# Pesticide Steering Network – IUCLID Subgroup 6<sup>th</sup> meeting



28 March 2023

General session: 09:00-13:00; Risk assessor's session: 14:30-16:30

Minutes agreed on 21 April 2023



Location: Web-conference

**Attendees:** 

o Network Participants:

<ul> <li>Network Partic</li> </ul>	
Country	Name
Austria	Klaus LEDER
Belgium	Philippe CASTELAIN
Belgium	Wim HOOGHE
Croatia	Ana ČALE
Croatia	Karlo HALTRICH
Croatia	Ana MRNJAVCIC VOJVODA
Croatia	Dubravka ČELIG
Czech Republic	Martin BENÍŠEK
Czech Republic	Milan SVOBODA
Czech Republic	Hana KUBÁTOVÁ-HIRSOVÁ
Denmark	Alf AAGARD
Estonia	Elise JOONAS
Finland	Marika PÄÄLLYSAHO
France	Suzanne PIERLOT
France	Mathieu BOURGET
Germany	Daniela MARUTZKY
Germany	Falko FRENZEL
Germany	Tobias OPIALLA
Greece	Ourania MELITA
Hungary	Flórián SÁNDOR
Hungary	György HEGEDÜS
Ireland	Sadhbh O'DWYER
Italy	Angela SANTILIO
Lithuania	Elena BARZDENIENE
Malta	Francesca PACE
Netherlands	Cornelia BLAGA
Netherlands	Hanneke WESTLAND
Norway	Louise ARNESEN
Poland	Monika DEBEK
Portugal	Bento CARVALHO
Slovak Republic	Lenka GURSKÁ KRAJČOVIČOVÁ
Slovenia	Polona SLOKAN
Slovenia	Sanja VRANAC
Spain	Jose Luis ALONSO-PRADOS
- 1	CL : L CC ÖCTEDWALL
Sweden	Christoffer ÖSTERWALL



#### Stakeholders:

Organization	Name
Crop Life Europe	Monika BROSS
Crop Life Europe	Andrew WHYTE
Crop Life Europe	Marc TEIWES
Crop Life Europe	Viktoria ERIKSSON (ad-hoc)
European Crop Care Association	Jose Luis JUANES
European Crop Care Association	Hans MATTAAR
European Crop Care Association	Manuel DUARTE
International Biocontrol Manufacturers Association	Adi CORNELESE
International Biocontrol Manufacturers Association	Agata JAKUBOWSKA

- European Commission: Valerio SPINOSI (DG SANTE)
- Other EU Agencies representatives:
   François De GOFF, Dorota BURCHARD-SOSNOWSKA (ECHA)

#### o EFSA:

Plant Health & Pesticides Residues Unit: Giovanni BERNASCONI (**chair**), Alessia Pia SCARLATO, Lucien FERREIRA

Front-Desk & Workforce Planning Unit: Päivi ARVILOMMI, Alessandro DELFINO, Alessandra GIAROLA, Chiara MACCHI, Silvia MAZZEGA, Bénédicte VAGENENDE

Integrated data Unit: Edoardo CARNESECCHI, Tomas ROVESTI, Adrián CÉSAR RAZQUIN

Legal Affairs Services Unit: Matthias HASLER, Federica Bruno Methodology and Scientific Support Unit: Jane RICHARDSON

Pesticides Peer Review Unit: Angelo COLAGIORGI

### 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Joanne BORG GALEA (Malta), Heike WOEHRMANN (CropLife Europe).

### 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Results of the Satisfaction Survey and action items from previous meetings

EFSA presented results from the IUCLID PSN Satisfaction survey launched in January 2023. Good overall feedback was collected from the survey. All comments and proposals for discussion were carefully taken into consideration and addressed during the meeting or noted for discussion at next meetings.



EFSA briefed on the list of action items resulting from previous IUCLID PSN sub-group meetings. Completed or still open action points were presented. EFSA invited members to actively contribute to open action items and reminded that an excel file listing all action points collected within the IUCLID sub-group is available for consultation under the relevant Teams space. The file is regularly updated after each meeting with new action items.

#### Q&A

- **IBMA** asked why presentation on the Admissibility and NoS check is discussed in the closed session as this topic is also important for applicants when updates of dossier are expected/requested.
  - **EFSA** clarified that the discussion will focus mostly on the NoS check by RMS/EMS and that the presentations from the afternoon session are always published on the EFSA website and are accessible to the public for consultation.
- IBMA also asked clarifications on OHTs and microorganisms.
   EFSA replied that a number of new documents have been created or updated to meet the new data requirements for microorganisms and before discussing further changes it would be better to test existing documents. EFSA also indicated that it would be important to address issues related to laboratory tests and OECD harmonised templates for biopesticides in the OECD expert groups.

