Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 on the procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (Text with EEA relevance)

### Article 9

### Confidentiality

- Food business operators may request the recipient Member State to agree that the disclosure of certain information submitted as part of the consultation request needs to benefit from confidential treatment where disclosure of such information may harm their competitive position.
- 2 For the purpose of paragraph 1, food business operators shall indicate to the recipient Member State the parts of the information provided that they wish to be treated as confidential and provide all the necessary details to substantiate their request for confidentiality.
- 3 The recipient Member State shall inform the food business operator of its views on which parts of the information are to remain confidential.

However, confidentiality shall not apply to the following information:

- a the name and address of the applicant;
- b the name and description of the food;
- c a summary of the studies submitted by the applicant;
- d where appropriate, the analysis method(s).
- 4 In case of the consultation of other Member States pursuant to Article 6(2), second subparagraph, the recipient Member State shall inform the Commission and the Member States about its views on confidentiality of the consultation request.
- 5 After being informed pursuant to paragraph 3, the food business operator may withdraw its consultation request within 3 weeks during which the confidentiality of the information provided shall be observed.
- The Commission and the Member States shall take necessary measures to ensure appropriate confidentiality of the information referred to in paragraphs 3 and received by them under this Regulation, except for information which is required to be made public in order to protect human health.
- Where a food business operator withdraws or has withdrawn its consultation request in accordance with paragraph 5, neither the Commission nor the Member States shall disclose information for which confidentiality was requested by the food business operator pursuant to paragraph 1.
- 8 The application of paragraphs 1 to 7 shall not affect the exchange of information between the Commission and the Member States necessary to consider the consultation requests submitted under this Regulation.

## **Changes to legislation:**

There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/456. 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:

- Art. 9 words substituted by S.I. 2019/702 reg. 73(a)
- Art. 9(4) omitted by S.I. 2019/702 reg. 73(b)
- Art. 9(6) word substituted by S.I. 2019/702 reg. 73(c)(ii)
- Art. 9(6) words substituted by S.I. 2019/702 reg. 73(c)(i)
- Art. 9(7) words substituted by S.I. 2019/702 reg. 73(d)
- Art. 9(8) words substituted by S.I. 2019/702 reg. 73(e)

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

- Signature words omitted by S.I. 2019/702 reg. 74
- Art. 2(a) words omitted by S.I. 2019/702 reg. 66(a)
- Art. 2(b) omitted by S.I. 2019/702 reg. 66(b)