



Notification procedure for traditional foods

The notification procedure for traditional food authorisation is set down in Article 14 of Regulation EU 2015/2283. Notifiers who intend to place on the EU market a traditional food from a third country, may opt to submit a notification to the European Commission (EC). When the Member State (MS) or EFSA submit duly reasoned safety objections to the EC the traditional food concerned shall not be authorised for its placing on the EU market. In that case, the notifier may submit an application for traditional food, as set down in Article 16.

Legend:

- Notifier
- Member State (MS)
- EC
- EFSA

Pre-submission phase

Potential notifier requests general pre-submission advice (optional)

Regulation EU 2015/2283

Potential notifier notifies studies commissioned or carried out as of 27 March 2021

Notifier submits notification via e-submission system to the EC

The EC may consult EFSA and MS on the suitability of the notification

EFSA and MS perform the suitability check of the notification

30 working days (legal deadline)*

EFSA and MS provide the suitability consultation outcome to the EC

Submission phase & Suitability check

The EC validates[#] the notification and forwards it to MS and EFSA

MS and EFSA perform the safety evaluation

4 months (legal deadline)*

If no safety objections have been submitted to the EC the traditional food concerned can be authorised for its placing on the market

Post-adoption phase

*In case certain parts of the notification need modification or completion in order to be considered valid, EC requests the missing information to the notifiers.

#In certain cases, the notification might be declared as non-valid.

Application procedure for traditional food

The application procedure for traditional foods authorisation is set down in Article 16 of Regulation EU 2015/2283. Where duly reasoned safety objections were raised by a Member State (MS) or EFSA for a notification for a traditional food from a third country, the applicant has the possibility to submit an application to the European Commission (EC), including the documented data relating to the safety objections raised, and following the requirements established in the legislation and EFSA's guidance documents.



Legend:

- Applicant
- EC
- EFSA

Regulation EU 2015/2283

Pre-submission phase

Potential applicant requests general pre-submission advice (optional)

Potential applicant notifies studies commissioned or carried out as of 27 March 2021

Applicant submits application via e-submission system to the EC

The EC may consult EFSA on the suitability of the application

Receipt of the application by EFSA and suitability check

30 working days (legal deadline)*

EFSA declares the application suitable

Submission phase & suitability check

EC validates[#] the application and mandates EFSA for risk assessment

EFSA launches public consultation on the application dossier

EFSA performs thorough risk assessment

EFSA Panel adopts the scientific output

6 months + Request of additional information*

Confidentiality decision-making and proactive disclosure

Risk assessment phase

EFSA publishes the scientific output

Based on EFSA's opinion the EC prepares a draft Implementing act

Post-adoption phase

*In case certain parts of the application need modification or completion in order to be considered valid, EC requests the missing information to the applicants.

[#]In certain cases, the application might be declared as non-valid (see EFSA administrative guidance for further information).

**In case of a request of additional information, the scientific risk assessment process is put on hold until the requested additional information is supplied by the applicant.