



## 5<sup>th</sup> Technical group meeting on IUCLID for PESTICIDES - Report

**9 November 2020**

### Introduction

EFSA's 5<sup>th</sup> Technical group meeting on IUCLID for PESTICIDES took place virtually. The main objective was to summarise the activities covered and milestones achieved since the last meeting, held in June 2020. Stakeholders, Member States, ECHA, DG SANTE and EFSA representatives participated in the meeting, with the full list of participants available on EFSA's website<sup>1</sup>.

### Items 1 & 2

The chair opened the virtual meeting and welcomed participants. The agenda was adopted with one item added under AoB.

### Item 3: Update status progress of TG IUCLID - Pesticides submission types and cross walks

An update was given on the status of the validation assistant, the submission portal, the 'secure Agency instance' of IUCLID, on the cross walks (i.e. the mapping of the current documents to the IUCLID ToC) and an overview of the milestones, both achieved and upcoming. It was highlighted that the validation assistant can still be refined at this stage so input on the rules is welcome and that currently there are no blocking rules but only warnings.

Technical Group members were informed that Member States need to inform EFSA on which authorities will need access to IUCLID as soon as possible. A survey will soon be sent out to the identified authorities in order to collect necessary information for establishing connectivity to IUCLID.

### Item 4: Feedback from meetings - EFSA IUCLID PSN meeting and EC PAFF meeting

Feedback was provided jointly by EFSA and DG SANTE on the IUCLID Pesticide Steering Network meeting held on 6 October 2020 and on the Standing Committee on Plants, Animals, Food and Feed- Section Phytopharmaceuticals - Legislation meeting held on 22 October 2020.

During the discussion that followed, the following was clarified:

- The decision on the deadline extension for a number of active substances does not imply that dossiers already submitted need to be converted to the IUCLID format. For renewal dossiers, if the submission deadline is later than 27 March 2021 the mandatory format is IUCLID.

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<sup>1</sup> <https://www.efsa.europa.eu/sites/default/files/event/2020/iuclid-5th/Participants.pdf>.

- For new active substances, an implementing act is currently being prepared, which should be published before 27 March 2021 making IUCLID the mandatory format for submission. MRLs is currently also under discussion, but will very likely be published at a later stage.
- The drafts of the three Practical Arrangements on transparency and confidentiality, confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009 and pre-submission phase and public consultations will be shared with Member States representatives of the DG SANTE Expert Group on the General Food Law and the stakeholders of the DG SANTE Advisory Group on the Food Chain and Animal and Plant Health and EFSA's Sounding Board, who will have the opportunity to send comments. The Draft Practical Arrangement on the pre-submission phase and public consultations makes reference to notification of studies, public consultations, and pre-submission advice.
- The requirements for the data format for the time being focuses on active substances and may be expanded to include products in the future. IUCLID would not require major changes as regards the data format as it is already being used for biocidal products.

#### Item 4.1: Feedback from meetings - ECPA technical workshop & ABIM conference on IUCLID implementation

Applicants and Member States expressed a lot of interest in IUCLID at both meetings and an overview of the feedback gathered was provided. On Hypercare, it was noted that, whereas the programme is appreciated, its starting is too soon (they would have wanted more time to plan resources) and does not foresee any submission pertaining to biopesticides. It is to be confirmed whether a new active substance will be available for submission in the relevant period and, if so, whether an exception can be made and participation granted in order not to exclude this sector from Hypercare.

#### Item 5: IUCLID 6.5 release LIVE 28 OCT

A presentation of the IUCLID 6.5 release was provided, highlighting the changes included after the last user testing performed with the feedback from the IUCLID Technical group. The release of IUCLID 6.5 including the 4 EFSA Pesticide submission types is one of the main achievements of the IUCLID Technical Group and close collaboration between EFSA and ECHA.

#### Item 6: Update on EFSA support IUCLID HYPERCARE programme & trainings & helpdesk

A status overview of the upcoming Hypercare programme and an update on the planning of the training activities were provided. It was clarified that Training (i.e. course, manuals, technical documentation, etc) represents the baseline of the support provided by EFSA and will be available to all users. Hypercare on the other hand will provide additional support to the early submitters in IUCLID.

#### Item 7: IUCLID Feature - Filtering rule consultation

An overview on the dissemination preview and on the filtering rules currently implemented was provided. All stakeholders, in particular applicants, are being consulted and are encouraged to provide feedback on the outcome of the filtering rules, in particular to make sure that confidential information will not be made publicly available. Feedback to be provided by 15 January 2021 at the latest using this Google Form; <https://forms.gle/eLXKBhkchsWhzRfb7>

As REACH rules (which have been used extensively over the years) are the baseline, it is recommended to focus on checking documents newly created in the PPP context.

#### Item 8: IUCLID feature: Report generator – modular approach – areas for collaboration

It was clarified that the report generator is available on the [dedicated webpage](#). Custom reports will be easier to generate with the modular approach. Modules will be updated regularly once the OHTs are also updated to the latest version of IUCLID.

#### Item 9: Update on submission portal and Agency instance of IUCLID

The presentation, including a DEMO, of the submission portal and Agency instance of IUCLID was given to illustrate the use of the functionalities by different users. ECHA highlighted the [ECHA webinar](#) planned on 11 November 2020 which covers the latest IUCLID version (6.5) published on 28 October 2020.

#### AoB

There was a request to provide an update on the technical group on the Notification of Studies. The minutes of the second meeting held on 20-21 October 2020 are available on the EFSA website: <https://www.efsa.europa.eu/en/events/event/2nd-meeting-efsa-technical-group-notification-studies-database>

The next IUCLID Technical Group Core meeting will be held in January 2021. Information on upcoming meetings is available [here](#).