EUROPEAN
COMMISSION

Brussels, 20.12.2017
C(2017) 8874 final

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of 20.12.2017

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)

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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)

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 13 and Article 35(3) 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) Pursuant to Article 13 of Regulation (EU) 2015/2283, the Commission has to adopt implementing acts laying down administrative and scientific data requirements for applications referred to in Article 10(1) of that Regulation.

(3) Without prejudice to Articles 5 and 10 of Regulation (EU) 2015/2283, the Commission should verify whether the application falls within the scope of that Regulation and its validity.

(4) Applications referred to in Article 10(1) of Regulation (EU) 2015/2283 should contain sufficient information and scientific documentation to allow the Commission to verify their validity and enable the European Food Safety Authority (the Authority) to conduct comprehensive risk assessments of the novel foods.

(5) The applications should include detailed descriptions of the safety evaluation strategy, the raw data, information on the relevance of the test material used in the toxicological studies, and detection and characterisation test methods for the engineered nanomaterials.

(6) Experience has shown that in certain cases a novel food intended for a particular group of the population may also reasonably be expected to be consumed by other groups of the population and that risk management measures may be necessary to mitigate potential health risks to those other population groups. Therefore, sufficient information should be provided in the application to enable the risks to those population groups to be assessed.

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

(7) Where the applicant submits an application to add, remove or change 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 for the risk assessment, where the applicant provides verifiable justification.

(8) In order to ensure that toxicological tests are performed to a certain standard, they should be carried out in accordance with the rules set out in Directive 2004/10/EC of the European Parliament and of the Council[2]. Where those tests are carried out outside the territory of the Union, they should follow the OECD Principles of Good Laboratory Practice[3].

(9) The opinion of the Authority should provide sufficient information to ascertain whether the proposed use of the novel food is safe for consumers.

(10) In order to benefit from data protection, as laid down in Article 26 of Regulation (EU) 2015/2283, requests for protection of proprietary data should be justified and all data concerned should be kept in a separate part of the application.

(11) Pursuant to Article 35 of Regulation (EU) 2015/2283, it is necessary to lay down transitional measures for the entry into force of that Regulation.

(12) 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
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[4] 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.

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2 Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44).

3 OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring. Number 1. OECD Principles on Good Laboratory Practice (as revised in 1997) ENV/MC/CHEM(98)17.

4 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).

Article 3

Structure, content and presentation of an application

1. An application shall be submitted electronically to the Commission and shall consist of the following:

   (a) a cover letter;

   (b) a technical dossier;

   (c) a summary of the dossier.

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:

   (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.

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.

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;

(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) a list of the parts of the dossier to be treated as confidential and verifiable justification in accordance with Article 23 of Regulation (EU) 2015/2283 and the rules set out in Annex II to this Regulation. Where the production process contains confidential data, a non-confidential summary of the production process shall be provided;

(g) 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. That information shall be included in a separate folder.

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.

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.

2. The Commission may consult the Authority. The Authority shall provide the Commission 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 working days.

3. The Commission 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 shall 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 Commission shall inform the applicant, the Member States and the Authority whether the application is considered valid or not. If the application is not considered valid, the Commission shall indicate the reasons why it is not valid.

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;

   (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.

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, paragraph 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 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 Regulation (EC) No 258/97.

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.

Done at Brussels, 20.12.2017

For the Commission
The President
Jean-Claude JUNCKER