PESTICIDES PEER REVIEW UNIT

Network on Pesticides Steering Minutes of the 26th meeting

Held on 6 October 2020, TELE-conference

(Agreed on 23 October 2020)

Participants

- **Network Representatives of Member States (including EFTA Countries):**

Country	Name
Austria	Klaus LEDER
Belgium	Philippe CASTELAIN
Denmark	Alf AAGAARD
Estonia	Eva LIND
Finland	Kaija KALLIO-MANNILA
France	Suzanne PIERLOT
Germany	Eva GOCLIK
Greece	Danae PITAROKILI
Hungary	Tamás GRIFF
Ireland	Aidan MOODY
Latvia	Līga BRENCE
Netherlands	Sjon KORTEKAAS, Carla HUIZING
Norway	Anna MEHL
Portugal	Bento de CARVALHO
Slovakia	Marta GALUSOVA
Spain	José Luis ALONSO-PRADOS

- **Observers**

  Agathi CHARISTOU

- **European Commission:**

  Valerio SPINOSI (DG SANTE)
  Marc LEGUEN DE LACROIX (DG SANTE)
  Volker WACHTLER (DG SANTE)

- **ECHA**

Francois LE GOFF
Zsolt GABOR
Eoin CREEDON

- **EFSA:**

Application Desk Unit (Karine LHEUREUX, Head of Unit, Chair)
Pesticide Residues Unit (Bénédicte VAGENENDE, Head of Unit a.i.)
Pesticide Peer Review Unit (Manuela TIRAMANI, Head of Unit)
Legal & Assurance services (Chiara MACCHI)
Application Desk Unit (Silvia MAZZEGA)
Pesticide Residues Unit (Hermine REICH)
Pesticide Peer Review Unit (Chloé DE LENTDECKER)
Pesticide Residues Unit (Lucien FERREIRA DA COSTA)
Evidence Management DATA Unit (Jane RICHARDSON)
Pesticide Peer Review Unit (Federica Adele CRIVELLENTE)
Pesticide Residues Unit (Giovanni BERNASCONI)
Pesticide Peer Review Unit (Maria CIAULA)
Pesticide Residues Unit (Alessia Pia SCARLATO)

1. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Kristina VALIONIENĖ (Lithuania)

2. Adoption of agenda

The agenda was adopted without changes.

3. Topics for discussion

4. IUCLID for pesticides – where do we come from and where are we today?

EFSA presented the current status of development of IUCLID for pesticides focusing on the activities of the Technical Group. Terms of reference, composition and timelines of the Technical Group were presented. Progresses and achievements have been shared. The documents and minutes of the core meetings of the group are publicly available to increase transparency of the process http://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation

Four submission types will be available with the 28 October release of the IUCLID update: New active substance dossier, Renewal dossier, MRL submission and Basic substance dossier.

Q&A

After the presentation the following questions have been received:

-clarification about the meaning of "Substance of concern".

EFSA clarified that IUCLID is structured in different datasets: one dataset for reporting data on the mixture, one for data on the active substance/s and one for data on "other substances" such as metabolites. It was clarified that the correct terminology is "Other substance".

-clarifications about the mandatory date for using IUCLID and specific implementation for basic substances.

EFSA clarified that IUCLID will be ready for receiving all submission types from March 2021 onwards and will strive to have all pesticides submissions in 1 single system.

EC (European Commission) indicated that the new Implementing Act for renewal applications is specifying IUCLID as dossier format and will be presented for vote in the October PAFF. For Basic substances an update of the guidance is under preparation. For the submission of new active substance and MRL dossiers there will be soon a communication regarding the dossier format. Furthermore, Commission is reflecting on how the IUCLID format can be formalised for all processes (see also PAFF Legislation 22-23 October agenda https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20201022_ppl_agenda.pdf). EC and EFSA are strongly supporting the use of IUCLID as dossier format for all EU approval and MRL applications as of March 2021.

