



Application procedure for nutrient sources added to food

The application procedure for nutrient sources added to food is set down in Regulation EC 1925/2006. The use of these substances is regulated by Directive 2002/46/EC. Applicants who intend to place on the EU market new substances as source of nutrients in food supplements, foods for the general population or foods for specific groups, 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

Pre-submission phase

Potential applicant requests general pre-submission advice (optional)

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

Regulation EC 1925/2006
Directive 2002/46/EC
Regulation EU 609/2013

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

EFSA performs thorough risk assessment

EFSA Panel adopts the scientific output

9 months + Request of additional information**

Confidentiality decision-making and proactive disclosure

Post-adoption phase

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.