



EFSA' s feedback on first IUCLID submissions

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APDESK

Trusted science for safe food

- **3 New Active Substance dossiers**
- **24 Renewal dossiers**
- **15 MRL applications**





- Until March 2022 applicants need to contact EFSA and inform us of a planned submission for renewal and new active substance dossiers
- This should be done **1 month** prior to the planned submission date
- We are currently facing problems in identifying and contacting applicants for renewal dossiers...

- Two issues related to IUCLID/the submission portal were identified early in the summer and they implied workarounds to be put in place in order to submit a dossier:
 - If the applicant is using a IUCLID 6 Desktop or IUCLID 6 Server installation, they must request a patch to increase the export size before exporting to i6z → this will be solved with IUCLID 6.6 go-live on 27 October
 - If the dossier size is >1GB, the dossier must be uploaded by means of an SFTP Client with support from EFSA and ECHA, including the scheduling of a slot for submission → this solution will be in place until March 2022
- Contact hypercare.iuclid@efsa.europa.eu for support

- **The owner of the dossier or the lead applicant in the case of a task force must be indicated in the Mixture document**
- If the dossier is being prepared by an organisation other than the Legal entity owner, we recommend that the Legal entity owner exports their legal entity details and provides them to the organization authoring the dossier. This legal entity information is exported from within ECHA's Identity Management solution (IDM) and not from within IUCLID.

UUID: fce09ab8-e542-4e99-a1a5-a7e3ec29afe1

Mixture/Product name*

Benzo - TEST for submission portal

Public name

This is test - to be deleted

Legal entity owner*

 (EFSA Pilot) EFSA | Helsinki | Finland

Third party

None

- **When generating the dossier for submission, make sure that the Legal entity owner is appearing in the 'Submitting Legal Entity' of the dossier subject of the dossier header**
- If the Legal entity owner is not in the dossier header, you will need to recreate the dossier and ensure the 'Include legal entity' is checked from the advanced settings of the 'Create dossier' function

Advanced Settings
Working Context: EU PPP Active substance application (product)

Include legal entity

Include legal entity

Dossier Subject

Dossier Subject
🔗 Benzo - TEST for submission portal

Submitting Legal Entity
🏢 (EFSA Pilot) EFSA | Helsinki | Finland

Dossier creation date/time
2021-07-02T16:50:57.152

Dossier submission remarks
This is a test

- If the submitter is a user of the Legal Entity owner organisation, ask the Legal Entity Manager to give the user the Submission Portal Manager role.
- If the submitter is a third-party consultant then they need to ask the Legal Entity Manager of the owner/lead applicant organisation to add the submitter as a foreign user with the role Submission Portal Manager

Username	Name	Email	User roles
 EFSA_DGSANTE	EFSA Pilot DG SANTE	iuclid6@echa.europa.eu	IUCLID Beta Full Access Submission Portal Manager

- Please see this short explanatory video for more information on foreign users:

<https://www.youtube.com/watch?v=YH5edrjBkxI&list=PLGDvgn1aAEEbL7dMwwWAjoAiK-DgoJmZrY&index=9>

- **Legal entities:** a legal entity should identify in an unambiguous manner a company or organisation with a role in the submission of dossiers – this LE information should be similar to what can be found in company registers
- Submissions attributed to a specific applicant should all be associated to the same legal entity, regardless of whether their dossiers were submitted e.g. by different consultants
- The same applies to third party consultants, who should also maintain a unique legal entity that can be included in the 'Third Party' field, regardless of which applicant they are submitting on behalf of

- In many cases very large dossiers can be avoided by **reducing the file size** for attachments:
 - Identify all the PDF attachments that have an unreasonably large size (e.g. >100MB)
 - Generate the attachment report for the dossier / dataset to be submitted to get an overview of all the attachments
 - Download the large PDF attachments and use Adobe features to reduce/compress the PDF file size
- If, despite compression, the file size still exceeds 100MB applicants must **split** the attachment
 - In IUCLID 6.5 use the “Attached full study report” + “Attached background material”
 - In IUCLID 6.6 each part of the full study report can be uploaded into a new “Attachments” repeatable entry

- Use the Light dossier for re-submissions so as to avoid unnecessary repetition of data → see p. 130 of this document: https://iuclid6.echa.europa.eu/documents/1387205/1809908/iuclid_functionalities_html_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395
- Pay attention to this text in all the manuals in the Confidentiality of dossiers submitted via *IUCLID - practical instructions for applicants* section. **Only CBI should be selected from the dropdown list** (this is fixed with IUCLID 6.6)

To claim certain fields subject to the filter rule "**UNLESS_CONF**" confidential, the applicant must:

- i. set a **confidentiality flag** in the designated field pertaining to the relevant IUCLID entity, summary, record or section (CBI - confidential business information should be selected as this is in alignment with the transparency regulation), and

- **Evaluation report:** applicants must ensure NOT to upload the draft evaluation report in IUCLID as this poses issues for publication
- Last but not least...
 - Consult the manuals before finalising dossiers
 - Active substance: <https://doi.org/10.5281/zenodo.5091464>
 - Micro-organisms: <https://doi.org/10.5281/zenodo.4773527>
 - MRL: <https://doi.org/10.5281/zenodo.4630194>
 - Familiarise with the filter rules (<https://doi.org/10.5281/zenodo.5118638>) and run the dissemination preview before submitting



- We have been made aware that when MS/EC receive an alert email from IUCLID upon submission of a dossier, the Active substance name is not always visible – we are working on a solution for this

Subject: EU PPP Dossier received in IUCLID Agency

Dear recipient,

A new dossier has been submitted with the following outcome: Succeeded with warnings

Submission information

Submission type: EU PPP Active substance application (product)

Submission date and time: 27/08/2021 10:50

Submission number: [REDACTED]

Legal entity name: [REDACTED]

Legal entity UUID: [REDACTED]

Dossier UUID: [REDACTED]

Active substance name: [REDACTED]

EU reference number: [REDACTED]

Reason for submission: renewal of an active substance for use in plant protection products

Recipients: [REDACTED]



RMS are you receiving this?

Including more fields from the dossier header in the e-mail notification

Review of content available to Third Party Submission Portal Managers

Need for an option to 'disable' a submission (e.g. wrong legal entity)

Need for aggregation function for submissions with separate confidential product dossiers

Improvement to templates to support Joint submissions prepared by third parties (clear differentiation of content by data owner)

Any comments /
questions / suggestions?



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