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ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

**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**

ANNEX

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 a modification of the conditions of use of an authorised traditional food. Please provide a reference to that notification.
- ☐ Notification for a modification of the specifications of an authorised traditional food. Please provide a reference to that notification.
- ☐ Notification for a modification of labelling requirements of an 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:

Confidentiality¹. 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 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)

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.

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:

Confidentiality². 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

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.

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.z (submitted on YYYY/MM/DD)</i>	
<i>Annex X (submitted on YYYY/MM/DD)</i>	