

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

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EUROPEAN PARLIAMENT AND OF THE COUNCIL

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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 ^{F1}... 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 ^{F2}... 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;
- [^{F3}b a procedure for the establishment of a list of authorised primary smoke condensates and primary tar fractions and their conditions of use in or on foods.]

Textual Amendments

- F1** Word in Art. 1(1) omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **11(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Word in Art. 1(2)(a) omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **11(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Art. 1(2)(b) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **11(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

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;

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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’;
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.
5. [^{F4}“Authority” means—
 - (a) as regards England and Wales, the Food Standards Agency;
 - (b) as regards Scotland, Food Standards Scotland
6. “prescribe”, means prescribe by regulations;
7. “appropriate authority” means—
 - (a) in relation to England, the Secretary of State;
 - (b) in relation to Wales, the Welsh Ministers;
 - (c) in relation to Scotland, the Scottish Ministers;
8. “Regulation 1321/2013” means Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings;]

Textual Amendments

- F4** Art. 3(5)-(8) inserted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/860), regs. 1, **12** (as amended by [S.I. 2020/1504](#), regs. 1(2), **18(3)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

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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 [^{F5}retained EU law], primary products may be further processed by appropriate physical processes for the production of derived smoke flavourings.
_{F6} ...

Textual Amendments

- F5** Words in Art. 5(3) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **13(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 5(3) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **13(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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Article 6

^{F7} ... List of authorised primary products

1 A list of the primary products authorised to the exclusion of all others ^{F8}... for use as such in or on foods and/or for the production of derived smoke flavourings shall be established ^{F9}....

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.

[^{F10}3 Following the establishment of the list referred to in paragraph 1, the appropriate authority may prescribe the addition of primary products to that list.]

Textual Amendments

- F7** Word in Art. 6 heading omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **14**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 6(1) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **15(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Words in Art. 6(1) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **15(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Art. 6(3) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **15(b)**; 2020 c. 1, Sch. 5 para. 1(1)

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 [^{F11}appropriate authority].

[^{F12}b The appropriate authority must acknowledge receipt of the application in writing to the applicant within 14 days of its receipt. The acknowledgement must state the date of receipt of the application;]

[^{F13}c The appropriate authority must inform the Authority of the application without delay and make the application and any supporting information supplied by the applicant available to the Authority.]

3 The application shall be accompanied by the following:

- a the name and address of the applicant;
- b the information listed in Annex II;

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- 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⁽⁹⁾.

Textual Amendments

- F11** Words in Art. 7(2)(a) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **16(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Art. 7(2)(b) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **16(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Art. 7(2)(c) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **16(c)** (as substituted by S.I. 2020/1504, regs. 1(2), **18(4)**); 2020 c. 1, **Sch. 5 para. 1(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 provide an explanation for the delay to the applicant ^{F14}....

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, ^{F15}... 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 [^{F16}appropriate authority] and the applicant.

6 The Authority shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 15.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

Textual Amendments

- F14** Words in Art. 8(1) omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **17(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** Words in Art. 8(3)(b) omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **17(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F16** Words in Art. 8(5) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **17(c)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 9

^{F17}... Authorisation

^{F18}1 Within three months of receiving the opinion of the Authority, the appropriate authority must take the decision whether to include a primary product in the list referred to in Article 6(1), taking account of the opinion of the Authority, the requirements of Article 4(1), any relevant provisions of retained EU law and other legitimate factors relevant to the matter under consideration. The appropriate authority must inform the applicant of its decision without delay. Where the decision is not in accordance with the opinion of the Authority, the appropriate authority must provide an explanation for the differences to the Authority and to the applicant.

2 Where the appropriate authority decides to include a primary product in the list referred to in Article 6(1) it must prescribe the addition of that product to the list together with the details referred to in Article 6(2) and amend Regulation 1321/2013.]

3 Without prejudice to Article 11, the authorisation granted in accordance with the procedure laid down in this Regulation shall be valid ^{F19}... 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 [^{F20}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 of the authorised primary product, derived smoke flavouring or food containing the authorised primary product or derived smoke flavouring.

Textual Amendments

- F17** Word in Art. 9 heading omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **18**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

- F18** Art. 9(1)(2) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **19(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 9(3) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **19(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F20** Word in Art. 9(5) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **19(c)**; 2020 c. 1, Sch. 5 para. 1(1)

^{F21} Article 10

Initial establishment of the Community list of authorised primary products

Textual Amendments

- F21** Art. 10 omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **20**; 2020 c. 1, Sch. 5 para. 1(1)

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 ^{F22}... 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.

[^{F23} The appropriate authority must examine the opinion of the Authority without delay and take the decision whether to modify the entry for that authorisation.]

[^{F24} Where the appropriate authority decides to modify the entry for that authorisation it must prescribe the modification of the entry for that product on the list and amend Regulation 1321/2013.]

^{F25}

6 The [^{F26}Authority] shall without delay inform the authorisation holder of the measure taken.

Textual Amendments

- F22** Words in Art. 11(2) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **21(a)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

- F23** Art. 11(3) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **21(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F24** Art. 11(4) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **21(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F25** Art. 11(5) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **21(d)**; 2020 c. 1, Sch. 5 para. 1(1)
- F26** Word in Art. 11(6) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **21(e)**; 2020 c. 1, Sch. 5 para. 1(1)

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 [^{F27}Authority] 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 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 [^{F28}, or provided to the European Food Safety Authority, if provided before IP completion day] 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 [^{F29}Authority] shall inform the authorisation holder ^{F30}... about the delay.

