
STATUTORY INSTRUMENTS

2019 No. 702

The Novel Food (Amendment) (EU Exit) Regulations 2019

PART 3

Amendment of retained direct EU legislation

Amendment of Regulation 2015/2283

29. For Article 23, substitute—

“Confidentiality of applications for updates of the list

1. Applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such information may harm their competitive position.

2. For the purposes of paragraph 1, applicants must indicate which parts of the information provided they wish to be treated as confidential and provide all the necessary details to substantiate their request for confidentiality. Verifiable justification must be given in such cases.

3. After being informed of the appropriate authority’s position on the request, applicants may withdraw their application within three weeks, during which the confidentiality of the information provided must be observed.

4. After expiry of the period referred to in paragraph 3, if an applicant has not withdrawn the application and in case of disagreement the appropriate authority must decide which parts of the information are to remain confidential and notify the applicant accordingly. However, the following information is not confidential—

- (a) the name and address of the applicant;
- (b) the name and description of the novel food;
- (c) the proposed conditions of use of the novel food;
- (d) a summary of the studies submitted by the applicant;
- (e) the results of the studies carried out to demonstrate the safety of the food;
- (f) where appropriate, the analysis method;
- (g) any prohibition or restriction imposed in respect of the food by a third country.

5. The appropriate authority and the Food Safety Authority must take necessary measures to ensure appropriate confidentiality of the information as referred to in paragraph 4 and received by them under this Regulation, except for information which is required to be made public in order to protect human health.

6. Where an applicant withdraws, or has withdrawn, its application, the appropriate authority and the Food Safety Authority must not disclose confidential information, including the information whose confidentiality is the subject of disagreement between the appropriate authority and the applicant.

7. The application of paragraphs 1 to 6 does not restrict the exchange of information concerning the application between the appropriate authority and the Food Safety Authority.

8. The appropriate authority may prescribe rules for the implementation of paragraphs 1 to 6.”