#### **Action Points**

No action points

### 4. IUCLID latest news and updates

Latest news and updates on IUCLID submissions were discussed.

EFSA informed that work to update the IUCLID Manuals and Administrative guidance is ongoing and invited members to contribute with suggestions to improve the IUCLID manuals using the Teams channel of the IUCLID PSN (see post from Jane Richardson of 20 February 2023).

EFSA reported that thanks to the measures put in place since April 2022 (light check by both MS and EFSA, awareness-raising with applicants, small process changes) the number of dossiers that EFSA published has increased considerably. EFSA also clarified at which stages in the process an IUCLID dossier is published.

On public consultations, EFSA reminded what are the relevant sources of information and clarified what are the applicable timelines. A brief video tutorial to facilitate public consultations on IUCLID dossiers has been published: <a href="https://zenodo.org/record/7567722#.ZC2NGXZByUl">https://zenodo.org/record/7567722#.ZC2NGXZByUl</a>

EFSA briefed on the main highlights from the participation to the CropLife Europe (CLE) annual conference.

EFSA clarified how to handle AIR/NAS applications submitted simultaneously to an MRL application and informed that a document clarifying in writing the process and responsibilities for **study notification** of pesticide dossiers has been published <a href="https://www.efsa.europa.eu/sites/default/files/2023-01/process-and-responsibilities-for-study-notification-of-pesticide-dossiers.pdf">https://www.efsa.europa.eu/sites/default/files/2023-01/process-and-responsibilities-for-study-notification-of-pesticide-dossiers.pdf</a>



On the admissibility check, EFSA informed that the Admissibility checklist developed with the support of the MSs has been slightly modified to accommodate a request by DK and will be published as an Annex to the Administrative guidance. Members were invited to give feedback on the admissibility process including NoS compliance using the excel file link provided in the presentation by the next IUCLID PSN meeting. EFSA explained that new fields have been included in the "Dossier Header" in IUCLID 6.7 (upcoming release) to indicate the reasons for dossier resubmissions in order to support the management of IUCLID submissions via the submission portal.

#### Q&A

- On the update of the IUCLID manuals, CLE expressed preference in having the instructions grouped for repeatable blocks rather than on each field. EFSA took note of the suggestion.
- On the new features of the Dossier Header, FR and ES flagged that spontaneous updates resubmissions should be discouraged, and that resubmission of dossier should be mainly triggered by a request from RMS/EMS/EFSA.
- **DE** also added that MSs should be always contacted by the applicant before any spontaneous re-submission.
  - **EFSA** clarified that the new fields in the dossier header are included to record the reason for submission. The drop-down lists of reasons for submission are taken from the IUCLID manual. The "spontaneous update" option should be limited to the cases foreseen by the current legislation as detailed in the "Resubmission" paragraph of the IUCLID manuals (cases 2.1 and cases 2.2 referring to changes in administrative information for renewal applications and identification of potentially harmful or unacceptable effects). EFSA also clarified that this feature is not intended to encourage spontaneous re-submissions (which were technically always possible) but to further reduce their number and to be able to adequately categorise all incoming dossiers.
- FR asked whether cases for spontaneous re-submission trigger a new NoS check.
  - **EFSA** clarified that in case of spontaneous re-submissions a new NoS check should be performed only in case further studies/information are notified in the NoS database, provided that the spontaneous dossier update is accepted by the RMS/EMS.
- **EC** asked whether also options for spontaneous re-submissions (cases 2.1. and 2.2) can be selected from a dropdown list in IUCLID or not. **EFSA** replied there is a list to select from with remarks and work is ongoing to include some additional information in the e-mail notification.

#### **Action Points**

-IUCLID PSN (all) members to give feedback on Admissibility and Nos check directly on the <u>excel file link</u> by the next PSN-IUCLID meeting.



### 5. Latest updates on confidentiality

EFSA briefed on the outcome of the meetings of the working party of the IUCLID PSN on filtering rules.

Activities focused on:

- establishing filter rules for all the new/updated IUCLID documents included in the new IUCLID 6.7 release;
- reducing the number of confidentiality requests by reducing the number of UNLESS\_CONF rules included in documents which are not included in the "Closed list for confidentiality". This list was made by mapping all items for which a confidentiality request can be made against IUCLID to identify which parts of the dossier may host them. The aim of the exercise is to lean the confidentiality process leaner for all actors involved.