Textual Amendments

- F27** Word in Art. 12(1) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **22(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F28** Words in Art. 12(2)(b) inserted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **22(b)** (as amended by S.I. 2020/1504, regs. 1(2), **18(5)**); 2020 c. 1, Sch. 5 para. 1(1)
- F29** Word in Art. 12(4) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **22(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F30** Words in Art. 12(4) omitted (31.12.2020) by virtue of The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **22(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

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:

- 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 ^{F31}retained EU law].

Textual Amendments

F31 Words in Art. 13(4) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **23**; 2020 c. 1, Sch. 5 para. 1(1)

^{F32}Article 14

Public access

Textual Amendments

F32 Art. 14 omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **24**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

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 [F³³Authority] shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant F³⁴... 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 point 4 of Annex II.

4 Notwithstanding paragraph 2, the Authority shall on request supply the [F³⁵appropriate authority] with all information in its possession.

5 The [F³⁶appropriate authority and the Authority] 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, [F³⁷and the appropriate authority] shall respect the confidentiality of the commercial and industrial information provided, including research and development information as well as information on which the [F³⁸Authority] and the applicant disagree as to its confidentiality.

Textual Amendments

- F33** Word in Art. 15(2) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **25(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F34** Words in Art. 15(2) omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **25(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F35** Words in Art. 15(4) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **25(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F36** Words in Art. 15(5) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **25(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F37** Words in Art. 15(6) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **25(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

F38 Word in Art. 15(6) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **25(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

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 [F39The Authority] 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 [F40appropriate authority], the Authority shall assist in developing technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1.

[F413 The appropriate authority may, taking account of available scientific evidence, supplement this Regulation by prescribing quality criteria for validated analytical methods referred to in point 4 of Annex 2, including substances to be measured.]

Textual Amendments

- F39** Words in Art. 17(1) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **26(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F40** Words in Art. 17(2) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **26(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F41** Art. 17(3) substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, **26(c)** (as substituted by S.I. 2020/1504, regs. 1(2), **18(6)**); 2020 c. 1, Sch. 5 para. 1(1)

[F42 Article 18

Amendments

The appropriate authority may, following a request to the Authority for scientific and/or technical assistance, prescribe amendments to—

- a the Annexes; and
- b the list referred to in Article 6(1).]

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

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Textual Amendments

F42 Art. 18 substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **27** (as substituted by [S.I. 2020/1504](#), regs. 1(2), **18(7)**); ; 2020 c. 1, **Sch. 5 para. 1(1)**

^{F43}Article 18a

Exercise of the delegation

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Textual Amendments

F43 Art. 18a omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **28** (as substituted by [S.I. 2020/1504](#), regs. 1(2), **18(8)**); 2020 c. 1, **Sch. 5 para. 1(1)**

^{F44}Article 19

Committee procedure

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Textual Amendments

F44 Art. 19 omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **28** (as substituted by [S.I. 2020/1504](#), regs. 1(2), **18(8)**); 2020 c. 1, **Sch. 5 para. 1(1)**

^{F45}Article 19A

Regulations and devolved powers

- 1 Any power to make regulations under this Regulation—
 - a so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
 - b so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
- 2 Any power to make regulations under this Regulation includes power—
 - a to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business);
 - b to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
- 3 Any statutory instrument or Scottish statutory instrument containing regulations under this Regulation is subject to annulment in pursuance of a resolution—
 - a in the case of England, of either House of Parliament;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

- b in the case of Wales, of Senedd Cymru;
 - c in the case of Scotland, of the Scottish Parliament;
- 4 In this Regulation, any power—
- a of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
 - b of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
 - c of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;]

Textual Amendments

F45 Art. 19A inserted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **29** (as amended by [S.I. 2020/1504](#), regs. 1(2), **18(9)**); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

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.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

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Textual Amendments

F46 Words in [Signature](#) omitted (31.12.2020) by virtue of [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **30**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

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 [^{F47}retained EU law]. 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.

Textual Amendments

F47 Words in [Annex 1 para. 1](#) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **31**; 2020 c. 1, Sch. 5 para. 1(1)

2. The smoke is condensed. Water and/or, without prejudice to other [^{F48}retained EU law], solvents may be added to achieve phase separation. Physical processes may be used for isolation, fractionation and/or purification to obtain the following phases:

Textual Amendments

F48 Words in [Annex 1 para. 2](#) substituted (31.12.2020) by [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/860\)](#), regs. 1, **32**; 2020 c. 1, Sch. 5 para. 1(1)

- (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’.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

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 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 [F⁴⁹ Authority].

Textual Amendments

F49 Word in Annex 2 point 6 substituted (31.12.2020) by The Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860), regs. 1, 33; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council. (See end of Document for details)

- (1) OJ C 262 E, 29.10.2002, p. 523.
- (2) OJ C 85, 8.4.2003, p. 32.
- (3) Opinion of the European Parliament of 5 June 2003 (not yet published in the Official Journal) and the Council Decision of 9 October 2003.
- (4) OJ L 184, 15.7.1988, p. 61; Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).
- (5) Reports of the Scientific Committee for Food, 34th series, pp. 1 to 7.
- (6) Council of Europe Publishing, 1992, reprinted 1998, ISBN 92-871-2189-3.
- (7) OJ L 31, 1.2.2002, p. 1.
- (8) OJ L 184, 17.7.1999, p. 23.
- (9) 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

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EC) No 2065/2003 of the European Parliament and of the Council.