Commission Implementing Regulation (EU) 2018/456 of 19 March 2018 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/456

of 19 March 2018

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[(1)], and in particular Article 4 thereof,

Whereas:

(1) Regulation (EU) 2015/2283 lays down rules for the placing on the market and use of novel foods in the Union.

(2) Article 4 of Regulation (EU) 2015/2283 lays down basic principles on the procedure for the determination of novel food status. Paragraph 1 of that Article requires food business operators to verify whether or not the food which they intend to place on the Union market falls within the scope of that Regulation.

(3) In order to determine the novel food status of a particular food, a consultation request should be submitted. The Member States should verify the validity of such requests. Therefore, it is necessary to establish rules for the verification process.

(4) Rules should be established in order to ensure that the consultation request for determination of novel food status provides all the information necessary for the evaluation by the Member States.

(5) In order to ensure that food business operators and the public are informed of the novel food status, the information on the novel food status should be made publicly available.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1 U.K.

Scope and subject matter

This Regulation lays down rules for the implementation of Article 4 of Regulation (EU) 2015/2283 as regards the procedural steps of the consultation process to determine whether or not a food falls within the scope of that Regulation.

Article 2 U.K.

Definitions

In addition to the definitions laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council[(2)] and Regulation (EU) 2015/2283, the following definitions shall apply:

(a) 'consultation request' means a request from a food business operator to a recipient Member State to determine the novel food status of a particular food;

(b) 'recipient Member State' means a Member State where the food business operator intends to place on the market a particular food for the first time.

Article 3 U.K.

Submission of a consultation request

1 The food business operator shall consult the recipient Member State as provided for in Article 4(2) of Regulation (EU) 2015/2283 by submitting a consultation request to that Member State.

2 Where the food business operator intends to place the food on the market simultaneously in several Member States, the food business operator shall submit the consultation request only to one of those Member States.

Article 4 U.K.

Content and presentation of a consultation request

1 The consultation request shall be submitted electronically to the recipient Member State and shall consist of the following:

a a cover letter;
b a technical dossier;
c supporting documentation;
d an explanatory note clarifying the purpose and relevance of the submitted documentation.

2 The cover letter referred to in paragraph 1(a) shall be drafted in accordance with the template provided in Annex I.

3 The technical dossier referred to in paragraph 1(b) shall contain the information necessary to enable the recipient Member State to conclude on the novel food status and shall be drafted in accordance with the template provided in Annex II.

4 By way of derogation from paragraph 3, an applicant is not required to provide all the elements referred to in Annex II, provided that the applicant has submitted verifiable justification for the absence of each missing element.

Article 5 U.K.

Procedures for verifying the validity of a consultation request

1 The recipient Member State shall without delay verify whether the consultation request complies with the requirements of Article 4.

2 Where the food business operator submits insufficient information in the consultation request, the recipient Member State shall request the food business operator to provide additional information or make the relevant updates to the consultation request within the time period specified by the recipient Member State.

3 The consultation request shall be considered not valid where:

a the food business operator does not provide requested additional information or updated consultation request within the period specified by the recipient Member State;

b the submitted additional information is insufficient to conclude that the consultation request is valid.

4 The recipient Member State shall decide on the validity of the consultation request and without delay inform the food business operator, the other Member States and the Commission of the decision. Where the consultation request is considered not valid, the recipient Member State shall provide the reasons for that conclusion.

Article 6 U.K.

Procedures for evaluating a valid consultation request

1 The recipient Member State shall conclude on the novel food status of a food within 4 months from the date on which it decided on the validity of the consultation request.

2 Where the recipient Member State identifies that it does not have sufficient evidence to decide on the novel food status of a food, it may request the food business operator to provide additional information. The period of that request shall be determined together with the food business operator.

The recipient Member State may consult the other Member States and the Commission.

3 Without prejudice to paragraph 4, a request for additional information referred to in paragraph 2 shall not extend the time period referred to in paragraph 1.

4 In duly justified cases, the recipient Member State may extend the time period referred to in paragraph 1 by a maximum of 4 months. The recipient Member State shall inform the food business operator, the other Member States and the Commission of their decision and shall provide justification.

5 On concluding on the novel food status of a food, the recipient Member State shall without delay notify the food business operator, the other Member States and the Commission of the decision and shall provide justification in accordance with Article 7 of this Regulation.

Article 7 U.K.

Information on the novel food status and publication

1 The notification referred to in Article 6(5) of this Regulation shall include the following:

a the name and description of the food concerned;

b a statement indicating whether the food concerned is novel, not novel or not novel only in food supplements;

c reasons justifying the statement referred to in point (b);

d where the food is novel food, the most appropriate food category under which it falls in accordance with Article 3(2) of Regulation (EU) 2015/2283.

2 The Commission shall without delay make the information on the novel food status publicly available on the Commission's website.

Article 8 U.K.

Competent authorities of the Member States

Member States shall provide the Commission with the contact details of the national competent authorities and the contact details of the respective contact points designated for the purposes of this Regulation by 1 March 2018.

The Commission shall publish those contact details on the Commission's website by 1 May 2018.

Article 9 U.K.

Confidentiality

1 Food business operators may request the recipient Member State to agree that the disclosure of certain information submitted as part of the consultation request needs to benefit from confidential treatment where disclosure of such information may harm their competitive position.