The next steps of the working party activities have been shared with members. On confidentiality assessment, EFSA reminded participants of the importance of consulting the User Guide on confidentiality (<a href="https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf">https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf</a>) and interacting with EFSA during the pre-submission phase in order to make effective use of commenting opportunity on EFSA's draft decision (2-weeks period available).

EFSA also highlighted the importance of making reasonable recourse to CBI requests and submit only compliant CBI requests and reminded to make sound masking of personal data and avoid duplication of attachments both in the endpoint study record and in the literature reference document.

#### Q&A

- **CLE** reported difficulties in managing confidentiality assessment as this requires specific expertise and must be performed in a limited time and asked whether EFSA could anticipate the timing of the commenting phase with regard to the draft confidentiality decision.
  - **EFSA** replied that often applicants are contacted to provide clarifications before the 2 weeks given to comment the draft confidentiality decision from EFSA which means that the 2 weeks commenting period is typically confined to a more narrow and targeted review of the confidentiality requests. It is only upon completion and notification of the draft confidentiality decision that applicants will know the details about EFSA's preliminary views regarding their confidentiality requests and can act upon them. EFSA also invited applicants to consult the relevant guidance documents and to ask questions already at the pre-submission stage to improve the quality of the confidentiality requests with a view to alleviating time pressure in the commenting phase.
- CLE asked whether it would be possible to simplify justifications for CBI claims and to provide a positive list of items that can be considered personal data. EFSA took note of the suggestions mentioning that, for what concerns claims on personal data, an update of the User Guide is planned that will clarify the concept of personal data. As for CBI claims, the option suggested is duly noted and will be further explored. In the meantime, the CBI justification template and examples in the User Guide may be consulted.

#### **Action Points**

No action points



#### 6. IUCLID 6.7 release

EFSA reported information on the upcoming IUCLID release available on the IUCLID 6 website (<a href="https://iuclid6.echa.europa.eu/it/format">https://iuclid6.echa.europa.eu/it/format</a> ) including the migration rules file (in XML). A test version of the last release is already available in IUCLID BETA in ECHA Cloud services; The key area for attention is the transition from PPP endpoint summaries to the OECD harmonised endpoint summaries. The list of PPP summaries subject to harmonisation has been shown.

EFSA explained that with the migration to the new version no data will be lost, the PPP format documents will still be available in the 'obsolete' sub-section of the same TOC section. No migration for these documents is included with the new IUCLID version but options for migration of data after April 2023 were proposed and feedback is encouraged. The question of retention time was discussed and industry proposed 18 years.

EFSA also gave recommendations on updating documents in dossiers at different stages of evaluation (in preparation, under admissibility, etc) providing the below recommendations reported in the presentation:

- Dossiers in preparation or not declared admissible: Strongly recommended to update documents to facilitate the evaluation of the dossier
- Admissible studies where the dossier is being updated with new studies: complete new documents according to the latest format and update existing documents which need to be amended (especially endpoint summaries)
- Older dossiers: as general principle it is recommended to keep your datasets up to date with the latest IUCLID format so that they can easily be reused in different regulatory actions. Await further information on the planned migration for PPP Endpoint Summary data

EFSA concluded sharing the roadmap for IUCLID until 2025 in terms of data integration, report generator automation ad use of annotations.

Lastly, EFSA reported that instructions on how to complete Robust Study Summaries is due for publication in March. These are now available <a href="https://echa.europa.eu/-/updated-practical-quide-3-how-to-report-robust-study-summaries">https://echa.europa.eu/-/updated-practical-quide-3-how-to-report-robust-study-summaries</a>

#### Q&A

- CLE asked whether migration requires a manual re-work as this would be time consuming when the volume of dossiers is high and reiterated that documents should be retained for the whole regulatory life of one active substance.
   EFSA clarified that for documents other than the OECD harmonised summaries format modifications are mainly additions of new documents not existing in the old format and repeated that no data will be lost in case of migration.
- CLE also expressed preference for one of the options shared for migration (migration of original summary tabular data to endpoint study record repeatable blocks).



**EFSA** noted the feedback and invited participants to send feedback to EFSA via the Teams channel of the IUCLID PSN group.

