



SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT (REPRO)

# 3<sup>rd</sup> Technical group meeting on IUCLID for PESTICIDES - Report

### 21-22 April 2020

## <u>Introduction</u>

EFSA's 3<sup>rd</sup> Technical group meeting on IUCLID for PESTICIDES took place virtually due to the COVID-19 restrictions on physical meetings in Italy. The meeting was organised in parallel sub-groups. The objective was to agree adaptations to OECD Harmonised Templates (OHTs) to be proposed on behalf of the EFSA Technical group to the OECD expert group by the end of April for possible endorsement and afterwards for inclusion in the October release of IUCLID (i.e. straight forward and non-controversial amendments). OHTs requiring a more thorough review (i.e. deeper review and further discussion needed) were identified and will be analysed at a later phase in the project. Stakeholder, Member State, ECHA, DG SANTE and EFSA representatives participated in the meeting, with the full list of participants available on EFSA's website.<sup>1</sup>

### Item 1: Section 3 /GAP of the PESTICIDE dossier

The sub-group discussed the OHT 88 'Effectiveness against target organisms and intended uses' and the link to the GAP table. It was agreed that one OHT template will cover one study. The most critical points discussed were the picklists 'Target organisms', 'Function addressed', 'Method of application', 'Mode of action' while a question was raised on the need to add the block 'Materials and methods' to the OHT 88. The GAP table was presented and discussed.

#### Item 2: Section 6/Residues of the PESTICIDE dossier

The sub-group discussed and proposed changes to OHT 85-2, OHT 85-3, OHT 85-4, OHT 85-5, OHT 85-8, OHT 85-9, OHT 85-10. The need for new templates were identified for: Metabolism in fish, Residues in fish & Residues in honey, pollen and bee products.

### <u>Item3: Section 8/Ecotoxicology of the PESTICIDE dossier</u>

The sub-group discussed the OHT 45, OHT 46, OHT 53 and proposed changes in the documents. In addition, the sub-group discussed OHT 53, OHT 48-2, OHT 75-3 for which more thorough review and further discussions were identified. The need for Endocrine Disruptor Assessment data outside of the OHTs were discussed.

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<sup>&</sup>lt;sup>1</sup> https://www.efsa.europa.eu/sites/default/files/event/2020/iuclid-3rd/Participants.pdf.

#### Item 4: Submission type MRL

EFSA presented a proposal for structuring the MRL application into IUCLID using the current IUCLID structure, eliminating sections not relevant. The proposal was well received and the following items were discussed: full studies for residues trials, avoid to submit studies already submitted/evaluated, the ability to select multiple MRL submission types, the necessity to access specific tools for MRL risk assessment, the proof of registration in third countries in case of Import Tolerance MRL applications. It was agreed that the data requirements from the MRL application form will be translated into an excel file for further comments.

## <u>Item 5: Submission type Micro-organisms</u>

The sub-groups were informed that the contractor (knoell Germany GmbH) is currently working at developing the proof of concept for the micro-organism active substance into IUCLID. A full submission type for the product specific for micro-organisms will be prepared for the October 2020 release of IUCLID according to Part B for both product and substance microorganism. The mapping of the existing IUCLID table of content for chemical products and the planned table of content for micro-organisms products have been developed and are available for commenting. Some comments were raised on the potential need for additional documents and possible changes for some OHTs.

### Item 6: Section 7/FATE of the PESTICIDE dossier

The sub-group discussed the OHT 29, OHT 30, OHT 34, OHT 37, OHT 39, OHT 40 and changes were proposed in the documents. The need for new template were identified for: aged sorption, transport via air. The sub-group identified the need for improved reporting of kinetic evaluation and assessment of validity criteria.

#### The next phase of the Technical group

The next meetings are scheduled to take place in June and October 2020.