
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 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 [F¹Authority].

Textual Amendments

- F1** 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](#)

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))