- CLE asked for clarifications on the confidentiality assessment after migration. EFSA clarified that if a dossier is still to be declared admissible the confidentiality assessment has not started and, if needed, the dossier can be amended. For cases where the confidentiality assessment/implementation is already ongoing, the applicant will receive appropriate guidance if and once a re-submission is requested in the context of the confidentiality assessment/implementation after the new IUCLID release. ES flagged that improving the csv upload would help with manual re-work after migration and asked whether documents M will still need to be provided after the release. EFSA replied that work on CSV upload is on-going and that goal is to eliminate requirement of sending documents M in the longer term as described in the slide on IUCLID planning to 2025
- **DE** asked for clarifications on annotations, namely whether they will be used only for evaluation or also for communicating with the applicants. **EFSA** clarified that aim is to use annotations for the evaluation by MSs, but further options can be explored.
- **EC** reminded MSs that admissibility check should be only a quantitative check and not a complete pre-evaluation of the dossier, otherwise given timelines for admissibility cannot be met.

#### **Action Points**

-IUCLID PSN (all) members to express feedback on options for migration via the Teams channel of the IUCLID PSN group by 10 May 2023

### 7. Validation assistant and Report generator

EFSA presented an update on validation assistant rules foreseen in the upcoming IUCLID 6.7 release and those proposed for the October 2023 IUCLID release. A new Business rule checking the reasons for re-submissions ('Official request' or 'Spontaneous update') will be operational with the new IUCLID 6.7 release. Members were consulted on three proposed new rules for the October IUCLID release (two Quality warnings and one Business rule) and one quality rule amending an existing one. Members were invited to give feedback via the Teams Channel of the IUCLID PSN by the next PSN-IUCLID meeting.

More information on the Validation Assistant rules can be found in the <u>Rules Master</u> File.

EFSA reported latest activities on the development of IUCLID Report Generator.

EFSA informed that a prototype of the new DAR report with evaluations from MS will be available in second half of 2023.

The new report "List of study summaries" has been presented. Members were reminded to report any feedback for improvement in the file available on the Teams channel of the IUCLID PSN.

The microorganism PSN subgroup will be restarted to define the evaluation report according to the new data requirements. Additional participants are welcome



**-ECCA** commented on the 3 new proposed rules confirming agreement with most of the proposals and expressing concerns on the rule checking the summary per section (details in slide number 12).

**EFSA** acknowledged feedback and will contact ECCA for further investigation on the indicated rule.

- **-ES** also asked whether the annotations will be used for the evaluation phase. **EFSA** clarified that annotations will be explored mainly with the purpose of reporting the authorities assessment and generating reports in this pilot phase.
- **-CLE** confirmed their agreement with feedback given by ECCA on the proposed rules and accepted that in the Beta version old summaries migrated are not checked by validation rules.
- **-DE** asked how to show interest in participating to the work on report generator especially regarding the reports for the microorganisms working context.
- **EFSA** clarified that intention is to re-open the MO working party to define the reports based on the applicability of the new data requirements. Members States will receive more information on timelines and scope of the working party before re-opening. MSs interested should confirm interest by contacting MRL FMB at: pesticides.mrl@efsa.europa.eu.

#### **Action Points**

- -IUCLID PSN (all) members to give feedback on new and modified validation rules by the next PSN-IUCLID meeting.
- -EFSA to contact ECCA to explore options for implementation of the proposed rule checking that only one summary per section can be created.
- MSs interested in joining the MO working party should confirm interest by contacting MRL FMB at: pesticides.mrl@efsa.europa.eu.

#### 8. Feedback from IUCLID PSN members

CLE reported feedback on IUCLID.

On migration to the new version it was flagged that management is difficult due to manual re-work and proposed a potential solution, namely enabling parallel versioning of dossiers.

CLE also flagged that management of dossiers undergoing different parallel regulatory processes is extremely complex as often changes are requested only for one dossier, but changing the dataset has an impact on all dossiers based on the same active substance dataset. To overcome this issue, currently, duplication of datasets is necessary with additional work from industry. Having a life management tool was proposed as potential solution.

#### **A**&**O**

**-EFSA** took on board comments from CLE and will come back at next IUCLID PSN meeting with different options for best migration strategy. EFSA also explained that efforts are being made to use OECD harmonised documents where possible, although regulation specific risk assessment aspects may need to be captured in flexible summaries. Future updates would be to increase structured data in existing documents .



