
Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2468. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

ANNEX I

Template cover letter accompanying a notification for traditional food from a third country following the requirements of Article 14 of Regulation (EU) 2015/2283

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date: ...

Subject: Notification for authorisation 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 specific 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⁽¹⁾. 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

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Food category	Specific conditions of use	Additional specific labelling requirement
—		

Yours sincerely,

Signature ...

Enclosures:

- # Complete technical dossier
- # Summary of the dossier
- # List of the parts of the dossier requested to be treated as confidential and verifiable justification for such claims
- # Copy of administrative data of applicant(s)

ANNEX II

Template cover letter accompanying an application for traditional food from a third country following the requirements of Article 16 of Regulation (EU) 2015/2283

EUROPEAN COMMISSION

Directorate General

Directorate

Unit

Date: ...

Subject: Application for authorisation of a traditional food from a third country following the requirements of 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:

...

...

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2468. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Confidentiality⁽²⁾. 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

List of the parts of the application requested to be treated as confidential and verifiable justification for such claims

Documented data relating to the duly reasoned safety objections

Copy of administrative data of applicant(s)

ANNEX III

Justification for confidential information

This Annex shall be updated during the notification or application procedure each time an applicant submits a request for information to be treated as confidential.

Where the production process contains confidential data, a non-confidential summary of the production process shall be provided.

Information requested to be considered as confidential	Justification
<i>Section x.y (submitted on YYYY/MM/DD)</i>	
<i>Annex X (submitted on YYYY/MM/DD)</i>	
<i>Section x.y. (submitted on YYYY/MM/DD)</i>	
<i>Annex X (submitted on YYYY/MM/DD)</i>	

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Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2468. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)*

- (1) Applicants should use the format established in Annex III to indicate which information they wish to have treated as confidential and should provide all necessary details to substantiate the request for confidentiality.
- (2) Applicants should use the format established in Annex III to indicate the information they wish to have treated as confidential and should provide all necessary details to substantiate the request for confidentiality.

Changes to legislation:

There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2468. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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Changes and effects yet to be applied to :

- Annex 1 word omitted by [S.I. 2019/702 reg. 50\(c\)](#) (This amendment not applied to legislation.gov.uk. Reg. 50 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(13))
- Annex 1 word omitted by virtue of S.I. 2019/702, reg. 50(c) (as substituted) by [S.I. 2020/1504 reg. 15\(13\)](#)
- Annex 1 words substituted by [S.I. 2019/702 reg. 50\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 50 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(13))
- Annex 1 words substituted by [S.I. 2019/702 reg. 50\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 50 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(13))
- Annex 1 words substituted by S.I. 2019/702, reg. 50(a) (as substituted) by [S.I. 2020/1504 reg. 15\(13\)](#)
- Annex 1 words substituted by S.I. 2019/702, reg. 50(b) (as substituted) by [S.I. 2020/1504 reg. 15\(13\)](#)
- Annex 2 word omitted by [S.I. 2019/702 reg. 51\(c\)](#) (This amendment not applied to legislation.gov.uk. Reg. 51 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(14))
- Annex 2 word omitted by virtue of S.I. 2019/702, reg. 51(c) (as substituted) by [S.I. 2020/1504 reg. 15\(14\)](#)
- Annex 2 words substituted by [S.I. 2019/702 reg. 51\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 51 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(14))
- Annex 2 words substituted by [S.I. 2019/702 reg. 51\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 51 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(14))
- Annex 2 words substituted by S.I. 2019/702, reg. 51(a) (as substituted) by [S.I. 2020/1504 reg. 15\(14\)](#)
- Annex 2 words substituted by S.I. 2019/702, reg. 51(b) (as substituted) by [S.I. 2020/1504 reg. 15\(14\)](#)
- Art. 3(1) words substituted by [S.I. 2019/702 reg. 41](#)
- Art. 4(1) words substituted by [S.I. 2019/702 reg. 42](#)
- Art. 7 words substituted by [S.I. 2019/702 reg. 44\(a\)](#) (This amendment not applied to legislation.gov.uk. Reg. 44 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(12))
- Art. 7(1) words substituted by S.I. 2019/702, reg. 44(a) (as substituted) by [S.I. 2020/1504 reg. 15\(12\)](#)
- Art. 7(2) words substituted by S.I. 2019/702, reg. 44(b) (as substituted) by [S.I. 2020/1504 reg. 15\(12\)](#)
- Art. 7(4) words omitted by [S.I. 2019/702 reg. 44\(b\)](#) (This amendment not applied to legislation.gov.uk. Reg. 44 substituted immediately before IP completion day by S.I. 2020/1504, regs. 1(2), 15(12))
- Art. 7(4) words substituted by S.I. 2019/702, reg. 44(c) (as substituted) by [S.I. 2020/1504 reg. 15\(12\)](#)
- Art. 8 words substituted by [S.I. 2019/702 reg. 45\(a\)](#)
- Art. 8(4) words omitted by [S.I. 2019/702 reg. 45\(b\)](#)
- Art. 9(1) words substituted by [S.I. 2019/702 reg. 46\(a\)](#)
- Art. 9(2) substituted by [S.I. 2019/702 reg. 46\(b\)](#)
- Art. 10(2) words substituted by [S.I. 2019/702 reg. 47](#)

- Art. 11 words substituted by [S.I. 2019/702 reg. 48](#)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/702 reg. 49](#)
- Art. 5(a) words substituted by [S.I. 2019/702 reg. 43](#)