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Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods

REGULATION (EC) No 2065/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 10 November 2003

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 Commission[(1)],

Having regard to the opinion of the European Economic and Social Committee[(2)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(3)],

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 foodstuffs and to source materials for their production[(4)], 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 concerns, 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

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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) This Regulation covers smoke flavourings as defined in 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 '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 should provide 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 1993[(5)], in which it 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[(6)]. 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 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 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[(7)].

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(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 should also propose a validated method of sampling and detection for the primary products 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 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 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.

(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 necessary that food business operators using primary 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,

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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) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[8],

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

1 The purpose of this Regulation is 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 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;

b 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:

1. smoke flavourings used or intended for use in or on foods;

2. source materials for the production of smoke flavourings;

3. the conditions under which smoke flavourings are prepared;

4. 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.

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The following definitions shall also apply:

1. ‘primary smoke condensate’ 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’;

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 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 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 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 give rise to potentially toxic substances during combustion.

The person who places on the market primary products must be able to demonstrate by appropriate certification or documentation that the requirements laid down in the first subparagraph have been met.

2 The conditions for the production of primary products are laid down in Annex I. 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 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 19(2).