Application procedure for feed additives

The application procedure for authorisations is described in Regulation EC 1831/2003. Further scientific and technical requirements and instructions are provided in Commission Regulation EC 429/2008 as well as in the administrative and scientific EFSA Guidance documents. Applications should be submitted to the European Commission (EC), which forwards the application to EFSA EFSA carries out the risk assessment whilst the European Commission decides whether or not to authorise the feed additive.

Legend:

- Applicant
- EC
- EFSA

Regulation EC 1831/2003
Regulation EC 429/2008

Potential applicant requests general pre-submission advice (optional)

For renewals: 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

Pre-submission phase

Applicant submits application via e-submission system to the EC

The EC check the application and forwards it to EFSA for the risk assessment procedure

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

Submission phase & completeness check

EFSA validates# the application

EFSA launches public consultation on the application dossier

6 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 specific Regulation granting or refusing the authorisation

Post-adoption phase

*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 additional information, the scientific risk assessment process is put on hold until the requested additional information is supplied by the applicant.

efsa
European Food Safety Authority