

9th meeting of the PSN IUCLID sub-group

29 February 2024



UPDATES ON CONFIDENTIALITY & FILTERING

SOME POINTS FOR ATTENTION TO APPLICANTS

- **If possible, always include the email address of an active contact person** in the dossier (in addition to the functional mailbox of the legal entity) and make sure they are **up-to-date** when re-submitting the dossier.
- **Make sure automated redaction tools deliver complete, accurate and consistent redaction of the personal data and CBI.** It is recommended to perform a **quality-check** of all the automated redactions.
- **Make best efforts to obtain and upload well-readable attachments (including for old studies) and to avoid to the extent possible non-user-friendly formats** (such as XML files).
- **Submit confidentiality requests, if any, on the notification of studies (NoS) extract in a timely manner** (when requested by EFSA – usually a **DL of 5 WDs** is set in our e-mail acknowledging receipt of the confidentiality requests), in the interest of optimising the confidentiality decision-making process).
- When asked to address issues in the dossier by reference to examples (e.g., unredacted PD in study report xyz, page 5), **screen the whole dossier to see if there are other instances of the same nature.**



REMINDERS TO APPLICANTS IN RELATION TO THE CONFIDENTIALITY JUSTIFICATION

Reminders on the following points:

- **indicate clearly and precisely each element claimed confidential** within an attachment and **provide the specific legal ground for each distinct item**, in accordance with Article 9(4)(b) and Article 10 of EFSA's Practical Arrangements on Transparency and Confidentiality.
- **make good use of the CBI justification templates** provided in the **updated EFSA User Guide on Confidentiality**, especially in relation to the **substantive requirements** (Article 10(b) criteria).
- When the justification exceeds the characters limit of the justification box, and therefore might need to be uploaded as a separate attachment, make sure the justification attachment is uploaded:
 - **under the same IUCLID summary/record that contains the field or attached study report** to which the confidentiality justification relates
 - **in the field 'AttachedDocument'** (subject to the filter rule 'NOT_PUBLISHED') and **not in the 'Remarks' field or in any other fields.**

Set Flags

Confidentiality CBI

Justification Insert existing templates

I. IDENTIFICATION OF THE RELEVANT ITEM: The item claimed confidential can be found in the file "Batch analysis study for substance xyz" in the following locations:

- on electronic page no. 8, table 4 (non-relevant impurity);
- on electronic page no. 8, table 5 (non-relevant impurity);
- on electronic page no. 8, table 7 (non-relevant impurity);
- on electronic page no. 9, figure 24 (results of production batches);
- on electronic page no. 11, summary, table, (results of production batches).

II. LEGAL BASIS: The items claimed confidential concern the specifications of impurities which are not toxicologically, ecotoxicologically or environmentally relevant within the meaning of Article 63(2)(b) of Regulation (EC) No 1107/2009 and the results of production batches in the meaning of Article 63(2)(c) of Regulation (EC) No 1107/2009.

III. RATIONALE FOR AWARD OF CONFIDENTIAL STATUS: I hereby declare that the item claimed confidential should be granted confidential status because it meets the following cumulative requirements:

- a) it is not publicly available;
- b) it is eligible or worthy legal protection and has not been acquired in an unlawful manner;
- c) it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006; and
- d) its disclosure would be liable to cause potential harm to a significant degree because:
 - i. it would result in financial damage corresponding to at least 5% of my gross annual turnover/earnings, and
 - ii. the information is not older than 5 years.

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Use restricted to selected regulatory programmes



SOME POINTS FOR ATTENTION TO RMS

- **While the confidentiality assessment is ongoing, coordinate with EFSA** (confidentialityrequestassessment@EFSA.europa.eu) **before asking for a re-submission** to reduce (to the extent possible) instances where this re-submission might interfere with EFSA's confidentiality assessment.
- For NAS/modifications of conditions of approval:
 - **consult EFSA on the draft confidentiality decision** (it is **mandatory**) in accordance with Article 7(6) of Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009.
 - **following the confidentiality check, communicate the dossier's latest UUID to EFSA on which the public consultation is to be launched.** This is to make sure that the public consultation is launched on the correct version of the dossier by EFSA.





Update on Filtering & Doc J



FILTERING RULES – APRIL RELEASE

- Reminder:
 - **Literature Reference Entity:** Test Laboratory & Report number will always be removed for unpublished studies
 - **UNLESS_CONF reduction** to be applied to new & existing documents (as per the outcome of the stakeholder consultation held 17/08 – 27/09/2023)
 - **Auxiliary rules to be switched OFF** (as per the consultation above)
 - This implies that the information included in the sections “Other” or “Remarks” in association with picklists will be PUBLISHED
 - Change to the filtering rules for **Mixture legal entity** (from PUBLISHED → UNLESS_CONF)
 - NEW filtering rule on **Analytical Methods**



FILTERING RULES – APRIL RELEASE

- Consultation on the draft configuration file launched with the Filtering WP members on 20 February 2024, **deadline 1 March**
- New rule on publication of **Impurities**
 - For **Relevant Impurities** all information will be PUBLISHED by default except the Manufacturing plant (if CBI flag is set)
 - For all other impurities (**Significant, Not significant & Theoretical**) all the information is set to UNLESS_CONF



DOCUMENT J DISMISSAL

- Document J scheduled for removal in **April 2025** and a “DAR Volume 4” report will be generated in support of the RMS
- The change will apply to **new submissions** made after go-live of the release (i.e. no impact on previously submitted dossiers)
- Mapping of Doc J elements to the fields in the IUCLID dossier is almost finalised and will be made available in the Applicants toolkit by end of March 2024
- For any items which are currently still missing a workaround will be suggested and a format change will be scheduled for April 2025

