General procedure for processing applications for regulated products (except pesticides)

Legend:

- Potential Applicant / Applicant
- European Commission (EC) / Member State Competent Authority (MS)
- EFSA

Potential applicant requests general pre-submission advice (optional)

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

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

Pre-submission phase

Applicant submits the application via e-submission system to EC / MS

EC / MS tasks (mandate) EFSA and makes the application available to EFSA

EFSA performs completeness / suitability check of the application

Submission phase & completeness check

EFSA / EC / MS validates the application

EFSA launches public consultation on the application dossier

EFSA performs thorough risk assessment

EFSA Panels adopt the scientific output

Confidentiality decision-making and proactive disclosure

Risk assessment phase

EFSA publishes the scientific output

Based on EFSA's advice the risk managers take the decision on granting authorisation of substances, products, claims, processes or organisms for their placing or use on the European Union market

Post-adoption phase

Please note that this chart is for general information purposes only. Depending on the relevant sectoral legislation certain details may or may not be applicable. For further information on the legislative framework please consult DG SANTE Health and Food Safety | European Commission (europa.eu) website https://ec.europa.eu/info/departments/health-and-food-safety_en

efsa
European Food Safety Authority