, including substances to be measured, in accordance with the procedure referred to in Article 18(2).

Article 17

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(2), after having consulted the Authority for scientific and/or technical assistance.

Article 18

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 19

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 foods that have been lawfully put on the market before the end of the periods referred to in (a) to (c) may be marketed until stocks are exhausted.

Article 20

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*.

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.

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

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.

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

   3,4 benzopyrene 10 µg/kg

   1,2 benzanthracene 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 10 µg/kg

   1,2 benzanthracene 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

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. Detailed information on the production methods of the primary smoke condensates or primary tar fractions and the further processing in the production of derived smoke flavourings.

2. 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 spectra.

3. Validated analytical method(s) for identification and characterisation of the primary product and of derived smoke flavourings.

4. Information on the intended use levels in or on specific food or food categories.

5. 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.