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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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) …/...

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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 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 obliges 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 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,

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

HAS ADOPTED THIS REGULATION:

Article 1
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
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 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
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
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.

[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).

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

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

Procedures for evaluating a valid consultation request

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

2. Where the recipient Member State does not have sufficient evidence to decide on the status of a novel food, it may request the food business operator to provide additional information. That request shall not extend the deadline of 4 months provided in paragraph 1.

   In that regard the recipient Member State may consult the other Member States and the Commission.

3. In duly justified cases, the recipient Member State may extend the time period referred to in paragraph 1 by a maximum of four 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.

Article 7

Information on the novel food status and publication

1. The recipient Member State shall notify to the food business operator, the other Member States and the Commission the status of the novel food.

2. The notification sent by the recipient Member State 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 food category under which it falls in accordance with Article 3(2) of Regulation (EU) 2015/2283.

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

Article 8

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

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,

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

ANNEX I

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_____
_____

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 the
_____

Yours sincerely,

Signature _____

Enclosures:

- ☐ Technical dossier
- ☐ Documents in support of the consultation request with the full information in electronic format
- ☐ Explanatory note

ANNEX II

TECHNICAL DOSSIER

Where applicable, the technical dossier shall contain a proposal on the category under which the novel food falls as defined in Article 3(2) of Regulation (EU) 2015/2283.

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 assessment, those parts shall be highlighted.

For foods, other than extracts and other than foods resulting from a production process not used for food production within the Union before 15 May 1997, Section 1 must be completed.

For extracts Section 1 and 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 other than extracts and foods resulting from a production process not used for food production within the Union before 15 May 1997

1.	Description of the food	
1.1	Name of the food	
1.2	Detailed description of the food	
1.3	Proposed category of the novel food in accordance with Article 3 (2) (a) of Regulation (EU) 2015/2283	

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	
B.	Chemical substances	
2.4	CAS number(s) (if this has been attributed)	

2.5	Chemical name(s) according to IUPAC nomenclature rules	
2.6	Synonyms, trade name, common name, where applicable	
2.7	Molecular and structural formulae	
2.8	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. Details shall be provided.	
5.2	To what extent was the food consumed to a significant degree in one Member State. Details shall be provided.	
5.3	Food consumed only regionally/on a small local scale in the Union.	
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)?	

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 shall 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 shall be provided.	
6.2	Is the food currently available on the market within the Union? Details shall 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[3]?	
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.	
8.2	Specification of the extract	
8.3	If extracted from a food source, will the intake of any extract components in the new food be higher than the intake of these components from the original food source?	

[3] 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).

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.	