

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;

“Regulation 2017/2468” means Commission Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods;

“Regulation 2017/2469” means Commission Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods;

“Regulation 2017/2470” means Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods;

“Regulation 2018/456” means Commission Implementing Regulation (EU) 2018/456 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.

PART 2

Amendment of subordinate legislation

Amendment of the Novel Foods (England) Regulations 2018

3. The Novel Foods (England) Regulations 2018(a) are amended as follows.
4. In Schedule 1, in column 2 of the Table—
 - (a) in the entry which relates to Article 6.2 as read with Article 24, omit “Union”;
 - (b) in the entry which relates to Article 25, for “Commission”, substitute “Food Safety Authority”.

PART 3

Amendment of retained direct EU legislation

Amendment of Regulation 2015/2283

5. Regulation 2015/2283 is amended as follows.
6. For Article 1, substitute—

“Subject matter and purpose

 1. This Regulation lays down rules for novel foods placed on the market within the United Kingdom.
 2. The purpose of this Regulation is to ensure a high level of protection of human health and consumers’ interests.”.
7. In Article 2 (1), for “Union”, substitute “United Kingdom”.
8. In Article 3—
 - (a) in paragraph 2—
 - (i) for the opening words of point (a), substitute—

(a) S.I. 2018/154.

“(a) “novel food” means any food that was not used for human consumption to a significant degree within the EU or the United Kingdom before 15 May 1997, irrespective of the dates of accession of member States, and that falls under at least one of the following categories—”;

(ii) for point (d), substitute—

“(d) “the applicant” means the third country or the interested party;”;

(iii) after paragraph (f), insert—

“(g) “third country” means a country or state other than the United Kingdom;

(h) “prescribe” means prescribe by regulations;

(i) “appropriate authority” means—

(i) in relation to England, the Secretary of State;

(ii) in relation to Wales, the Welsh Ministers;

(iii) in relation to Scotland, the Scottish Ministers;

(iv) in relation to Northern Ireland, the Northern Ireland devolved authority;

(j) “Food Safety Authority” means—

(i) as regards England, Wales and Northern Ireland, the Food Standards Agency;

(ii) as regards Scotland, Food Standards Scotland;

(k) “list” means the list referred to in Article 6(1);

(l) “Northern Ireland devolved authority” means the Department of Health.”;

(b) in each place in which it occurs, for “Union”, substitute “EU or the United Kingdom”.

9. For Article 4, substitute—

“Procedure for determination of novel food status

1. Food business operators must verify whether or not the food which they intend to place on the market within the United Kingdom falls within the scope of this Regulation.

2. Where they are unsure whether or not a food which they intend to place on the market within the United Kingdom falls within the scope of this Regulation, food business operators must consult the Food Safety Authority. Food business operators must provide the necessary information to the Food Safety Authority to enable it to determine whether or not a food falls within the scope of this Regulation.”.

10. For Article 5, substitute—

“Implementing power concerning the definition of novel food

The appropriate authority may prescribe that a particular food is a novel food within the meaning of this Regulation.”.

11. In the Title of Chapter 2, for “Union”, substitute “United Kingdom”.

12. For Article 6, substitute—

“List of authorised novel foods

1. The appropriate authority must establish and update a list of novel foods authorised to be placed on the market within the United Kingdom in accordance with Articles 7 and 9.

2. Only novel foods authorised and included in the list may be placed on the market within the United Kingdom as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified in the list.”.

13. In Article 7—

(a) in each place in which it occurs (including the heading), omit “Union”;

(b) for “Commission shall”, substitute “appropriate authority must”.

14. Omit Article 8.

15. In Article 9—

- (a) in each place in which it occurs (including the heading), omit “Union”;
- (b) in paragraph 1, for “Commission shall”, substitute “appropriate authority must”.

16. For Article 10, substitute—

“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 the United Kingdom 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 the United Kingdom 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.”.

