



SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT

Version 2 - 03/04/2020

EFSA Technical group on IUCLID for PESTICIDES

Terms of Reference (ToR)

1. Background

In September 2019, EFSA and ECHA agreed to launch an IUCLID for PESTICIDES pilot project aiming at testing the suitability of IUCLID functionalities for Pesticides Dossiers management and assessment for possible inclusion in the deliverables expected in March 2021 in relation to the Transparency Regulation implementation. The pilot investigated how much of the IUCLID eco-system could be adopted or adapted in the short or long term. The pilot focused on the technical aspects of the usage of IUCLID cloud instances as a managed service, knowledge transfer and support to build expertise with IUCLID. The first phase of the pilot was successful, demonstrating IUCLID to be suitable for pesticides dossiers. It provided the information necessary to define a minimum viable product (MVP) which could be delivered for the submission and management of pesticides dossiers by March 2021. EFSA has accepted ECHA's proposal of the MVP. This decision also supports the proposed amendments to EU pesticides legislation specifying IUCLID format for renewal dossiers and further aligns the data requirements for biocides and pesticides dossiers. The project foresees the participation of all relevant actors in order to review and propose modifications to IUCLID, to test IUCLID releases for suitability for pesticides and to contribute to the development of features and tools which could automate pesticide dossier processing. EFSA established a dedicated forum for technical exchanges, for informing and gathering input from participants on a specific technical area. The continuation of technical exchanges on IUCLID in this case will take place through the Technical Group on "EFSA Technical group on IUCLID for PESTI-CIDES".

The Project

Project will implement the work packages defined in a revised Service Legal Agreement between EFSA and ECHA. The major deliverable being the deployment of IUCLID MVP cloud services for industry, authorities and the public. The Technical group will continue its activities, providing technical expertise on pesticide information management, to support implementation by March 2021.

The project deliverables are the following

- Web based solution for creating PPP dossiers in an IUCLID format (taking into account the findings of the pilot project)
- Submission of PPP dossiers using a submission portal
- Dossier validation against agreed PPP validation rules
- Dossier annotation functionality to support the reviewers work
- Support for collecting and accessing confidentiality claims

Support for creating a public version of the dossier for use in the EFSA publication process

2. Terms of Reference

Members of the EFSA Technical group on IUCLID for PESTICIDES are expected to:

- Agree tasks to be included in the execution phase and nominate people to perform them
- Attend specific meetings (face-to face meetings, several teleconferences)
- Contribute to the analysis and definition of changes to IUCLID
- Provide input to IUCLID for Pesticides configuration, filtering rules, validation rules and report templates
- Participate in testing of IUCLID releases
- · Review documentation and training materials
- Share knowledge and expertise with other stakeholders
- Provide feedback from experience to define developments beyond March 2021

3. Composition of the Technical group

The composition of the Technical group IUCLID for PESTICIDES has evolved over time.

- In August and September 2019, a call for expression of interest was send to all Member States, to specific registered stakeholders dedicated to Pesticides area (category: Business and food industry, Environmental/Health NGOs and Advocacy groups), to ECHA and to the European Commission. All expressions of interest received were accepted as members of the EFSA Technical group IUCLID for PESTICIDES – pilot.
- In March 2020, a call for expression of interest was sent to all Member States and to one stake-holder representative (category: Business and food industry) with the objective to reinforce the competence of the EFSA Technical group with 3 additional members with experience in microorganism PESTICIDE dossiers. 3 new members were selected (2 Member States, 1 Business and food Industry) based on the experience in PESTICIDES DAR-RAR for pesticide microorganisms risk assessment and gender balance.
- Today, the EFSA Technical group on IUCLID for PESTICIDES is currently composed of representatives from EFSA, ECHA, European Commission, 7 Member States, 3 pesticide Industry associations (registered stakeholders, category: Business and food industry).

4. Timelines

The EFSA Technical group on IUCLID for PESTICIDES will last for 20 months, between October 2019 to June 2021 with an EFSA-ECHA milestone set at mid-term (targeted February 2020) to report back experience and make recommendations for the next steps. Each meeting (tele-meeting, physical meeting) of the EFSA Technical group will be announced publicly and the following documents will be made available on the EFSA webpage: agenda, participants list, presentations and a summary of the main issues discussed.

Technical group planning:

 September 2019: creation of the EFSA Technical group on PESTICIDES – IUCLID MILE-STONE 1 (finalised)

Pilot phase:

- 6-7 November 2019: face-to-face meeting, EFSA, Parma
- November 2019 to February 2020: Pilot phase I execution
- 26-27 February 2020: face-to-face meeting, Parma (transformed into physical meeting) MILE-STONE 2 (finalised)

Design phase:

- February 2020 to March 2021: project phase II development, including ad-hoc teleconferences on specific topics
- 21-22 April 2020: teleconference, EFSA
- June 2020: physical meeting, EFSA, Parma
- October 2020: physical meeting, EFSA, Parma
- January 2021: teleconference, EFSA
- March 2021: go live of MVP Solution ECHA-EFSA IUCLID for PESTICIDES **MILESTONE 3** Implementation phase:
- March 2021 June 2021: implement, collect feedback for improvement, identify new requirements to be implemented, revise training materials.