Commission Implementing Regulation (EU) 2020/1824 of 2 December 2020 amending Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries 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) 2020/1824

of 2 December 2020

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(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 20 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) 2017/2468[(2)] lays down administrative and scientific requirements concerning traditional foods from third countries.

(3) Regulation (EU) 2019/1381 of the European Parliament and the Council[(3)] amended Regulation (EC) No 178/2002 of the European Parliament and of the Council[(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 traditional foods from third countries.

(4) As regards the placing on the market of traditional foods from third countries, 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 or notifier and the obligation to notify studies commissioned or carried out by business operators to support an application or notification 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 provide for the public disclosure by the Authority of notifications where it submits duly reasoned safety objections as well as 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) 2017/2468 should be adjusted to accommodate the changes as regards the content, drafting and presentation of notifications and applications referred to in Articles 14 and 16 of Regulation (EU) 2015/2283, the arrangements for verifying the validity of notifications and applications and the information to be included in the opinion of the Authority. In particular, Implementing Regulation (EU) 2017/2468 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.

(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 be made possible for the Commission to consult the Authority as part of the verification of the validity of notifications and applications, in particular with a view to ascertaining that the notification or 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 notifications and 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) 2017/2468

Implementing Regulation (EU) 2017/2468 is amended as follows:

(1) Article 3 is amended as follows:

(a) paragraph 1 is replaced by the following:

1. A notification 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 notification 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 notification 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. The summary of the dossier referred to in paragraph 1(c) shall provide evidence that the use of a traditional food from a third country 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 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.
   d duly reasoned safety objections referred to in Article 15(2) of Regulation (EU) 2015/2283;
   e the applicant's response to duly reasoned safety objections.

   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. The summary of the dossier referred to in paragraph 1(c) shall provide evidence that the use of a traditional food from a third country

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1824. (See end of Document for details)*

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.;

(3) Article 5 is amended as follows:

(a) point (e) is replaced by the following:

(e) 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;;

(b) point (f) is added:

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

(4) Article 7 is replaced by the following:

Article 7

Verification of the validity of a notification

1 On receipt of a notification of a traditional food from a third country, the Commission shall, without delay, verify whether the food concerned falls within the scope of Regulation (EU) 2015/2283 and whether the notification fulfils the requirements set out in Articles 3, 5 and 6 of this Regulation and in Article 32b of Regulation (EC) No 178/2002.

2 The Commission may consult the Member States and the Authority on whether the notification fulfils the requirements referred to in paragraph 1. The Member States and the Authority shall provide the Commission with their views within a period of 30 working days.

3 The Commission may request additional information from the applicant as regards the validity of the notification 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 14 of Regulation (EU) 2015/2283 and to Article 32b(4) and (5) of Regulation (EC) No 178/2002, a notification may be considered valid even if it does not contain all the elements required under Articles 3, 5 and 6 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 notification is considered valid or not. Where the notification is not considered valid, the Commission shall indicate the reasons for that finding.;

(5) Article 8 is replaced by the following:

Article 8

Verification of the validity of an application

1 On receipt of an application for the authorisation of a traditional food from a third country the Commission shall, without delay, verify whether the application fulfils the requirements of Articles 4 to 6 of this Regulation and of Article 32b of Regulation (EC) No 178/2002.

2 The Commission may consult the Authority on whether the application fulfils the 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 on matters regarding 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 16 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 4 to 6 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.;

(6) Article 10 is amended as follows:

point (e) is added:

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

(7) Annexes I and II are replaced in accordance with the Annex to this Regulation;

(8) Annex III 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 notifications and applications submitted to the Commission from that date.

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