14th meeting of the PSN IUCLID sub-group
04 November 2025

IUCLID – LATEST NEWS & UPDATES

EUROPEAN FOOD SAFETY AUTHORITY

IUCLID VIRTUAL TOUR

- 13 meetings of the **Virtual Tour** with the Member States held so far (AT, DK, GR, FR, NL, IT, ES, FI, DE, SI, LV, PT, **BE**)
  - BE reiterated the question as to why a confidential Volume 4 of the DAR is still required in the absence of Doc J for new dossiers
    - Considering that for post-Transparency applications the complete DAR/RAR (including Vol. 4) is made publicly available, it could be interesting for the MSs and the Commission to reflect on whether it would be more efficient to re-distribute the Vol.4 information in the respective Vol.3 documents and/or incorporated in Vol.1
    - The current structure of the DAR/RAR, including Vol. 4, is described in SANCO/12592/2012 and any changes should be raised by the MS and discussed at the PAFF and/or the general PSN meeting
  - We aim to schedule at least one more Virtual Tour meeting before the end of the year

IUCLID MANUALS

- The IUCLID 6.9 manuals for chemical active substances and MRL were published on 12 September
  - Micro-organisms will be published by the end of the year
  - EFSA will make a mini manual on Safeners & Synergists available by April 2026
- The Doc J standalone instructions (https://www.efsa.europa.eu/en/applications/toolkit#iuclid-software) were updated on 14 October and now include an FAQ section
- The survey for feedback on the manuals and on the use of test dossiers is open – deadline for providing feedback on **7 November**
  - The feedback will be analysed and considered as from the 2026 revision

DATA ON CO-FORMULANTS

- EFSA continues recommending that data (e.g. tox, ecotox, etc) on co-formulants are managed outside IUCLID, as is done for pre-TR dossiers
- The names and chemical identifiers **must** be provided in the IUCLID dossier (Section 1.4 Mixture composition) as taken from the SDS. These are managed appropriately from a confidentiality & publication perspective
- More clarity is needed on the type of data provided by applicants/suppliers in order to perform an analysis, identify potential issues and reconsider a better approach (possibly also using IUCLID) in the future
- Main issue from a publication perspective is that in the filtered/published dossier we cannot mask either the number of co-formulants or the name of their owner

STRENGTHENED SUBMISSION CHECKS

- In May 2025 EFSA strengthened the checks in the submission portal to avoid unsolicited changes to the European Reference Number (ERN)
  - The ERN is linked to the active substance identifiers, the applicant legal entity and concatenates subsequent submissions
- The rules are very effective on new submissions but are causing several failures in resubmissions of existing dossiers for which an ERN/LE change was made over time
  - EFSA will fine-tune by adding a parameter checking the purpose of the application
- If applicants experience issues they must reach out to EFSA through Ask a Question

CONFIDENTIALITY FOR A NAS – IMPORTANT REMINDERS

- For a new active substance application dossier, the RMS is responsible for the confidentiality request assessment. It is important to remember the following:
  - To follow the chronology of steps (admissibility – dossier publication - confidentiality request assessment – check with EFSA – communication of the draft decision to the applicant – ADRs, etc related to the evaluation, finalisation of the DAR, etc) in order to facilitate the overall process, including the mandatory public consultation on the dossier
  - NOT to request the applicant to upload the exchange on the confidentiality request assessment (e.g. the report on confidentiality claims generated by report generator) to the dossier itself
  - The above recommendation is NOT to be confused with the fact that if an applicant's individual confidentiality request exceeds 32000 characters (e.g. for Doc J), the remaining justification should be uploaded as a separate file, which will not appear in the file generated by report generator, but will be linked to an existing confidentiality request

FILTERING CONFIGURATION

- Amendments to the IUCLID for PPP filtering configuration file were included in two patch releases this summer (29 July & 12 September)
- Cloud instances are updated by default and both releases were made available as a downloadable package on the IUCLID 6 website (https://iuclid6.echa.europa.eu/) and the change to PPP filtering configuration was mentioned in the release notes (https://iuclid6.echa.europa.eu/documents/1387205/1809509/IUCLID_6_Release_Notes.pdf/9d7a65ce-e1db-83dd-43f5-8ec04797c7b2?t=1731278116575)
- For both releases EFSA:
  - Updated the online filtering configuration file and highlighted the changes made
  - Informed applicants by means of the Highlights section of the Toolkit and on our LinkedIn channel
- **Important** for applicants to regularly check the Toolkit for any EFSA-specific updates related to IUCLID

FILTERING OF TEST ANIMALS: STRAINS

- Animal strains could represent a link to a specific supplier and/or to personal data
- Within an Endpoint study record, the dedicated field (MaterialsAndMethods.TestAnimals.Strain) is currently set to PUBLISHED
- Based on the input received, EFSA suggests changing this to UNLESS_CONF and the field will be governed by the Flag on the Administrative data (as is the standard in an Endpoint study record)
- This change can be implemented in the April 2026 release
- Reminder: such concerns should be raised as early as possible by means of Ask a Question to enable EFSA to take action

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