It has been highlighted that the Report generator is a flexible tool and the format will be further developed to support the Assessment Report preparation. Initially SANCO guidance will be followed, but later on amendments can be implemented. EFSA clarified that the use of the Report generator is not mandatory for the preparation of the Assessment Reports.

5. IUCLID training and supporting material

EFSA is aware of the need to provide support to MSs and applicants in the use of IUCLID for PPP and has launched a call for tender for seeking support with

providing training and generating the necessary documentation. The contract is foreseen to be awarded soon and the first supporting materials is expected by the end of year 2020 while the first training is expected to be delivered in January 2021.

Objectives of the tender.

- Analyse existing IUCLID training material and set up an inventory (e.g. a knowledge management platform/portal) to catalogue and provide public access to old and new material
- Prepare technical documentation to support applicants in preparing pesticides dossiers in IUCLID and scientists (risk assessors) in evaluating the information submitted
- Develop training material for stakeholders involved in the European Pesticides approval process on the use of IUCLID for the submission and evaluation of pesticide dossiers
- Deliver trainings. Trainings will be delivered virtually initially, afterwards physically whenever possible due to contingency.
- Support the EFSA Helpdesk in building and maintaining an inventory of frequently asked questions and to use the feedback to further improve the documentation and training material.

The next IUCLID release will be live on October 28th2020 and EFSA has encouraged participants to login and start using the tool.

Q&A

After the presentation MSs shared input on training needs for Member State Competent Authorities.

- EFSA clarified that a cross walk from KCA - KCP to IUCLID ToC is under preparation and will be available shortly.
- MS expressed differing training needs based on their level of knowledge of IUCLID and phases of the workflow, whilst clarifying that training on dossier preparation is a specific need for applicants. It was also highlighted that special training on the use of annotations is required.
- Training on procedural steps (e.g. receipt of dossier, completeness check, cut-off criteria assessment) is also desired together with specific training on assessing the completeness of the information presented. This should be in alignment with existing guidance and guidelines. The IUCLID manual should provide clear indications on the mandatory fields and documents to be completed by the applicant and to be checked by the MS during the completeness check.
- Training at a later stage is also needed as first dossiers will be received in August 2021 and practical help might be needed also later on. Recording of trainings will help achieving the constant availability of the material online (but courses will be repeated if possible).
- Concerns were raised by several MS about potential delays in the evaluation caused by the introduction of the new system.

EFSA took note of all input and reassured that training will address MS concerns and needs.

Training is foreseen on a variety of topics and both for beginner and advanced level, addressing specific needs for different user groups to the extent possible. Knowledge platform will be in place as a single point of access to supporting materials related to the New Transparency Regulation.

Similar trainings will be organised for applicants, starting in January 2021, with a focus on completion of IUCLID documents.

Action points: EFSA asked participants to share further input on training needs by 30 October 2020. Also, at a later stage, MS are invited to share their feedback on the training material in order to optimise the training material.

6. Hypercare programme for first dossiers submissions

EFSA presented the draft HYPERCARE programme, that will start from November 2020 and will last for one year (end November 2021).

The HYPERCARE team will be horizontal, involving different EFSA teams, ECHA and the EC.

The programme is meant to give early submitters and evaluators special support with IUCLID implementation. The RMS and applicants of the selected dossiers will be active participants and Co-RMS and other MS will be observers and invited to all meetings.

Participants to the programme will be selected by EFSA by the end of October based on the following selection criteria:

- Deadline for renewal of the active substance on or after March 2021
- Newly extended deadlines (extension to be confirmed by EC) fall between July-August 2021 and application form for renewal received by EFSA
- Joint submission will be preferred
- One application/one applicant
- If the application for renewal of approval includes also an MRL application, it will be preferred.

The draft list of possible candidates before application of selection criteria by EFSA has been shown and is following the EC proposal (PAFF committee July and Oct).

