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► **B** **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)

(OJ L 351, 30.12.2017, p. 55)

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► <u>M1</u>	Commission Implementing Regulation (EU) 2020/1824 of 2 December 2020	L 406	51	3.12.2020

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**laying down administrative and scientific requirements concerning
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*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 ⁽¹⁾ 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****▼M1**

1. A notification shall consist of the following:

- (a) a cover letter;
- (b) a technical dossier;
- (c) a summary of the dossier.

⁽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).

▼ M1

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.

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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.

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.

▼ M1

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.

▼ B*Article 4***Structure, content and presentation of an application****▼ M1**

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.

▼ M1

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

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.

▼ M1

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.

▼ B*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;

▼ M1

- (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;
- (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.

▼ B*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.

▼ M1*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.

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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.

*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.

▼ B*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;

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- (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;

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- (e) 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 11***Transitional measures**

The notifications as referred to in Article 35(2) of Regulation (EU) 2015/2283 shall be submitted to the Commission not later than 1 January 2019.

*Article 12***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.

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ANNEX I

TEMPLATE COVER LETTER ACCOMPANYING A NOTIFICATION OF A TRADITIONAL FOOD FROM A THIRD COUNTRY IN ACCORDANCE WITH ARTICLE 14 OF REGULATION (EU) 2015/2283

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date: ...

Subject: Notification of a traditional food from a third country in accordance with Regulation (EU) 2015/2283

(Please indicate clearly by ticking one of the boxes)

- Notification for an authorisation of a new traditional food.
- Notification for adding, removing or changing the conditions of use of an already authorised traditional food. Please provide a reference to that notification.
- Notification for adding, removing or changing the specifications of an already authorised traditional food. Please provide a reference to that notification.
- Notification for adding, removing or changing additional labelling requirements of an already authorised traditional food. Please provide a reference to that notification.
- Notification for adding, removing or changing the post-market monitoring requirements of an already authorised traditional food. Please provide a reference to that notification.

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

(name(s), address(es)...)

...

...

...

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

Identity of the traditional food:

...

...

Confidentiality. Where appropriate, state whether the application includes confidential data in accordance with Article 23 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
-		

▼ **M1**

Yours sincerely,

Signature ...

Enclosures:

- Complete technical 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
- 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

▼ **M1***ANNEX II***TEMPLATE COVER LETTER ACCOMPANYING AN APPLICATION FOR THE AUTHORISATION OF A TRADITIONAL FOOD FROM A THIRD COUNTRY IN ACCORDANCE WITH ARTICLE 16 OF REGULATION (EU) 2015/2283**

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date: ...

Subject: Application for the authorisation of a traditional food from a third country in accordance with Article 16 of Regulation (EU) 2015/2283

The Applicant(s) or their Representative(s) within the European Union

(name(s), address(es)...) ...

...

...

...

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

Identity of the traditional food:

...

...

Confidentiality. Where appropriate, state whether the application includes confidential data in accordance with Article 23 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 application Summary of the application (non-confidential) List of the parts of the application 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

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- Documented data relating to the duly reasoned safety objections
 - 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
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