General overview of application procedure for approval of new pesticide active substances and amendment of approval conditions

The application procedure of approval of pesticide active substances is set down in Regulations (EC) No 1107/2009 and Commission Implementing Regulation (EU) 2021/428. Data requirements for active substances are set in Regulation EU 283/2013 and for plant protection products in Regulation EU 284/2013. Further instructions are provided in EFSA administrative guidance and other EFSA scientific Guidance documents and EC guidelines.

Legend:

- Applicant
- European Commission (EC)
- Rapporteur Member State (RMS)
- EFSA

Potential applicant requests general pre-submission advice (optional)

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

Pre-submission phase

Applicant submits IUCLID dossier

RMS performs admissibility check and verifies notified studies

EFSA publishes non-confidential IUCLID dossier and launches public consultation

RMS drafts the Draft Assessment Report (DAR)

RMS submits CLH proposal to ECHA*

EFSA examines DAR and launches public consultation

Confidentiality decision-making and proactive disclosure

Submission phase & completeness check

EFSA performs peer review in consultation with MS experts**

RAC opinion on CLH proposal

EFSA drafts and finalises conclusion taking into account comments received

Risk assessment phase

EFSA publishes final conclusion

EC prepares draft Review Report and Regulation

Standing Committee on Plants, Animals, Food and Feed opinion

Post-adoption phase

* The classification of pesticides is covered by Regulation (EC) No 1272/2008. Proposals for Harmonised Classification and Labelling (CLH) are handled at Risk Assessment Committee (RAC) of ECHA. To allow alignment of the EFSA peer review and ECHA classification processes, the RMS is strongly encouraged to submit a joint DAR/CLH report in parallel to both Agencies. EFSA and ECHA proceed to align procedures to facilitate that a RAC opinion on the harmonised classification of the active substance could be available in time for consideration in the EFSA peer review.

** EFSA organises a consultation of experts, including experts from the RMS and co-RMS and other MSs.

efsa European Food Safety Authority