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

Article 10[F1]

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.

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(1)**

[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.**]**

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

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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.
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

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))