

Regulation (EC) No 1331/2008 of the European Parliament and of the Council  
of 16 December 2008 establishing a common authorisation procedure for  
food additives, food enzymes and food flavourings (Text with EEA relevance)

CHAPTER III

MISCELLANEOUS PROVISIONS

*Article 12*

**Confidentiality**

1 Among the information provided by applicants, confidential treatment may be given to information the disclosure of which might significantly harm their competitive position.

Information relating to the following shall not, in any circumstances, be regarded as confidential:

- a the name and address of the applicant;
- b the name and a clear description of the substance;
- c the justification for the use of the substance in or on specific foodstuffs or food categories;
- d information that is relevant to the assessment of the safety of the substance;
- e where applicable, the analysis method(s).

2 For the purposes of implementing paragraph 1, applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.

3 The Commission shall decide after consulting with the applicants which information can remain confidential and shall notify applicants and the Member States accordingly.

4 After being made aware of the Commission's position, applicants shall have three weeks in which to withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality shall be preserved until this period expires.

5 The Commission, the Authority and the Member States shall, in accordance with Regulation (EC) No 1049/2001, 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, animal health or the environment.

6 If an applicant withdraws, or has withdrawn, its application, the Commission, the Authority and the Member States shall not disclose confidential information, including information the confidentiality of which is the subject of disagreement between the Commission and the applicant.

7 The implementation of paragraphs 1 to 6 shall not affect the circulation of information between the Commission, the Authority and the Member States.

**Changes to legislation:**

There are outstanding changes not yet made to Regulation (EC) No 1331/2008 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.

[View outstanding changes](#)

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

- Regulation applied (with modifications) by [S.I. 2023/959 reg. 4\(a\)Sch. 1](#)
- Art. 12(3) word substituted by [S.I. 2019/860 reg. 50\(a\)\(i\)](#)
- Art. 12(3) words omitted by [S.I. 2019/860 reg. 50\(a\)\(ii\)](#)
- Art. 12(4) word substituted by [S.I. 2019/860 reg. 50\(b\)](#)
- Art. 12(5) omitted by [S.I. 2019/860 reg. 50\(c\)](#)
- Art. 12(6) word substituted by [S.I. 2019/860 reg. 50\(d\)\(ii\)](#)
- Art. 12(6) words substituted by [S.I. 2019/860 reg. 50\(d\)\(i\)](#)
- Art. 12(7) words substituted by [S.I. 2019/860 reg. 50\(e\)](#)

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

- Signature words omitted by [S.I. 2019/860 reg. 54](#)
- Art. 2(3)-(7) added by [S.I. 2019/860 reg. 39\(c\)](#)
- Art. 2(3) words substituted in earlier amending provision [S.I. 2019/860, reg. 39\(c\)](#) by [S.I. 2020/1504 reg. 18\(10\)\(a\)](#)
- Art. 2(5) words omitted in earlier amending provision [S.I. 2019/860, reg. 39\(c\)](#) by [S.I. 2020/1504 reg. 18\(10\)\(b\)](#)
- Art. 2(7) omitted in earlier amending provision [S.I. 2019/860, reg. 39\(c\)](#) by [S.I. 2020/1504 reg. 18\(10\)\(c\)](#)
- Art. 14A inserted by [S.I. 2019/860 reg. 52](#)
- Art. 14A(1)(c) omitted in earlier amending provision [S.I. 2019/860, reg. 52](#) by [S.I. 2020/1504 reg. 18\(11\)\(a\)](#)
- Art. 14A(3) words substituted in earlier amending provision [S.I. 2019/860, reg. 52](#) by [S.I. 2020/1504 reg. 18\(11\)\(b\)\(i\)](#)
- Art. 14A(3)(b) words substituted in earlier amending provision [S.I. 2019/869, reg. 52](#) by [S.I. 2020/1504 reg. 18\(11\)\(b\)\(ii\)](#)
- Art. 14A(3)(d) omitted in earlier amending provision [S.I. 2019/860, reg. 52](#) by [S.I. 2020/1504 reg. 18\(11\)\(b\)\(iii\)](#)
- Art. 14A(3)(d) words substituted by [S.I. 2019/1013 reg. 75](#) (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. 14A(4)(d) omitted in earlier amending provision [S.I. 2019/860, reg. 52](#) by [S.I. 2020/1504 reg. 18\(11\)\(c\)](#)