17. For Article 11, substitute—

“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 the United Kingdom;
 - (b) the composition of the novel food and the conditions of its use do not pose a safety risk to human health in the United Kingdom;
 - (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.”.

18. For Article 12, substitute—

“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 the United Kingdom 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).”.

19. Omit Article 13.

20. In Article 14—

- (a) for “Union”, substitute “United Kingdom”;
- (b) for “Commission”, substitute “appropriate authority”.

21. For Article 15, substitute—

“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 the United Kingdom 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.
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 the United Kingdom 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 the United Kingdom 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.”.

22. For Article 16, substitute—

“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 the United Kingdom 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.”.

23. For Article 17, substitute—

“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 the United Kingdom;
 - (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.
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.”.

24. For Article 18, substitute—

“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 the United Kingdom 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.”.

25. In Article 19, in each place in which it occurs (including the heading), omit “Union”.

26. Omit Article 20.

27. For Article 21, substitute—

“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.”.

28. For Article 22, substitute—

“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.”.

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.”.

30. In Article 24, for “Commission”, substitute “appropriate authority”.

31. For Article 25, substitute—

“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.”.

32. In Article 26—

- (a) in paragraph 2, for “Commission”, substitute “appropriate authority”;
- (b) in paragraph 3, for “Union”, substitute “United Kingdom”.

33. For Article 27, substitute—

“Authorisation of a novel food and inclusion in the list based on protected proprietary scientific evidence or scientific data

1. Where a novel food is authorised and included in the list pursuant to Articles 10 to 12 based on proprietary scientific evidence or scientific data that are granted data protection as provided for in Article 26(1), the entry of that novel food in the list must indicate, in addition to the information referred to in Article 9(3)—

- (a) the date of inclusion of the novel food in the list;
- (b) the fact that that inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26;
- (c) the name and address of the applicant;
- (d) the fact that during the period of data protection the novel food is authorised for placing on the market within the United Kingdom only by the applicant specified in point (c) of this paragraph, unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 or with the agreement of the initial applicant;
- (e) the end date of the data protection provided for in Article 26.

2. Scientific evidence or scientific data protected in accordance with Article 26 or for which the protection period under that Article has expired is not to be granted renewed protection.”.

34. In Article 28—

- (a) in each place in which it occurs, for “Commission”, substitute “appropriate authority”;
- (b) in both places in which it occurs, for “Authority”, substitute “Food Safety Authority”.

35. Omit Articles 29 and 30.

36. For Article 31, substitute—

“Engineered nanomaterials

For the purposes of achieving the objectives of this Regulation, the appropriate authority may prescribe changes to the definition of engineered nanomaterials referred to in point (f) of Article 3(2) to reflect technical and scientific progress or definitions agreed at international level.”.

37. Omit Article 32.

38. Insert a new Article 32A—

“Article 32A

Regulations and devolved powers

1. Any power to make regulations under this Regulation—
 - (a) so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;
 - (b) so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument;
 - (c) so far as exercisable by the Northern Ireland devolved authority is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 (SI 1979/1573 (NI 12)) (and not by statutory instrument).
2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(a) (Scottish statutory instruments).
3. Any power to make regulations under this Regulation includes power—
 - (a) to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
 - (b) to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
4. Any statutory instrument, Scottish statutory instrument or statutory rule containing regulations made under this Regulation is subject to annulment in pursuance of a resolution—
 - (a) in the case of England, of either House of Parliament;
 - (b) in the case of Wales, of the National Assembly for Wales;
 - (c) in the case of Scotland, of the Scottish Parliament;
 - (d) in the case of Northern Ireland, being a negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954(b).
5. In this Regulation, any power—
 - (a) of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
 - (b) of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
 - (c) of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only;
 - (d) of the Northern Ireland devolved authority to make regulations is limited to regulations which apply in relation to Northern Ireland only.”.

