Application procedure for novel foods

The application procedure for novel food authorisation is set down in Article 10 of Regulation EU 2015/2283. Applicants who intend to place on the EU market a novel food should submit an application to the European Commission (EC), following the requirements established in the legislation and EFSA's guidance documents.

Legend:

- Applicant
- European Commission (EC)
- EFSA

Regulation EU 2015/2283

Potential applicant requests general pre-submission advice (optional)

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

Pre-submission phase

Applicant submits the 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

9 months + Request of additional information***

EFSA performs thorough risk assessment

Confidentiality decision-making and proactive disclosure

EFSA Panel adopts the scientific output

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 applicant.

** 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.

EUROPEAN FOOD SAFETY AUTHORITY