

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Text with EEA relevance)

## CHAPTER IV

### ADDITIONAL PROCEDURAL RULES AND OTHER REQUIREMENTS

#### *[<sup>F1</sup> Article 21*

#### **Additional information concerning risk management**

1 Where the appropriate authority requests from an applicant additional information on matters concerning risk management, the appropriate authority must determine, together with the applicant, the period within which that information is to be provided. In such cases, the period provided for in Article 12(1) or (2) or in Article 18(1) may be extended accordingly.

2 Where the additional information referred to in paragraph 1 is not received within the additional period referred to in that paragraph, the appropriate authority must act on the basis of the available information.]

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#### **Textual Amendments**

**F1** Art. 21 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **27**; 2020 c. 1, Sch. 5 para. 1(1)

#### *[<sup>F2</sup> Article 22*

#### **Extension of time periods**

In exceptional circumstances, the appropriate authority may extend the time periods provided for in Articles 11(1), 12(1) or (2), 17(1) and 18(1) on its own initiative or, where applicable, at the Food Safety Authority's request, where the nature of the matter in question justifies an appropriate extension.]

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#### **Textual Amendments**

**F2** Art. 22 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **28**; 2020 c. 1, Sch. 5 para. 1(1)

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*Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2015/2283 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*

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### [<sup>F3</sup> Article 23

#### **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.]

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#### **Textual Amendments**

- F3** [Art. 23](#) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **29**; 2020 c. 1, Sch. 5 para. 1(1)

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## Article 24

### Post-market monitoring requirements

The [<sup>F4</sup>appropriate authority] may, for food safety reasons and taking into account the opinion of the Authority, impose post-market monitoring requirements. Such requirements may include, on a case-by-case basis, the identification of the relevant food business operators.

#### Textual Amendments

- F4** Words in [Art. 24](#) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **30**; 2020 c. 1, Sch. 5 para. 1(1)

## [<sup>F5</sup>Article 25

### Additional information requirements

Any food business operator which has placed a novel food on the market must immediately inform the Food Safety Authority of any information of which it has become aware concerning—

- (a) any new scientific or technical information which might influence the evaluation of the safety of use of the novel food;
- (b) any prohibition or restriction imposed by a third country in which the novel food is placed on the market.]

#### Textual Amendments

- F5** [Art. 25](#) substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **31**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:**

There are outstanding changes not yet made to Regulation (EU) 2015/2283 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.

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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. 32A(4)(d) words substituted by [S.I. 2019/1013 reg. 101](#) (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))