



EFSA – Ctgb Framework partnership

11th PSN IUCLID network
meeting November 2024

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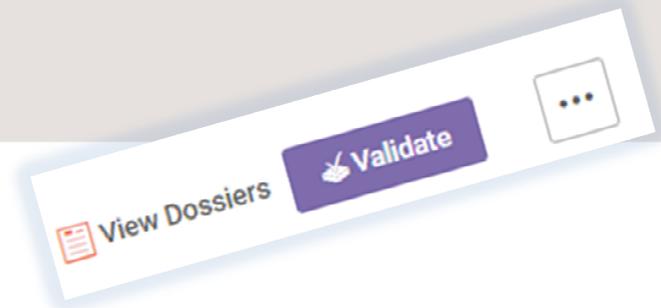
EFSA – CTGB FRAMEWORK PARTNERSHIP - OBJECTIVE

Support in all pre and post-submission activities related to the:

- intake of pesticide dossiers
- further development of dossier Completeness Checks, Notification of Studies (NoS)
- check and light check on confidential/personal data in IUCLID dossiers
- IUCLID improvements.



Intake of dossiers



- Feedback was provided on the content of the IUCLID users manuals → the manuals were revised by EFSA.

Oxyfluorfen 240 g/L EC (SAP24H)

1 Identity of the plant protection product and applicant	5
> 1.1 Identity of the plant protection product, trade name or proposed trade name, and applicant	1
> 1.2 Producer of the plant protection product	2
> 1.3 Producer's development code number if appropriate	
> 1.4 Detailed quantitative and qualitative information on the composition of the plant protection product	2
> Detailed quantitative and qualitative information on the composition of the plant protection product	

Oxyfluorfen AIR4 Renewal

Validation assistant report

Submission checks 0 Quality checks 160

Quality concerns have been detected for this substance dataset / dossier. They are ignored. The use of this tool is without prejudice to the expert assessment of the dossier.

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NoS Assessment

- Further development/adaptation of NoS checklist
- NoS instructions document was published and made available for MSs

Step-by-step instructions for Member States during the notification of studies (NoS) assessment



Instructions for Member States during the notification of studies (NoS) assessment

Publication of the notified information of the studies (NoS) in accordance with Article 32(2) of Regulation (EC) No 178/2002, as amended by the Reg (EU) 2019/1381 of the European Parliament and of the Council of 30 June 2019, and Article 6(1)(b) of EFSA's Practical Arrangements. Pursuant to Article 24 of the EFSA Practical Arrangements on pre-submission phase and public consultation the assessment of the compliance with the obligations of study notifications laid down in Article 32(2) and (3) of Regulation (EU) 2019/1381 was carried out exclusively by the RMS/EMS. The NoS information was extracted from the NoS database during the admissibility check of the dossier.

EFSA Study Identification	Study Title	Study Title (English)	Study Objective	Business Operator	Laboratory Name	Test Item	Notification Date	Study Starting Date	Study Planned Completion Date	Study Type	International Standard Organisation	Intended study area
EFSA-2021-0000000X	Template	Template	Template	Template	Template	Template	Template	Template	Template	Template	Template	Template

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IUCLID IMPROVEMENTS

- Feedback provided on the proposed rule checking completeness of FLEXIBLE_RECORD.GAP.

Rules	Description	Flexible summary
QLT_PPP_116	FLEXIBLE_SUMMARY.ResiduesInLivestock must be provided in case KS, WoE is present in the section Feeding studies (ENDPOINT_STUDY_RECORD.ResiduesInLivestock)	FLEXIBLE_SUMMARY.ResiduesInLivestock
QLT_PPP_124	Flexible Summary Endocrine disrupting properties must be provided	FLEXIBLE_SUMMARY.EndocrineDisruptingPropert
QLT_PPP_125	Flexible Summary MRL Proposal must be provided	FLEXIBLE_SUMMARY.MRLProposal
QLT_PPP_126	Flexible Summary Expected Exposure must be provided	FLEXIBLE_SUMMARY.ExpectedExposure
QLT_PPP_127	Flexible Summary Residue Definition Fate must be provided	FLEXIBLE_SUMMARY.DefinitionResidueFate
QLT_PPP_131	Flexible Summary Ecotoxicology Risk Assessment must be provided	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPes
QLT_PPP_128	Flexible Summary Effects on aquatic organisms must be provided	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting
QLT_PPP_129	Flexible Summary Relevance of metabolites in ground water must be provided	FLEXIBLE_SUMMARY.RelevantMetabolitesGround
QLT_PPP_057	Flexible Summary Toxicological reference values must be provided	FLEXIBLE_SUMMARY.ToxRefValues
QLT_PPP_132	Flexible Summary Data on exposure must be provided	FLEXIBLE_SUMMARY.NonDietaryExpo
QLT_PPP_133	Flexible Summary Information on metabolites must be provided	FLEXIBLE_SUMMARY.Metabolites
QLT_PPP_134	Flexible Summary Estimation of concentrations in soil must be provided	FLEXIBLE_SUMMARY.EstConcSoil
QLT_PPP_135	Flexible Summary Estimation of concentrations in groundwater must be provided	FLEXIBLE_SUMMARY.EstConcGroundwater
QLT_PPP_136	Flexible Summary Estimation of concentrations in surface water and sediment must be provided	FLEXIBLE_SUMMARY.EstConcWaterSed



FORESEEN ACTIVITIES

- Feedback and support during completeness check of DAR/RAR
- Review of the CLH report and generated report on corresponding section of the DAR/RAR Vol. 1
- Feedback on already rolled out templates for Doc M CA, CP Physical and Chemical properties and List of Endpoints
- Feedback on the report Appendix 1 for the assessment of secondary metabolites.

