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# COMMISSION IMPLEMENTING REGULATION (EU) 2017/2469

**of 20 December 2017**

**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**

**(Text with EEA relevance)**

(OJ L 351, 30.12.2017, p. 64)

Amended by:

| | | Official Journal | | |
|---|---|---|---|---|
| | | No | page | date |
| ►**M1** | Commission Implementing Regulation (EU) 2020/1772 of 26 November 2020 | L 398 | 13 | 27.11.2020 |

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# COMMISSION IMPLEMENTING REGULATION (EU) 2017/2469

**of 20 December 2017**

**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**

**(Text with EEA relevance)**

*Article 1*

**Scope and subject matter**

This Regulation lays down rules for the implementation of Article 13 of Regulation (EU) 2015/2283 as regards the administrative and scientific requirements for applications referred to in Article 10(1) and the transitional measures referred to in Article 35(3) of that Regulation.

*Article 2*

**Definitions**

In addition to the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council [1] and Regulation (EU) 2015/2283, the following definition shall apply:

'application' means a stand-alone dossier containing the information and the scientific data submitted for the authorisation of a novel food pursuant to Article 10(1) of Regulation (EU) 2015/2283.

*Article 3*

**Structure, content and presentation of an application**

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1. An application shall consist of the following:

(a) a cover letter;

(b) a technical dossier;

(c) a summary of the dossier.

Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission, in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission in accordance with those standard data formats.

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

[1] 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).

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3. The technical dossier referred to in paragraph 1(b) shall contain:

(a) the administrative data as provided for in Article 4;

(b) the scientific data as provided for in Article 5.

4. Where the applicant submits an application to modify the conditions of use, the specifications, additional specific labelling requirements or post-market monitoring requirements of an authorised novel food, it may not be necessary for the applicant to provide all the data required under Article 5 of this Regulation where the applicant provides verifiable justification explaining that the proposed changes do not affect the results of the existing risk assessment.

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5. In addition to the information referred to in points (a), (b) and (e) of Article 10(2) of Regulation (EU) 2015/2283, the summary of the dossier referred to in paragraph 1(c) of this Article shall set out the reasons why the use of the novel food complies with the conditions laid down in Article 7 of Regulation (EU) 2015/2283. The summary of the dossier shall not contain any information subject to a request for confidential treatment pursuant to Article 23 of Regulation (EU) 2015/2283 and Article 39a of Regulation (EC) No 178/2002.

*Article 4*

**Administrative data requirements**

In addition to the information set out in Article 10(2) of Regulation (EU) 2015/2283, the application shall include the following administrative data:

(a) the name(s) of the manufacturer(s) of the novel food, if different than the applicant's, address and contact details;

(b) the name, address and contact details of the person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission and the Authority;

(c) the date of submission of the dossier;

(d) a table of contents of the dossier;

(e) a detailed list of documents annexed to the dossier, including references to titles, volumes and pages;

(f) where the applicant submits, in accordance with Article 23 of Regulation (EU) 2015/2283, a request to treat as confidential certain parts of the information of the dossier, including supplementary information, a list of the parts to be treated as confidential accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree;

(g) where the production process contains confidential data, a non-confidential summary of the production process;

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(h) separately included information and explanations substantiating the existence of the applicant's right of reference to the proprietary scientific evidence or scientific data in accordance with Article 26 of Regulation (EU) 2015/2283;

(i) a list of the studies submitted to support the application, including information demonstrating compliance with Article 32b of Regulation (EC) No 178/2002.

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*Article 5*

**Scientific data requirements**

1. The dossier submitted in support of an application for the authorisation of a novel food shall enable a comprehensive risk assessment of the novel food.

2. Where the application for the authorisation of a novel food involves the use of engineered nanomaterials as referred to in points (a) (viii) and (ix) of Article 3(2) of Regulation (EU) 2015/2283, the applicant shall provide detection and characterisation test methods in compliance with the requirements of Article 10(4) of that Regulation.

3. The applicant shall provide a copy of the documentation on the procedure and strategy followed when gathering the data.

4. The applicant shall provide a description of the safety evaluation strategy and the corresponding toxicological testing strategy and shall justify the inclusion or exclusion of specific studies or information.

5. The applicant shall provide on request the raw data for the individual studies, published and unpublished, undertaken by the applicant, or on their behalf, to support their application. This information includes data used to generate the conclusions of the individual studies and results of examinations.

6. Where it cannot be excluded that a novel food intended for a particular group of the population would be also consumed by other groups of the population the safety data provided shall also cover those groups.

7. For each biological or toxicological study, the applicant shall clarify whether the test material conforms to the proposed or existing specification. Where the test material differs from that specification, the applicant shall demonstrate the relevance of those data to the novel food under consideration.