- **-ECHA** clarified that overall, 300 changes have been introduced with the new release, but lot of them are minor changes re-applied to different documents e.g study period converted to s range in all OHTs.
- **-AT** proposed alternative name to the sections where old documents will be migrated for archiving ("Old summaries" instead of "Obsolete")
- **-ES** asked clarifications on the time period for keeping the documents and whether the obsolete documents will disappear from the database or only from the Table of Content.

**ECHA** clarified that documents will be maintained at local level.

#### **Action Points**

-EFSA plans to participate in the OECD IUCLID user group activity on 'Using the same dataset for multiple recipients'

#### 9. Any Other Business

- AT asked EFSA to consider including in the Validation assistant report the date of implementation of each rule. DE and CLE agreed with AT on this. EFSA took note and will take into consideration this proposal for implementation at next release.
- EFSA informed that next meeting will be held in presence in Parma on 19 and 20 June.

#### **Action Points**

-EFSA to consider amending the validation assistant report to include the date/IUCLID version in which the rule was implemented.

#### **End of General session**

#### Risk assessor's sessions

#### 10. Feedback from EFSA

EFSA reported feedback on different topics of interest for Member States.

On the admissibility step, EFSA clarified that this is fully the responsibility of the EMS/RMS and once the EMS/RMS declares the dossier admissible EFSA will only check the presence of the documents indicated in the Administrative Guidance and proceed with the acknowledgement of the admissibility. Therefore, EFSA underlined that comments on the NoS extractions will no longer be provided as the NoS Check is under the remit of the RMS/EMS, as defined in the Transparency Regulation.

Still on admissibility, EFSA shared best practices for managing admissibility of combined NAS/AIR and MRL applications and joint submissions/individual submissions of the same substance and emphasized the importance of ensuring that confidentiality assessment and public consultation on these dossiers are held



simultaneously, when relevant. The above points were added to the admissibility checklist as "additional checks".

EFSA also reminded that the admissibility checklist will be included in the EFSA Administrative guidance and reminded as well all MSs of the opportunity offered to discuss topics/issues encountered during the admissibility check and receive support, through pre-admissibility teleconferences.

EFSA continued with clarifying when to re-run NoS check in case of dossier updates received during the admissibility and referred members to the document "Process and responsibilities for study notification of pesticides dossiers": <a href="https://www.efsa.europa.eu/sites/default/files/2023-01/process-and-responsibilities-for-study-notification-of-pesticide-dossiers.pdf">https://www.efsa.europa.eu/sites/default/files/2023-01/process-and-responsibilities-for-study-notification-of-pesticide-dossiers.pdf</a>. As explained in the document, EFSA highlighted that dossier updates received during the scientific risk

assessment by the RMS/EMS do not trigger a new NoS check.

Following request from MSs, EFSA shared links to video tutorials on how to use the comparison tool and reminded where to find a troubleshooting document helping MSs having problems in accessing IUCLID (document available under the channel IUCLID PSN – All participants: <u>Supporting info for MSs organisations to access EFSA Agency v1.pdf</u>). For the comparison tool, the relevant videos are: <u>SPC Comparison tool demonstration - YouTube</u> (for dossiers' comparison) and <a href="https://www.youtube.com/watch?v=cUy6ahta3dE">https://www.youtube.com/watch?v=cUy6ahta3dE</a> (for documents' comparison).

EFSA mentioned that round of bilateral meetings with Member States to discuss relevant issues and challenges encountered during the evaluation of post-transparency applications are on-going.

Lastly, EFSA informed MSs that measures have been taken with regards to public consultation to enable the progression of the Risk Assessment of MRL applications. EFSA reminded that MSs contact points for MRL applications were notified and requested to upload pre-public consultation Evaluation Reports.

#### Q&A

**FR** asked clarifications on how to manage the admissibility of dossiers received within the same task force from different applicants but with very different quality.

**EFSA** reminded that a strong justification should be provided to not submit a joint submission and considering that public consultation should be launched together and only one DAR will be prepared for the task force, advised to proceed with the admissibility check in parallel.

- **DK** asked clarifications on the time of applicability of the stop by EFSA for sending comments on the NoS extraction.
  - **EFSA** clarified that it is already applicable.
- **NL** asked clarifications on how to deal with one specific case for which applicants created two IUCLID dossiers, one for each formulation but both referring to the same active substance.

**EFSA** clarified that technically IUCLID allows to create more than one product dataset in the same dossier and reminded NL that applicants can always contact EFSA for support via Ask a question service before submission.



 FR also asked whether it is confirmed that the active substance name and the crop (in case of MRL applications) will be displayed in the communications linked to the submissions.

