

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 2065/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

## 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 [F1retained 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**

- F1** 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 [F2retained 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**

- F2** 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’.

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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 [F<sup>3</sup>Authority].

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#### Textual Amendments

- F3** 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)

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#### Changes and effects yet to be applied to :

- Regulation applied (with modifications) by [S.I. 2023/959 reg. 4\(a\)Sch. 1](#)
- Art. 17(3) words substituted by [S.I. 2019/860 reg. 26\(c\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 26(c) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 18(6))
- Art. 17(3) words substituted by [S.I. 2019/860 reg. 26\(c\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 26(c) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 18(6))
- Art. 18(1) word substituted by [S.I. 2019/860 reg. 27\(a\)\(ii\)](#) (This amendment not applied to legislation.gov.uk. Reg. 27 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 18(7))
- Art. 18(1) words substituted by [S.I. 2019/860 reg. 27\(a\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Reg. 27 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 18(7))
- Art. 18(2) word substituted by [S.I. 2019/860 reg. 27\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 27 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 18(7))
- Art. 19 omitted by [S.I. 2019/860 reg. 28](#) (This amendment not applied to legislation.gov.uk. Reg. 28 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 18(8))

#### Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 3(5)(b) word substituted by [S.I. 2019/1013 reg. 34](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))
- Art. 7(2)(c) inserted by [S.I. 2019/1013 reg. 35](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))
- Art. 7(2)(c) omitted by [S.I. 2019/860 reg. 16\(c\)](#) (This amendment not applied to legislation.gov.uk. Reg. 16(c) substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 18(4))
- Art. 19A(3)(d) words substituted by [S.I. 2019/1013 reg. 36](#) (This amendment not applied to legislation.gov.uk. S.I. 2019/1013 revoked immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 21(e))