►B 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

(OJ L 309, 26.11.2003, p. 1)

Amended by:

		Official Journal		
		No	page	date
►M1	Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009	L 188	14	18.7.2009
►M2	Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019	L 198	241	25.7.2019

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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.

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';

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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).

Article 6

Community list of authorised primary products

1. A list of the primary 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 19(2).

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2. In respect of each authorised primary product, the list referred to in paragraph 1 shall give a unique code for that product, the name of the product, the name and address of the authorisation holder, a clear description and characterisation of the 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 products may be added to that list in accordance with the procedure referred to in Article 19(2).

Article 7

Application for authorisation

1. To obtain the inclusion of a primary product in the list referred to in Article 6(1), an application shall be submitted in accordance with the following provisions.

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

(b) The 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.

(c) 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.

3. The application shall be accompanied by the following:

(a) the name and address of the applicant;

(b) the information listed in Annex II;

(c) a reasoned statement affirming that the product complies with Article 4(1), first indent;

(d) a summary of the dossier.

4. The Authority shall publish detailed guidance concerning the preparation and the submission of the application [1].

[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

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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 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 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) 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:

(a) any conditions or restrictions which should be attached to the use of the evaluated primary product either as such and/or as derived smoke flavourings in or on specific foods or food categories;

(b) an assessment as to whether the analytical method proposed in accordance with point 4 of Annex II 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 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 primary product 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.

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The measure referred to in the first subparagraph shall be

(a) 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

(b) a draft decision, addressed to the applicant, refusing authorisation.

2. The measure shall be adopted in accordance with the procedure referred to in Article 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 10 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 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 of the authorised primary 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 primary products

1. During the 18 months following the entry into force of this Regulation, business operators shall submit an application in accordance with Article 7 with a view to 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).

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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. On its own initiative or following a request from a Member State or the Commission, the Authority shall deliver 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 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. The final measure, i.e. the modification, suspension or revocation of the authorisation, shall be adopted in accordance with the procedure referred to in Article 19(2).

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

Article 12

Renewal of authorisations

1. Without prejudice to Article 11, authorisations under this Regulation shall be renewable for 10-year periods on application to the Commission by the authorisation holder, at the latest 18 months before the expiry date of the authorisation.

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 II 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 *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 six months. 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 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:

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(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 making it 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 shall be without prejudice to other specific requirements under Community legislation.

Article 14

Public access

1. Applications for authorisation, supplementary information from applicants and opinions from the Authority, excluding confidential information, shall be made accessible to the public in accordance with Articles 38, 39 and 41 of 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 [1] 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 or her competitive position. Verifiable justification must be given in such cases.

2. Without prejudice to paragraph 3, the 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.

[1] OJ L 145, 31.5.2001, p. 43.

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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 point 4 of Annex II.

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 this Regulation except for information which must be made public if circumstances so require 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 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 at 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.

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3. The Commission is empowered to adopt delegated acts in accordance with Article 18a in order to supplement this Regulation by establishing quality criteria for validated analytical methods referred to in point 4 of Annex II, including substances to be measured. Those delegated acts shall take into account available scientific evidence.

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Article 18

Amendments

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1. The Commission is empowered to adopt delegated acts in accordance with Article 18a amending the Annexes following a request to the Authority for scientific and/or technical assistance.

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2. Amendments to the list referred to in Article 6(1) shall be adopted in accordance with the regulatory procedure referred to in Article 19(2) following a request to the Authority for scientific and/or technical assistance.

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Article 18a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 17(3) and Article 18(1) shall be conferred on the Commission for a period of five years from 26 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 17(3) and Article 18(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([1]).

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 17(3) and Article 18(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

([1]) OJ L 123, 12.5.2016, p. 1.

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Article 19

Committee procedure

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, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

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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 16 June 2005 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 16 June 2005 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 16 June 2005 and/or derived smoke flavourings: until 16 June 2006.

Foods that have been lawfully placed on the market before the end of the periods referred to in (b) 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 Union*.

Article 4(2) shall apply from 16 June 2005. 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.

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ANNEX I

Conditions for the production of primary products

1. Smoke is generated from the wood 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	10 µg/kg
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:

benzo[a]pyrene	10 µg/kg
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.

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ANNEX II

Information necessary for the scientific evaluation of primary 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 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 analytical methods, e.g. chromatographic or spectrometric methods;
4. a validated analytical method for sampling, identification and characterisation of the primary product;
5. information on the intended use levels in or on specific foods 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.