Toxicological studies shall be conducted in facilities which comply with the requirements of Directive 2004/10/EC or, if they are carried out outside the territory of the Union, they shall follow the OECD Principles of Good Laboratory Practice. The applicant shall provide evidence of compliance with those requirements and shall justify any deviation from the standard protocols.

8. The applicant shall propose an overall conclusion on the safety of the proposed uses of the novel food. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

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*Article 6*

**Verification of the validity of an application**

1. On receipt of an application, the Commission shall, 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, Articles 3 to 5 of this Regulation and in Article 32b of Regulation (EC) No 178/2002.

2. The Commission may consult the Authority on whether the application fulfils the relevant requirements referred to in paragraph 1. The Authority shall provide the Commission with its views within a period of 30 working days.

3. The Commission may request additional information from the applicant as regards the validity of the application and inform the applicant of the period within which that information has 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 and to Article 32b(4) and (5) of Regulation (EC) No 178/2002, an application may be considered 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 Commission shall inform the applicant, the Member States and the Authority whether the application is considered valid or not. Where the application is not considered valid, the Commission shall indicate the reasons for that finding.

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*Article 7*

**Information to be included in the opinion of the Authority**

1. The opinion of the Authority shall include the following information:

(a) the identity of the novel food;

(b) the assessment of the production process;

(c) compositional data;

(d) specifications;

(e) the history of use of the novel food and/or its source;

(f) the proposed uses and use levels and anticipated intake;

(g) absorption, distribution, metabolism and excretion (ADME);

(h) nutritional information;

(i) toxicological information;

(j) allergenicity;

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(k) an overall risk assessment for the novel food under the proposed uses and use levels and highlighting uncertainties and limitations where relevant;

(l) when the dietary exposure exceeds the health-based guidance value identified in the overall risk assessment, the dietary exposure assessment of the novel food shall be detailed, providing the contribution to the total exposure of each food category or foodstuff for which the use is authorised or has been requested;

(m) conclusions;

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(n) the results of consultations performed during the risk assessment process in accordance with Article 32c(2) of Regulation (EC) No 178/2002.

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2. The Commission may ask for additional information in its request for an opinion of the Authority.

*Article 8*

**Transitional measures**

1. By 1 January 2018 the Member States shall notify to the Commission the lists of requests referred to in Article 35(1) of Regulation (EU) 2015/2283.

2. The Members States shall make available all the information they have received on each request referred to in paragraph 1 to the Commission.

3. Any request referred to in paragraph 1 of this Article shall be updated by the applicant in order to comply with the requirements set out in Article 10(2) of Regulation (EU) 2015/2283 and in this Regulation.

4. By way of derogation, paragraphs 1 and 2 shall not apply to requests referred to in paragraph 1 of this Article for which an initial assessment report has been forwarded to the Commission pursuant to Article 6(4) of Regulation (EC) No 258/97 of the European Parliament and of the Council [1] by 1 January 2018, and for which no reasoned objections have been made to the marketing of the novel food concerned within the period established in Article 6(4) of that Regulation.

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

*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.

[1] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

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*ANNEX*

**Template cover letter accompanying an application for novel food**

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date: .....

Subject: **Application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283**

*(Please indicate clearly by ticking one of the boxes)*

☐ Application for an authorisation of a new novel food.

☐ Application for adding, removing or changing the conditions of use of an already authorised novel food. Please provide a reference to that authorisation.

☐ Application for adding, removing or changing the specifications of an already authorised novel food. Please provide a reference to that authorisation.

☐ Application for adding, removing or changing additional specific labelling requirements of an already authorised novel food. Please provide a reference to that authorisation.

☐ Application for adding, removing or changing post market monitoring requirements of an already authorised novel food. Please provide a reference to that authorisation.

The Applicant(s) or their Representative(s) in the Union

(name(s), address(es)…)

.....

.....

.....

submit(s) this application in order to update the Union list on novel foods.

Identity of the novel food (Please provide information on the identity of the novel food depending on the category(ies) under which the novel food falls):

.....

.....

Confidentiality. Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283:

☐ Yes

☐ No

Data Protection ([1]). Where appropriate, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283:

☐ Yes

☐ No

([1]) Applicant should specify the part(s) of the application which include(s) proprietary data for which protection is requested, clearly stating section(s) and page number(s). Applicant should provide verifiable justification/declaration for the proprietary claim.

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Food categories, conditions of use and labelling requirements

| Food category | Specific conditions of use | Additional specific labelling requirement |
|---|---|---|
| | | |
| | | |

Yours sincerely,

Signature .....

Enclosures:

☐ Complete dossier

☐ Summary of the dossier (non-confidential)

☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree

☐ Information supporting the protection of proprietary data relating to the novel food application

☐ Copy of administrative data of applicant(s)

☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002