Application procedure for infant formula and follow-on formula

The application procedure for infant formula and follow-on formula authorisation is set down in Regulation EU 609/2013 and Regulation EU 2016/127. Applicants who intend to place on the EU market a formula, should submit an application to the European Commission (EC), following the requirements established in the legislation and EFSA's guidance documents.

Legend:

- Applicant
- EC
- EFSA

Regulation EU 609/2013
Regulation EU 2016/127

Pre-submission phase

Potential applicant requests general pre-submission advice (optional)

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 the EC

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

1 year negotiated deadline + Request of additional 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 specific measure

*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