EFSA highlighted the benefits deriving from the implementation of the HYPERCARE programme:

- Smooth transition for both applicants and evaluator MS
- All the feedback and input from the programme will help prioritisation of future IUCLID developments
- Adjust training material for all with feedback and comments received from early submitters during the HYPERCARE programme.

In order to run the HYPERCARE programme a specific sub-group of the PSN will be created. The sub-group HYPERCARE PSN will have bi-weekly tele-meetings on specific topics and every six weeks more general topics will be discussed. Topics to be discussed will be planned in advance. Follow-up will be provided with one-to-one sessions, if needed. 2 tele-meetings will be dedicated to MRLs and training

materials on MRLs will be prioritised. No confidential information will be handled by the group.

Q&A

After the presentation, the following points have been discussed:

- MS proposed to extend the duration of the programme in order to cover also the assessment phase and also requested to consider extending the applicability to other active substances. EFSA will consider the extension of the duration of the programme. About proposal of extending duration and number of substances, EFSA clarified that limiting the scope of the HYPERCARE programme will help delivering better quality support to early submitters but training material and developed experience will be of help to all future applicants.
- It was also proposed that MS should participate to the selection of participants. EFSA confirmed that expectation is that all MS participate, but expression of interest will be taken into account.
- Question has been made on how EFSA will manage direct involvement of observer participants. EFSA reassured MS that the agenda will be shared well in advance and material will be made available and all MS will be invited to all meetings that will be primarily held in tele format.
- MS requested to consider including also NAS applications in the Hypercare programme. As currently information on expected NAS and MRL dossiers after 27 March 2021 is not available, MS are invited to share such information with EFSA and EC.
- MS question why no transitional period for the implementation is discussed since the legal background for all planned submission types is still missing and MS are not familiar with IUCLID for PPP related evaluation.

EFSA has taken notes of all comments received and will further revise the list of substances that will be selected for the programme.

EC added further clarifications on the scope of the programme. The HYPERCARE programme is under the lead of EFSA and EFSA should decide on the number of selected substances. Nevertheless, the selection of a limited number of substances guarantees a balance between workability and inclusivity. 15 applications is considered a workable number. The programme is of high value as it will help developing best practice on the completion of IUCLID documents and no confidential information will be shared. Learning time will pay at long term in quality of the dossiers.

EFSA also clarified that the HYPERCARE programme is limited to give technical support on the use of IUCLID and will not provide pre-submission advice nor pre-risk assessment support.

EFSA also confirmed that previous communication on the future use of IUCLID and the HYPERCARE programme has been done to applicants (ECPA, EFSA, IBMA), and MSs are strongly encouraged to support IUCLID for all dossier submissions from 27 March 2021 and avoid double submission in another format than IUCLID.

All the feedback and input from the HYPERCARE programme will help prioritisation of future IUCLID developments and adjust EFSA training material publicly available for all and regularly updated over time.

Action points: MS to share names of referent experts that will participate in PSN Hypercare sub-group by 30 October 2020.

MS to inform EFSA and EC by 30 October 2020 on expected NAS and MRL dossiers that will be submitted shortly after 27/03/2021.

7. IUCLID in practice: format and features

EFSA presented IUCLID format. The Table of Contents (TOC) functionality has been shown together with a quick overview of the structure of the MRL submission type as example. The general organisation of IUCLID in endpoint study records and endpoint study summaries has been explained. EFSA also clarified that harmonisation has been sought with existing terminologies e.g. EPPO codes.

The main features of IUCLID (validation assistant rules, PDF creation, filtering tool of confidential information, advanced search, compare function, versions of the dossiers, commenting/annotation) have been described, reminding that these features are optional, not mandatory.

Specific work done on the GAP reporting has been shown. One generic format for describing the GAP was developed so to describe the GAP in an unambiguous way. The form has been developed to be applicable to both chemicals and microbials applications. Picklists for certain parameters have been implemented.

