COMMISSION IMPLEMENTING REGULATION (EU) 2020/1772

of 26 November 2020

amending 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

(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 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) Commission Implementing Regulation (EU) 2017/2469 ([2]) lays down administrative and scientific requirements for applications referred to in Article 10(1) of Regulation (EU) 2015/2283.

(3) Regulation (EU) 2019/1381 of the European Parliament and the Council ([3]) amended Regulation (EC) No 178/2002 ([4]) and Regulation (EU) 2015/2283. Those amendments are aimed at strengthening the transparency and the sustainability of the EU risk assessment in all areas of the food chain where the European Food Safety Authority ('the Authority') delivers a scientific risk assessment, including in the area of novel foods.

(4) As regards the placing on the market of novel foods, the amendments to Regulation (EC) No 178/2002 introduced new provisions concerning amongst other issues: general pre-submission advice by the staff of the Authority at the request of a potential applicant and the obligation to notify studies commissioned or carried out by business operators to support an application and the consequences of non-compliance with that obligation. It also introduced provisions on the public disclosure by the Authority of all scientific data, studies and other information supporting applications, with the exception of confidential information, early on in the risk assessment process, followed up by a consultation of third parties. The amendments also set out specific procedural requirements for the submission of confidentiality requests and the assessment thereof by the Authority in relation to the information submitted by an applicant, where the Commission requests the opinion of the Authority.

(5) Regulation (EU) 2019/1381 also amended Regulation (EU) 2015/2283 to include provisions ensuring consistency with the adaptations of Regulation (EC) No 178/2002 and taking into account sectoral specificities with respect to confidential information.

(6) Given the scope and application of all those amendments, Implementing Regulation (EU) 2017/2469 should be adjusted to accommodate the changes as regards the content, drafting and presentation of applications referred to in Article 10 of Regulation (EU) 2015/2283, the arrangements for verifying the validity of applications, and the information to be included in the opinion of the Authority. In particular, Implementing Regulation (EU) 2017/2469 should make reference to the standard data formats and require that applications provide information demonstrating compliance with the notification requirement laid down in Article 32b of Regulation (EC) No 178/2002. It should also clarify that the assessment of compliance with the notification requirement forms part of the verification of the validity of an application.

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

([2]) 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 (OJ L 351, 30.12.2017, p. 64).

([3]) Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and the sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

([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).

(7) Furthermore, taking into account the fact that the Authority is responsible for managing the database of studies in accordance with Article 32b of Regulation (EC) No 178/2002, it should also be made possible for the Commission to consult the Authority as part of the verification of the validity of applications to ascertaining that the application fulfils the relevant requirements that are laid down in that Article.

(8) Where public consultations are performed during the risk assessment in accordance with Article 32c(2) of Regulation (EC) No 178/2002, the opinion of the Authority should also include the results of those consultations, in line with the transparency requirements to which the Authority is subject.

(9) This Regulation should apply from 27 March 2021 and to applications submitted as of that date, which is the date of application of Regulation (EU) 2019/1381.

(10) 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

Amendments to Implementing Regulation (EU) 2017/2469

Implementing Regulation (EU) 2017/2469 is amended as follows:

(1) Article 3 is amended as follows:

(a) paragraph 1 is replaced by the following:

'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.';

(b) paragraph 5 is replaced by the following:

'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.';

(2) Article 4 is replaced by the following:

'*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;

(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.';

(3) Article 6 is replaced by the following:

'*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.';

(4) in Article 7(1), the following point (n) is added:

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

(5) Annex I is replaced in accordance with the Annex to this Regulation;

(6) Annex II is deleted.

Article 2

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*.

It shall apply from 27 March 2021 and to applications submitted to the Commission from that date.

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

Done at Brussels, 26 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

'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)…)

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.....

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):

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

☐ Yes

☐ No

Data Protection (*). 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

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'

(*) 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.