Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 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) 2017/2468

of 20 December 2017

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)

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) Pursuant to Article 20 of Regulation (EU) 2015/2283 the Commission has to adopt implementing acts laying down administrative and scientific requirements concerning traditional foods from third countries.

(3) Without prejudice to Articles 5, 15 and 16 of Regulation (EU) 2015/2283, the Commission should verify whether the notification falls within the scope of that Regulation and the validity of the notification or the application.

(4) Notifications referred to in Article 14 of Regulation (EU) 2015/2283 should contain sufficient information and scientific documentation to allow the Commission to verify the validity and enable Member States and the Authority to evaluate the history of safe use of the traditional food from a third country.

(5) Applications referred to in Article 16 of Regulation (EU) 2015/2283 should contain sufficient information and scientific documentation to allow the Commission to verify the validity and enable the Authority to conduct comprehensive risk assessments.

(6) Where the applicant submits a notification or 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 traditional food from a third

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country, it may not be necessary for the applicant to provide all the data required for the safety assessment where the applicant provides adequate verifiable justification.

(7) The exchange of information between the Commission, the Member States and the Authority should allow that duly reasoned safety objections are submitted to the Commission where necessary.

(8) The opinion of the Authority should provide sufficient information to ascertain whether the proposed use of the traditional food from a third country is safe for consumers.

(9) Pursuant to Article 35(3) of Regulation (EU) 2015/2283 the Commission has to adopt implementing acts laying down the requirements referred to in Article 20 of that Regulation.

(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

Scope and subject matter

This Regulation lays down rules for the implementation of Article 20 of Regulation (EU) 2015/2283 as regards the administrative and scientific requirements concerning traditional foods from third countries and transitional measures referred to in Article 35(3) of that Regulation.

It applies to notifications and applications as referred to in Articles 14 and 16 of Regulation (EU) 2015/2283.

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[(2)] and Regulation (EU) 2015/2283, the following definitions shall apply:

(a) ‘notification’ means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 14 of Regulation (EU) 2015/2283.

(b) ‘application’ means a stand-alone dossier containing the information and the scientific data submitted in accordance with Article 16 of Regulation (EU) 2015/2283.

Article 3

Structure, content and presentation of a notification

1 A notification shall be submitted electronically to the Commission and shall consist of the following:

a a cover letter;

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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 5;

b the scientific data as provided for in Article 6.

4 Where the applicant submits a notification to modify the conditions of use, the specifications, specific labelling requirements or post-market monitoring requirements of an authorised traditional food from a third country, it may not be necessary for the applicant to provide all the data required under Article 6 where the applicant provides verifiable justification explaining that the proposed changes do not affect the results of the existing safety assessment.

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.

Article 4

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;

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.

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

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

a the administrative data as provided for in Article 5;

b the scientific data as provided for in Article 6.

4 Where the applicant submits an application to modify the conditions of use, the specifications, specific labelling requirements or post-market monitoring requirements of an authorised traditional food from a third country, it may not be necessary for the applicant to provide all the data required under Article 6 where the applicant provides verifiable justification explaining that the proposed changes not affect the results of the existing safety assessment.

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.

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Article 5

Administrative data to be provided in a notification or an application

In addition to the information set out in Article 14 of Regulation (EU) 2015/2283, the notifications and the applications shall include the following administrative data:

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

(b) the date of submission of the dossier;

(c) a table of contents of the dossier;

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

(e) a list of the parts of the dossier to be treated as confidential in accordance with Article 23 of Regulation (EU) 2015/2283 and the rules set out in Annex III to this Regulation.

Article 6

Scientific data to be provided in a notification or an application

1 The dossier submitted in support of a notification or an application for the authorisation of a traditional food from a third country shall enable a history of safe use of the traditional food from a third country to be assessed.

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

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

4 The applicant shall propose an overall conclusion on the safety of the proposed uses of the traditional food from a third country. The overall evaluation of potential risk to human health shall be made in the context of known or likely human exposure.

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.

2 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 shall be provided.

3 By way of derogation from paragraph 1 of this Article and without prejudice to Article 14 of Regulation (EU) 2015/2283, a notification may be considered valid even if it does not

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contain all the elements required under Articles 3, 5 and 6 of this Regulation, provided that the applicant has submitted verifiable justification for each missing element.

4 The Commission shall inform the applicant, the Member States and the Authority of the reasons why the notification is considered not valid.

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.

2 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 shall be provided.

3 By way of derogation from paragraph 1 of this Article and without prejudice to Article 16 of Regulation (EU) 2015/2283, 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 verifiable justification for each missing element.

4 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 9

Duly reasoned safety objections

1 On receipt of a valid notification, consultation between the Commission, the Member States and the Authority may be carried out in the first three months of the period established in Article 15(2) of Regulation (EU) 2015/2283.

2 The duly reasoned safety objections submitted by a Member State or the Authority to the Commission in accordance with Article 15(2) of Regulation (EU) 2015/2283 shall include the following information:

a the name and description of the traditional food from a third country;

b a scientific statement indicating why the traditional food from a third country may pose a safety risk to human health.

Article 10

Information to be included in the opinion of the Authority

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

a the identity and characterisation of the traditional food from a third country;

b the assessment of the history of safe use in a third country;

c an overall risk assessment establishing if possible the safety of the traditional food from a third country and highlighting uncertainties and limitations where relevant;

d conclusions.