The same GAP format is used for the different submission types.

A practical demonstration with the DEMO version of IUCLID has been given.

Advanced search tool has been shown.

The tool allows to view all the selected records shown from the newest one. Also, a comparison tool is available, allowing to compare dossiers and highlighting details and differences between versions.

Annotation function has also been shown.

The option to attach supporting documents to section 11 in separate entries (so to attach the draft evaluation report prepared by the applicant for example) has been demonstrated.

The benefits of the tool have been highlighted as IUCLID will contribute to develop better practice, promote harmonisation and will function as single hub for all submissions.

Q&A

After the presentation, clarification on how to manage attachments/ refined documents has been sought by MS.

EFSA clarified that additional supportive documents can be uploaded by the applicant in section 11 if they do not fit in other dossier sections. Indeed, some of the documents currently submitted by the applicant e.g. document N2 (LoEP) or document M (study summaries) would be in the future, with the developments of IUCLID, generated by the tool automatically.

The IUCLID format is available for dossier building, EFSA will work with the RMS to define mandatory fields and include this in the validation assistant as an iterative process.

EFSA has also clarified that dossiers cannot be edited, but they can be annotated. Applicant can submit another version taking into account the comments from the RMS. Discussion is ongoing in the Technical Group IUCLID for PESTICIDES about the best way to tackle cases where the MS has to make changes to the dossier during the risk assessment phase (e.g. refinements to the modelling has to be done by the MS) and this will be further discussed.

The exhaustive list of the new features available in IUCLID will be provided at the time of the release of October 2020, together with the supporting documentation. Among others, the following features linked to the endpoint study records were evidenced during the meeting:

- Bibliographic metadata can be added to the literature references
- EPPO harmonisation of terminology has been implemented.

8. Roadmap for future steps –medium and long-term perspectives

Overall project plan was presented by EFSA.

The first phase of the project has been focussing on format development.

Three further areas will be developed starting from November 2020:

- validation tool refining

- report generator development

- ECHA cloud services

Regarding confidentiality assessment, there is the possibility to flag as confidential documents or dossier sections. The dissemination preview function will show if data will be published or not, based on confidentiality filtering function. Further details on confidentiality decisions will be clarified in the respective practical arrangements EFSA is developing. EFSA clarified that IUCLID has a migration function, meaning that when IUCLID is updated to a newer version, stored data will be migrated to the new format
EFSA has also highlighted the areas of further work and the long-term goals in view of the European Strategy requirements (One substance, one assessment approach).

Action points: MS will receive a request to complete (via EU Survey) the expected number of IUCLID users and name of IT contact person in their organisation.

9. Cooperation and governance for IUCLID for pesticides

EFSA has proposed the governance actions that will be put into place at longer term.

At this scope an IUCLID subgroup of EFSA Pesticides steering Network will be created.

The subgroup will meet yearly starting from the first half of 2021. In between the meetings written consultations on proposed changes resulting from development work of EFSA Technical Group on IUCLID might take place.

The IUCLID subgroup will channel all requests for changes coming from pesticides submissions to the OECD IUCLID User Group Expert Panel who is the body deciding on the IUCLID changes to be implemented.

Member states will be invited at a later stage to nominate experts with IUCLID expertise.

Increased cooperation with MS is envisaged in the Transparency Regulation. New tasking grant is under preparation for this scope including call for support from MS in further IUCLID developments.

Action points: MS to express potential interest to cooperate on IUCLID through Tasking grant, by 30 October 2020.

10. AoB

- **Update on the workshop on the use of BMD approach**

As agreed during the Peer Review Meeting on general recurring issues in mammalian toxicology (October 2019), a workshop to discuss the use of the benchmark dose approach for pesticide risk assessment should have been organised in 2020, as anticipated during the last PSN meeting (March 2020). However, considering the guidance on BMD is still under development, the workshop will be postponed to 2022 and an info session will be organized with MSs in 2021.