

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 III

AUTHORISATION PROCEDURES FOR A NOVEL FOOD

SECTION I

General rules

[^{F1}Article 10

Procedure for authorising the placing on the market of a novel food and updating the list

1 The procedure for authorising the placing on the market within Great Britain of a novel food and updating the list provided for in Article 9 must start either on the initiative of the appropriate authority or following an application to the appropriate authority by an applicant. The appropriate authority must make the summary of the application, based on the information referred to in points (a), (b) and (e) of paragraph 2 of this Article, publicly available.

2 The application for an authorisation must include—

- a the name and address of the applicant;
- b the name and description of the novel food;
- c the description of the production process;
- d the detailed composition of the novel food;
- e scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
- f where appropriate, the analysis method;
- g a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.

3 Upon request by the appropriate authority, the Food Safety Authority must give its opinion as to whether the update is liable to have an effect on human health.

4 When test methods are applied to engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2), an explanation must be provided by the applicants of their scientific appropriateness for nanomaterials and, where applicable, of the technical adaptations or adjustments that have been made in order to respond to the specific characteristics of those materials.

5 The procedure for authorising the placing on the market within Great Britain of a novel food and updating the list as provided for in Article 9 ends when the appropriate authority prescribes an update of the list in respect of that novel food in accordance with Article 12.

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

6 By way of derogation from paragraph 5, the appropriate authority may terminate the procedure at any stage, and decide not to proceed with an update of the list where the appropriate authority considers that an update is not justified.

7 The applicant may withdraw its application at any time, thereby terminating the procedure.]

Textual Amendments

F1 Art. 10 substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, 16 (as amended by S.I. 2020/1504, regs. 1(2), 15(5)); 2020 c. 1, Sch. 5 para. 1(I)

[^{F2}Article 11

Opinion of the Food Safety Authority

1 Where the appropriate authority requests an opinion from the Food Safety Authority, it must forward the valid application to the Food Safety Authority without delay, and not later than one month after having verified its validity. The Food Safety Authority must adopt its opinion within nine months from the date of receipt of a valid application.

2 In assessing the safety of novel foods, the Food Safety Authority must, where appropriate, consider whether—

- a the novel food concerned is as safe as food from a comparable food category already placed on the market within Great Britain;
- b the composition of the novel food and the conditions of its use do not pose a safety risk to human health in Great Britain;
- c a novel food, which is intended to replace another food, does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

3 The Food Safety Authority must forward its opinion to the appropriate authority and, where applicable, to the applicant.

4 In duly justified cases, where the Food Safety Authority requests additional information from the applicant, the nine month period provided for in paragraph 1 may be extended. After consulting the applicant, the Food Safety Authority must specify a period within which that additional information is to be provided.

5 Where the additional information referred to in paragraph 4 is not provided to the Food Safety Authority within the additional period referred to in that paragraph, the Food Safety Authority must draw up its opinion on the basis of the available information.

6 Where an applicant submits additional information on its own initiative, it must send that information to the Food Safety Authority. In such cases, the Food Safety Authority must give its opinion within the nine month period provided for in paragraph 1.

7 The Food Safety Authority must make the additional information provided in accordance with paragraphs 4 and 6 available to the appropriate authority.]

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

Textual Amendments

- F2** Art. 11 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **17** (as amended by S.I. 2020/1504, regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F3 Article 12

Authorisation of a novel food and updates of the list

1 Within seven months from the date of publication of the Food Safety Authority's opinion, the appropriate authority must, by prescribing an update of the list, authorise the placing on the market within Great Britain of a novel food, taking into account the following—

- a the conditions provided for in points (a) and (b) of Article 7 and, where applicable, in point (c) of that Article;
- b any relevant provision of retained direct EU legislation, including the precautionary principle as referred to in Article 7 of Regulation [\(EC\) No. 178/2002](#);
- c the Food Safety Authority's opinion;
- d any other legitimate factors relevant to the application under consideration.

2 Where the appropriate authority has not requested an opinion from the Food Safety Authority in accordance with Article 10(3), the seven month period provided for in paragraph 1 of this Article starts from the date on which the valid application is received by the appropriate authority in accordance with Article 10(1).]

Textual Amendments

- F3** Art. 12 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **18** (as amended by S.I. 2020/1504, regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 13

Implementing acts laying down administrative and scientific requirements for applications

F4

Textual Amendments

- F4** Art. 13 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **19**; 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. (See end of Document for details) View outstanding changes

SECTION II

Specific rules for traditional foods from third countries

Article 14

Notification of a traditional food from a third country

Instead of following the procedure referred to in Article 10, an applicant, who intends to place on the market within [^{F5}Great Britain] a traditional food from a third country, may opt to submit a notification of that intention to the [^{F6}appropriate authority].

The notification shall include the following information:

- (a) the name and address of the applicant;
- (b) the name and description of the traditional food;
- (c) the detailed composition of the traditional food;
- (d) the country or countries of origin of the traditional food;
- (e) documented data demonstrating the history of safe food use in a third country;
- (f) a proposal for the conditions of intended use and for specific labelling requirements, which do not mislead the consumer, or a verifiable justification why those elements are not necessary.