39. After Article 36, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

Amendment of Regulation 2017/2468

- 40.** Regulation 2017/2468 is amended as follows.
- 41.** In Article 3(1), for “Commission”, substitute “appropriate authority”.
- 42.** In Article 4(1), for “Commission”, substitute “appropriate authority”.
- 43.** In Article 5, at subparagraph (a), for “Commission”, substitute “appropriate authority”.

(a) 2010 asp 10.
(b) 1954 c. 33 (N.I.).

44. In Article 7—

- (a) in each place in which it occurs, for “Commission”, substitute “Food Safety Authority”;
- (b) in paragraph 4, omit “the Member States and the Authority”.

45. In Article 8—

- (a) in each place in which it occurs, for “Commission”, substitute “Food Safety Authority”;
- (b) in paragraph 4, omit “the Member States and the Authority”.

46. In Article 9—

- (a) in paragraph 1, for “Commission, the Member States and the Authority”, substitute “appropriate authority and the Food Safety Authority”;
- (b) for paragraph 2, substitute—

“2. The duly reasoned safety objections submitted by the Food Safety Authority to the appropriate authority in accordance with Article 15(2) of Regulation (EU) 2015/2283 must include the following information—

- (a) the name and description of the traditional food from a third country;
- (b) a scientific statement indicating why the traditional food from a third country may pose a safety risk to human health.”.

47. In Article 10(2), for “Commission”, substitute “appropriate authority”.

48. In Article 11, for “Commission”, substitute “appropriate authority”.

49. After Article 12, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

50. In Annex 1—

- (a) for the opening words “European Commission Directorate General Directorate Unit”, substitute “To the Food Safety Authority”;
- (b) in the first place in which it occurs, for “Union”, substitute “United Kingdom”;
- (c) in the second place in which it occurs, omit “Union”.

51. In Annex 2—

- (a) for the opening words “European Commission Directorate General Directorate Unit”, substitute “To the Food Safety Authority”;
- (b) for “European Union”, substitute “United Kingdom”;
- (c) omit “Union”.

Amendment of Regulation 2017/2469

52. Regulation 2017/2469 is amended as follows.

53. In Article 3(1), for “Commission”, substitute “appropriate authority”.

54. In Article 4, in subparagraph (b), for “Commission”, substitute “appropriate authority”.

55. In Article 5(7), in the second subparagraph, omit “, if they are carried out outside the territory of the Union,”.

56. For Article 6, substitute—

“Verification of the validity of an application

1. On receipt of an application the appropriate authority must without delay verify whether the application falls within the scope of Regulation (EU) 2015/2283 and whether the application fulfils the requirements set out in Article 10(2) of that Regulation.

2. The Food Safety Authority must, on request by the appropriate authority, provide the appropriate authority with its views on whether the application fulfils the relevant requirements set out in Article 10(2) of Regulation (EU) 2015/2283 within a period of 30 days.

3. The Food Safety Authority may request additional information from the applicant as regards the validity of the application and agree with the applicant of the period within which that information is to be provided.

4. By way of derogation from paragraph 1 of this Article, and without prejudice to Article 10(2) of Regulation (EU) 2015/2283, an application may be considered as valid even if it does not contain all the elements required under Articles 3 to 5 of this Regulation, provided that the applicant has submitted appropriate justification for each missing element.

5. The appropriate authority must inform the applicant whether the application is considered valid. If the application is not considered valid, the appropriate authority must indicate the reasons why it is not considered valid.”.

57. In Article 7(2), for “Commission”, substitute “appropriate authority”.

58. For Article 8, substitute—

“Transitional measures

The deadline for the submission of the applications referred to in Article 35(2) of Regulation (EU) 2015/2283 is 1 January 2019.”.

59. After Article 9, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

60. In Annex 1—

- (a) for the opening words “European Commission Directorate General Directorate Unit”, substitute “To the Food Safety Authority”;
- (b) in the first place in which it occurs, for “Union”, substitute “United Kingdom”;
- (c) in the second place in which it occurs, omit “Union”.

