Application procedure for GM food and feed

The application procedure is described in Regulation EC 1829/2003 and Commission Implementing Regulation EU 503/2013. Applications should be submitted to the competent Authority of a Member State, which will make the application available to EFSA. The application submitted must be compiled according to EFSA's guidelines. Applications for renewal of authorisations should be submitted to the European Commission (EC).

Regulation EC 1829/2003
Regulation EU 503/2013

Legend:

- Applicant
- Member State
- EC
- EFSA

Pre-submission phase

Potential applicant requests general pre-submission advice (optional)

For renewals only: potential applicant notifies list of intended studies and receives renewal pre-submission advice

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

Submission phase & completeness check

Applicant submits application via e-submission system to Member State Authority or to the EC in case of renewal

The Member State Authority or the EC tasks (mandate) EFSA and makes the application available to EFSA

Receipt of the application by EFSA and completeness check — **30 working days***

Risk assessment phase

EFSA validates# the application

EFSA launches public consultation on the application dossier

6 months + Request of supplementary information**

EFSA performs thorough risk assessment

Confidentiality decision-making and proactive disclosure

EFSA Panel adopts the scientific output

Post-adoption phase

EFSA publishes the scientific output

Based on EFSA's opinion the EC prepares a draft decision granting or refusing the authorisation

*EFSA aims at providing its 1st feedback on Completeness check within 30 working days after receipt of the application. In case certain parts of the application need modification or completion in order to be considered valid, EFSA 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 supplementary information, the scientific risk assessment process is put on hold until the requested supplementary information is supplied by the applicant.

efsa
European Food Safety Authority