

3rd PSN IUCLID subgroup meeting – 4 May 2022

IUCLID submissions: latest news and updates

Trusted science for safe food

Communication related to IUCLID

- As of **19 April 2022** all requests related to IUCLID (e.g. support with preparation and/or submission of IUCLID dossiers, support on related tools e.g. MetaPath, support to MS during the admissibility check, etc) must be submitted via the **Ask a question** service (<https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request>)
- To ensure the full functionality of the service, before submitting a new request in Connect.EFSA **please make sure to log in** (<https://connect.efsa.europa.eu/RM/s/login/>)
- Registered users can access additional functionalities e.g. ability to exchange communication with an EFSA operator when additional clarification is needed.
 - To ensure a smooth transition, EFSA has raised the number of contacts that can be registered for each account up to **nine**

- As of 26 April **all dossiers** can be submitted by means of the submission portal (<https://ecs.echa.europa.eu/cloud/home.html>) and the SFTP scheduling is no longer needed
- Regularly check the **Applicants Toolkit** (<https://www.efsa.europa.eu/en/applications/toolkit>) for any news
- All IUCLID manuals have been updated to the IUCLID 6.6 format – no update in April as no format changes foreseen
- Trainings are being prepared (*Most common mistakes & IUCLID for the general public*) and dates will be advertised soon

Key messages: Resubmission of IUCLID dossiers

- When resubmitting, remember to **export as a Light Dossier**
- When an applicant resubmits a dossier upon request by EFSA/MS/COMM it is important to state in the “**Dossier submission remarks**” field of the **dossier header**:
 - That it is a requested update
 - Which authority requested it and the reason why (admissibility, confidentiality, etc)
 - The risk is that the newer version of the dossier will otherwise be ignored

- Changes to filter rules prior to dossier publication:
 - IUCLID is updated twice per year and we do not foresee filter rule changes outside the normal IUCLID go-live cycle
 - Further changes to PPP filter rules are required (e.g. analytical methods, test material)
 - Any future major changes will be discussed within the filtering working group of the PSN IUCLID and brought to the PSN IUCLID for approval
 - Applicants will be informed with advance notice before the changes become applicable so that, if a dossier update is required prior to publication, there is a window of opportunity for doing it

Key messages: personal data in the dossier

EFSA has been implementing a “light check” for personal data after a dossier is declared admissible and prior to its publication

During the light check, the following issues have been most frequently the cause of non-publication to avoid personal data disclosure:

- Attachments with personal (*or confidential*) data in the dossier header
 - Remember that the dossier header is published in full
 - We have added a backlog item to remove the attachments from the dossier header as they can be placed in “Summary and evaluation”
- Personal data left in the Legal Entity section
 - only provide generic contact details (functional mailbox, switchboard phone number, etc)

Key messages: personal data in attachments

“Sanitised” attachments – verify that:

- All names of natural persons & signatures are blackened
- The blackening is permanent (i.e. that the “box” cannot be removed)
- A sanitised attachment corresponds to the original/earmarked version (i.e. no summaries, abstracts, etc)
- A sanitised version is provided for every confidential document (QLT warning helps with this)

Other issue: removal of attachments in a requested update after personal data was identified in the light check

Proposal for personal data mgmt. in IUCLID

- At present CBI & PD claims within a document are flagged using the Confidential Business Information (CBI) flag
- An interim proposal would be to:
 - Use the CBI flag + justification (as is done currently) when CBI is present in the document
 - Fill in the justification but **DO NOT** set the CBI flag if the document includes PD but **NO CBI**
- This would improve transparency as it would enable publication of the data subject to the CBI flag in IUCLID for those study reports in which only personal data is claimed confidential

Set Flags

Confidentiality ⓘ

Please select

CBI-[confidential business information] ✓

Insert existing templates

ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestMaterials
Article 39(e)(2) of Regulation (EC) No 178/2002

This information is not publicly available, is worthy of protection and it's disclosure would cause financial harm as details on test material could reveal manufacturing and production details for the active substance.

340/32768

Use restricted to selected regulatory programmes ⓘ

EU: PPP

...any feedback on the proposal?

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