Amendment of Regulation 2017/2470

61. Regulation 2017/2470 is amended as follows.

62. For Article 1, substitute—

“List of authorised novel foods

The list of novel foods authorised to be placed on the market within the United Kingdom as referred to in Article 6(1) of Regulation (EU) 2015/2283 is hereby established and set out in the Annex to this Regulation.”.

63. After Article 2, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

64. In the Annex—

- (a) in the Title, omit “Union”;
- (b) in paragraph 1, omit “Union”.

Amendment of Regulation 2018/456

65. Regulation 2018/456 is amended as follows.

66. In Article 2—

- (a) in paragraph (a), omit “to a recipient Member State”;

(b) omit paragraph (b).

67. In Article 3—

(a) in paragraph 1—

(i) for “recipient Member State”, substitute “Food Safety Authority”;

(ii) for “that Member State”, substitute “the Food Safety Authority”;

(b) omit paragraph 2.

68. In Article 4, in both places in which it occurs, for “recipient Member State”, substitute “Food Safety Authority”.

69. In Article 5—

(a) in each place in which it occurs, for “recipient Member State”, substitute “Food Safety Authority”;

(b) in paragraph 4, for “other Member States and the Commission”, substitute “appropriate authority”.

70. In Article 6—

(a) in paragraph 2, omit “The recipient Member State may consult the other Member States and the Commission.”;

(b) in each place in which it occurs, for “recipient Member State”, substitute “Food Safety Authority”;

(c) in paragraph 4, for “other Member States and the Commission”, substitute “appropriate authority”;

(d) in paragraph 5, for “other Member States and the Commission”, substitute “appropriate authority”.

71. In Article 7(2)—

(a) for “Commission”, substitute “Food Safety Authority”;

(b) for “Commission’s”, substitute “Food Safety Authority’s”.

72. Omit Article 8.

73. In Article 9—

(a) in each place in which it occurs, for “recipient Member State”, substitute “Food Safety Authority”;

(b) omit paragraph 4;

(c) in paragraph 6—

(i) for “Commission and the Member States”, substitute “Food Safety Authority”;

(ii) for “them”, substitute “it”;

(d) in paragraph 7, for “neither the Commission nor the Member States shall”, substitute “the Food Safety Authority must not”;

(e) in paragraph 8, for “Commission and the Member States”, substitute “Food Safety Authority and the appropriate authority”.

74. After Article 10, omit “This Regulation shall be binding in its entirety and directly applicable in all Member States.”.

75. In Annex 1, for “Competent authority of the Member State”, substitute “To the Food Safety Authority”.

76. For Annex 2, substitute the insert the Annex set out in the Schedule to these Regulations.

Signed by authority of the Secretary of State for Health and Social Care.

Address
Date

Name
Parliamentary Under-Secretary of State,
Department of Health and Social Care

SCHEDULE

Regulation 76

Wording for inclusion in Commission Implementing Regulation (EU) 2018/456 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

“Annex 2

Template technical dossier

1. The connection between the different pieces of information must be explained in an explanatory note. In particular, as regards the evidence presented to support a human consumption to a significant degree within the United Kingdom or the EU before 15 May 1997, where documents from a range of sources must be considered to be able to reach a conclusion.

2. Where only parts of the documents are relevant for the determination of the novel food status, those parts must be highlighted.

3. For all foods, Section 1 must be completed.

4. For extracts, in addition to Section 1, Section 2 must be completed.

5. For foods resulting from a production process not used for food production within the United Kingdom or the EU before 15 May 1997, Section 1 (points 1 to 3, and point 7) and Section 3 must be completed.

Section 1: All foods (for foods resulting from a production process not used for food production within the United Kingdom or the EU before 15 May 1997 only points 1 to 3 and point 7)

1. Description of the food

1.1 Name of the food.

1.2 Detailed description of the food, including information whether the food consists of engineered nanomaterials as referred to in points (a)(viii) and (ix) of Article 3(2) of Regulation (EU) 2015/2283.

1.3 Proposed category of the novel food in accordance with Article 3(2)(a) of Regulation (EU) 2015/2283, where applicable.