**EFSA** confirmed that the active substance name will be displayed in all automated communications. EFSA also suggested to follow the indications of naming the dossier using the ISO name of the active substance. Concerning MRL applications, the crops will not be displayed in the alert email however, as mentioned in the slides and in the IUCLID manual, EFSA recommends that applicants use the ISO name + the crops in the dossier name since this facilitates dossier identification at all levels.

#### **Action Points**

No action points

#### 11. Feedback from Member States

Feedback was reported by two member States: Germany and France.

DE informed that, at MS level, they are still experiencing issues with IUCLID access and some instability in the connection and raised questions on the security of the IUCLID cloud. DE also flagged that for minor crops applications more support would be needed for applicants due to the size of the companies usually applying for such request.

DE finally raised questions on the timelines for using IUCLID Annotations and on the need to improve the search function.

FR in its presentations asked clarifications on the absence or presence of comments received from EFSA in the NoS extraction and flagged that systematic presubmission meetings on each dossier should be avoided and held only when soundly justified.

#### Q&A

- On IUCLID technical issues EFSA replied that the problems should have been solved in the last weeks and encouraged MSs to open a ticket if connection issues are persisting. It is important to use the dedicated checklist provided by ECHA before/when opening such a ticket since it ensures that all the necessary information is provided. On storing of dossiers, ECHA clarified that there is no plan of deleting the dossiers stored in the Agency Instance in ECHA cloud services and that all submitted dossiers are currently maintained.
- On the use of annotations, **EFSA** confirmed that a pilot project is on-going with Anses and further updates will be presented at the next PSN.
- On the search function, EFSA reminded participants to <u>check the IUCLID PSN</u> <u>channel</u> where indications on how to search using the UUID has been posted.
   In cases where a UUID is not available, filtering for a specific study in the generated "list of study report" could be the solution.
- On NoS extraction, **EFSA** confirmed that commenting has been stopped as it is not under EFSA's responsibility to check NoS status. EFSA will continue extracting the NoS report, but without comments.
- On pre-submission teleconferences, **EFSA** clarified that they are not mandatory, but strongly recommended (at least for less experienced Member



States) so as to speed up the admissibility check and to harmonise it across MS.

- NL asked clarifications on light dossier definition and on the difference between "Default" reports and "Uploaded" reports.
  - **EFSA** replied that the light dossiers are the simplest way of sending small incremental dossiers. Once submitted the dossier will look complete.
  - On the Reports, **EFSA** clarified that the top reports are the ones uploaded in conjunction with each new IUCLID release. When bugs are identified or changes are needed, without waiting for a new release, new reports can be made available and they are added under the section "Uploaded" reports. EFSA also gave advice to start always using the official ones on the top and only if they have issues to use the ones below.
- **DK** asked updates on the comparison tool. **EFSA** replied that the issue has been recognised as a bug and will be fixed in the upcoming release, in the meantime ECHA will run the report on the problematic dossiers for DK as a workaround.

#### **Action Points**

- -EFSA to inform DE when background jobs for reports are available
- -EFSA to report at next PSN updates on Annotations

### 12. Feedback from European Commission

EC reported feedback related to the use of IUCLID reminding the importance of having structured information on substances and reinforcing the message that IUCLID is the legally binding format for applications and CADDY is dismissed. EC also reminded IUCLID PSN members to participate in the development of the templates for the DAR/RAR on microorganisms dossiers and summarised main regulatory areas for future use of IUCLID and on-going work in view of a EU-common data platform on chemicals within the 1S1A program.

#### Q&A

- **DE** asked for clarifications on timelines for having a common data platform. **EC** replied that this topic was discussed at the PAFF, but no common agreement was reached by MS and discussion is ongoing.
- DE asked for clarification on the development of the Assessment Report for microorganisms and how the activities will be coordinated by EFSA.
   EFSA clarified that intention is to re-open the MO working party to refine the microorganism evaluation reports based on the applicability of the new data requirements. Members States will receive more information on timelines and
  - scope of the working party before re-opening. MSs interested should confirm interest by contacting MRL FMB at: pesticides.mrl@efsa.europa.eu.
- **DE** also asked clarifications on the use of IUCLID for the Drinking Water Directive.



**EFSA** replied that ECHA has developed the first version of a WFD working context which is already available and can be tested in IUCLID Beta. This will be further developed based on feedback from testing.

### 13. Open discussion

Chair summarised key messages of the day and reminded date for next meeting (19 and 20 June 2023).

**Closure of the meeting**