2 For the purpose of paragraph 1, food business operators shall indicate to the recipient Member State the parts of the information provided that they wish to be treated as confidential and provide all the necessary details to substantiate their request for confidentiality.

3 The recipient Member State shall inform the food business operator of its views on which parts of the information are to remain confidential.

However, confidentiality shall not apply to the following information:

a the name and address of the applicant;

b the name and description of the food;

c a summary of the studies submitted by the applicant;

d where appropriate, the analysis method(s).

4 In case of the consultation of other Member States pursuant to Article 6(2), second subparagraph, the recipient Member State shall inform the Commission and the Member States about its views on confidentiality of the consultation request.

5 After being informed pursuant to paragraph 3, the food business operator may withdraw its consultation request within 3 weeks during which the confidentiality of the information provided shall be observed.

6 The Commission and the Member States shall take necessary measures to ensure appropriate confidentiality of the information referred to in paragraphs 3 and received by them under this Regulation, except for information which is required to be made public in order to protect human health.

7 Where a food business operator withdraws or has withdrawn its consultation request in accordance with paragraph 5, neither the Commission nor the Member States shall disclose information for which confidentiality was requested by the food business operator pursuant to paragraph 1.

8 The application of paragraphs 1 to 7 shall not affect the exchange of information between the Commission and the Member States necessary to consider the consultation requests submitted under this Regulation.

Article 10 U.K.

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 March 2018.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX I U.K.

TEMPLATE COVER LETTER ACCOMPANYING A CONSULTATION REQUEST FOR DETERMINATION OF THE NOVEL FOOD STATUS

Competent authority of the Member State

Date: …

Subject: Consultation request for determination of the novel food status of …

…

The Food business operator(s)/consulting party:

Company: …

Address: …

Telephone: …

Email: …

Contact person: …

submit(s) the present consultation request in order to determine the novel food status of …

Yours sincerely,

Signature …

Enclosures:

Technical dossier

Documents in support of the consultation request

Explanatory note

ANNEX II U.K.

TEMPLATE TECHNICAL DOSSIER

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

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

For all foods, Section 1 must be completed.

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

For foods resulting from a production process not used for food production within the Union 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 UNION 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])	
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 Union 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 Union before 15 May 1997**	
5.1	To what extent was the food consumed to a significant degree throughout the Union before 15 May 1997? Details shall be provided.	
5.2	To what extent was the food consumed to a significant degree in one Member State before 15 May 1997? Details shall be provided.	
5.3	Was the food consumed only regionally/on a small local scale in the Union before 15 May 1997? Details shall be provided.	
5.4	Was the food available before 15 May 1997 in the Union as an ingredient designed for specific target population (e.g. food for a special medical purpose)? Details shall be provided.	

6.	**Consultations on availability in the Union**	
	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 Union 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 Union? Details should be provided.	
7.	**Additional information**	
7.1	Is there any information that the product concerned is used within the Union as medicinal product in accordance with Directive 2001/83/EC ([2])?	
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 shall 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 shall be provided.	
8.2	Specification of the extract. Details shall 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 shall be provided.	

SECTION 3: FOODS RESULTING FROM A PRODUCTION PROCESS NOT USED FOR FOOD PRODUCTION WITHIN THE UNION 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 shall be provided.	
9.3	Is the food produced from a source that in itself is not normally consumed as part of the diet? Details shall be provided.	

([1]) 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 (OJ L 327, 11.12.2015, p. 1).

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(**1**) OJ L 327, 11.12.2015, p. 1.

(**2**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Changes to legislation:
There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/456. 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 :

- Annex 1 words substituted by S.I. 2019/702 reg. 75
- Annex 2 substituted by S.I. 2019/702 Sch.
- Art. 3(1) words substituted by S.I. 2019/702 reg. 67(a)(i)
- Art. 3(1) words substituted by S.I. 2019/702 reg. 67(a)(ii)
- Art. 3(2) omitted by S.I. 2019/702 reg. 67(b)
- Art. 4 words substituted by S.I. 2019/702 reg. 68
- Art. 5 words substituted by S.I. 2019/702 reg. 69(a)
- Art. 5(4) words substituted by S.I. 2019/702 reg. 69(b)
- Art. 6 words substituted by S.I. 2019/702 reg. 70(b)
- Art. 6(2) words omitted by S.I. 2019/702 reg. 70(a)
- Art. 6(4) words substituted by S.I. 2019/702 reg. 70(c)
- Art. 6(5) words substituted by S.I. 2019/702 reg. 70(d)
- Art. 7(2) words substituted by S.I. 2019/702 reg. 71(a)
- Art. 7(2) words substituted by S.I. 2019/702 reg. 71(b)
- Art. 8 omitted by S.I. 2019/702 reg. 72
- Art. 9 words substituted by S.I. 2019/702 reg. 73(a)
- Art. 9(4) omitted by S.I. 2019/702 reg. 73(b)
- Art. 9(6) word substituted by S.I. 2019/702 reg. 73(c)(ii)
- Art. 9(6) words substituted by S.I. 2019/702 reg. 73(c)(i)
- Art. 9(7) words substituted by S.I. 2019/702 reg. 73(d)
- Art. 9(8) words substituted by S.I. 2019/702 reg. 73(e)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/702 reg. 74
- Art. 2(a) words omitted by S.I. 2019/702 reg. 66(a)
- Art. 2(b) omitted by S.I. 2019/702 reg. 66(b)