Textual Amendments

- F5** Words in Art. 14 substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **20(a)** (as substituted by S.I. 2020/1504, regs. 1(2), **15(8)**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F6** Words in Art. 14 substituted (31.12.2020) by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702), regs. 1, **20(b)**; 2020 c. 1, Sch. 5 para. 1(1)

[^{F7}Article 15

Procedure for notifying the placing on the market of a traditional food from a third country

1 The appropriate authority must forward the valid notification provided for in Article 14 without delay, and not later than one month after having verified its validity, to the Food Safety Authority.

2 Within four months from the date on which a valid notification under Article 14 is received by the appropriate authority, the Food Safety Authority may issue to the appropriate authority duly reasoned safety objections to the placing on the market within Great Britain of the traditional food concerned.

3 The appropriate authority must inform the applicant of any duly reasoned safety objection as soon as it is issued.

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

4 Where no duly reasoned safety objections have been issued in accordance with paragraph 2 within the time limit laid down in that paragraph, the appropriate authority must authorise the placing on the market within Great Britain of the traditional food concerned by prescribing an update to the list without delay. The entry in the list must specify that it concerns a traditional food from a third country. Where applicable, certain conditions for use, specific labelling requirements, or post market monitoring requirements may be specified.

5 Where duly reasoned safety objections have been issued in accordance with paragraph 2, the appropriate authority must not authorise the placing on the market within Great Britain of the traditional food concerned or update the list. In that case, the applicant may submit an application to the appropriate authority in accordance with Article 16].

Textual Amendments

F7 Art. 15 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **21** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[^{F8}Article 16

Application for the authorisation of a traditional food from a third country

Where the appropriate authority does not authorise the placing on the market within Great Britain of a traditional food from a third country, the applicant may submit an application including, in addition to the information already provided in accordance with Article 14, documented data relating to the duly reasoned safety objections issued in accordance with Article 15(2). The appropriate authority must, without delay, forward the valid application to the Food Safety Authority.]

Textual Amendments

F8 Art. 16 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **22** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[^{F9}Article 17

Opinion of the Food Safety Authority on a traditional food from a third country

1 The Food Safety Authority must adopt its opinion within six months from the date of receipt of a valid application.

2 In assessing the safety of a traditional food from a third country, the Food Safety Authority must consider the following matters—

- a whether the history of safe food use in a third country is substantiated by reliable data submitted by the applicant in accordance with Articles 14 and 16;
- b whether the composition of the food and the conditions of its use do not pose a safety risk to human health in Great Britain;
- c where the traditional food from the third country is intended to replace another food, whether it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

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

3 The Food Safety Authority must forward its opinion to the appropriate authority and the applicant.

4 In duly justified cases, where the Food Safety Authority requests additional information from the applicant, the six month period provided for in paragraph 1 may be extended. After consulting the applicant, the Food Safety Authority must specify a period within which that additional information is to be provided and the six month period provided for in paragraph 1 is extended by that additional period.

5 Where the additional information referred to in paragraph 4 is not provided to the Food Safety Authority within the additional period referred to in that paragraph, the Food Safety Authority must draw up its opinion on the basis of the available information.

6 Where an applicant submits additional information on its own initiative, it must send that information to the Food Safety Authority. In such cases, the Food Safety Authority must give its opinion within the six month period provided for in paragraph 1.

7 The Food Safety Authority must make the additional information provided in accordance with paragraphs 4 and 6 available to the appropriate authority.]

Textual Amendments

F9 Art. 17 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **23** (as amended by [S.I. 2020/1504](#), regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(I)**

F¹⁰ Article 18

Authorisation of a traditional food from a third country and updates of the list

1 Within three months of the date of publication of the Food Safety Authority's opinion, the appropriate authority must authorise the placing on the market within Great Britain of the traditional food from a third country by prescribing an update of the list, taking into account the following—

- a the conditions provided for in points (a) and (b) of Article 7 and, where applicable, point (c) of that Article;
- b any relevant provision of law, including the precautionary principle as referred to in Article 7 of Regulation [\(EC\) No. 178/2002](#);
- c the Food Safety Authority's opinion;
- d any other legitimate factors relevant to the application under consideration.

2 By way of derogation from paragraph 1, the appropriate authority may, having taken account of the Food Safety Authority's opinion and any other legitimate factors relevant to the update under consideration, terminate the procedure at any stage and decide not to proceed with an update of the list where it considers that such an update is not justified. The appropriate authority must inform the applicant of the reasons for not considering the update to be justified.

3 The applicant may withdraw its application referred to in Article 16 at any time, thereby terminating the procedure.]

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

Textual Amendments

- F10** Art. 18 substituted (31.12.2020) by [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **24** (as amended by S.I. 2020/1504, regs. 1(2), **15(5)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 19

Updates to the ^{F11}... list as regards authorised traditional foods from third countries

Articles 10 to 13 apply to removing a traditional food from a third country from the ^{F12}... list or to adding, removing or changing specifications, conditions of use, additional specific labelling requirements or post-market monitoring requirements associated with the inclusion of a traditional food from a third country on the ^{F12}... list.

Textual Amendments

- F11** Word in Art. 19 heading omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **25**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Word in Art. 19 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **25**; 2020 c. 1, Sch. 5 para. 1(1)

^{F13}Article 20

Implementing acts laying down administrative and scientific requirements concerning traditional foods from third countries

Textual Amendments

- F13** Art. 20 omitted (31.12.2020) by virtue of [The Novel Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/702\)](#), regs. 1, **26**; 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))