2. *Further characterisation of the food and/or source of the food (where relevant)*

A. Organisms (microorganisms, fungi, algae, plants, animals).

2.1 Taxonomic name (full Latin name with author name).

- 2.2 Synonyms, other names, where applicable.
 - 2.3 Specification of which part of the organism the use for human consumption before 15 May 1997 within the United Kingdom or the EU refers to, where applicable.
 - 2.4 Specification about purity/concentration.
- B. Chemical substances.
- 2.5 CAS number(s) (if this has been attributed).
 - 2.6 Chemical name(s) according to IUPAC nomenclature rules.
 - 2.7 Synonyms, trade name, common name, where applicable.
 - 2.8 Molecular and structural formulae.
 - 2.9 Specification about purity/concentration.
3. *Conditions of use*
- 3.1 How is the food intended to be used?
 - 3.2 Type of product(s) in which the food is intended to be used.
 - 3.3 Level/concentration (or range of levels) in the product(s) in which the food is intended to be used.
4. *Production process*
- 4.1 Detailed description of the production process. Include a flow process chart to describe the production process.
5. *History of human consumption of the food within the United Kingdom or the EU before 15 May 1997*
- 5.1 To what extent was the food consumed to a significant degree throughout the United Kingdom or the EU before 15 May 1997? Details must be provided.
 - 5.2 To what extent was the food consumed to a significant degree in one Member State before 15 May 1997? Details must be provided.
 - 5.3 Was the food consumed only regionally/on a small local scale in the United Kingdom or the EU before 15 May 1997? Details must be provided.
 - 5.4 Was the food available before 15 May 1997 in the United Kingdom or the EU as an ingredient designed for specific target population (e.g. food for a special medical purpose)? Details must be provided.
6. *Consultations on availability in the United Kingdom or the EU: where food business operators are unsure whether the information in their possession is sufficient to prove that the food concerned has been used for human consumption to a significant degree within the United Kingdom or the*

EU before 15 May 1997, they may consult other food business operators or food business operator federations in order to gather sufficient information

6.1 Have other food business operators or food business operator federations been consulted? Details should be provided.

6.2 Is the food currently available on the market within the United Kingdom or the EU? Details should be provided.

7. Additional information

7.1 Is there any information that the product concerned is used within the United Kingdom or the EU as medicinal product in accordance with Directive 2001/83/EC?

7.2 Is there any other information which would assist in determining the novel food status? Any information which is relevant even if not specifically requested must be submitted.

Section 2: Extracts

8. Extracts

8.1 Any further details of the source material for the extract, if not provided in Section 1. Details must be provided.

8.2 Specification of the extract. Details must be provided.

8.3 If extracted from a food source, will the intake of any extract components in the food be higher than the intake of these components in the food source? Details must be provided.

Section 3: Foods resulting from a production process not used for food production within the United Kingdom or the EU before 15 May 1997

9. Production process

9.1 Detailed description of the production process. Include a flow process chart to describe the production process.

9.2 Is the structure or composition of the food affecting its nutritional value, metabolism or level of undesirable substances because of the process by which the food has been prepared? Details must be provided.

9.3 Is the food produced from a source that in itself is not normally consumed as part of the diet? Details must be provided.”

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU law to operate

effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union. In particular, the Regulations address the deficiency specified in section 8(2)(b) of that Act, namely the conferral of functions by retained EU law on, or in relation to, EU entities which no longer have functions in that respect under EU law in relation to the United Kingdom.

These regulations make amendments to legislation relating to the safety of novel food. Part 2 amends subordinate legislation in England. Part 3 amends retained direct EU legislation for the whole of the United Kingdom.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the public, private or voluntary sector is foreseen.

© Crown copyright 2019

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

£6.90

UK201902011018 02/2019 19585

<http://www.legislation.gov.uk/id/ukdsi/2019/9780111180266>

ISBN 978-0-11-118026-6



9 780111 180266