Application procedure for exemption from mandatory labelling of food allergens

Regulation EU 1169/2011 establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling. The labelling rules of certain substances or products causing allergies or intolerances are set down in Article 21 of Regulation EU 1169/2011. Applicants who intend to obtain an exemption from mandatory labelling for a food allergen-derived preparation, 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 1169/2011

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

EFSA performs thorough risk assessment

EFSA Panel adopts the scientific output

1 year negotiated deadline + Request of additional information**

Confidentiality decision-making and proactive disclosure

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