15th meeting of the PSN IUCLID sub-group
15 April 2026

IUCLID – LATEST NEWS & UPDATES



EUROPEAN FOOD SAFETY AUTHORITY

IUCLID MANUALS

- The IUCLID 6.9 manual for micro-organisms was published on 30 January and can be accessed through the Toolkit (https://www.efsa.europa.eu/en/applications/toolkit#iuclid-software)
- The standalone Doc J instructions will be further updated and published on 28 April based on the input of the WP on the Confidential Information Report. The changes will be highlighted and subsequently integrated in the next revision of the active substance manual
- Some of the feedback provided in the survey (e.g. better tracking of changes, focus on the introduction) will be implemented in the next update of the manuals

IUCLID SUPPORT - APPLICANTS

- For **technical issues** (failure in dossier creation/export, dissemination preview fails, etc) → contact **ECHA** (https://echa.europa.eu/contact/technical-support)
- For **all other issues** (e.g. dossier content, filtering rules, business rule failures) → contact **EFSA**
- EFSA must always be contacted through Ask a Question (https://connect.efsa.europa.eu/RM/s/help/scientificapplicationquestion)
- AVOID opening multiple tickets (with EFSA & ECHA, within EFSA, additional emails, other channels) → this slows down the resolution process
- EFSA always recommends attempting early submission, in particular for legal deadlines (as per active substance renewal programme) and initial submissions

IUCLID SUPPORT - AUTHORITIES

- For all issues, reach out to **EFSA**
  - IUCLID access issues through Ask a Question (https://connect.efsa.europa.eu/RM/s/help/scientificapplicationquestion)
  - Issues with the use of IUCLID, contents of a dossier, admissibility, etc either Ask a Question or the relevant functional mailbox can be used
- Multiple tickets must be avoided

STRENGTHENED SUBMISSION CHECKS

- In May 2025 EFSA strengthened the checks in the submission portal to avoid unsolicited changes to the European Reference Number (ERN), which is linked to the active substance identifiers, the applicant legal entity and concatenates subsequent submissions
- The rules are very effective on new submissions but can cause failures in dossier resubmissions when an ERN/LE change was made over time
- On 30 March 2026 two new BRs were deployed to ensure better handling of parallel submissions for the same active substance:
  - **BR914** checks the “Purpose of application” and ensures ERN consistency within the regulatory process
  - **BR915** checks the “Confirmatory information” tick box and ensures ERN consistency within the regulatory process
  - If applicants experience issues they must reach out to EFSA through Ask a Question and never change the ERN spontaneously

ADMISSIBILITY PROCESS

- For a new active substance application dossier, when the dossier is declared admissible, the RMS is requested to provide the following attachments:
  - Validation assistant report
  - Report containing the notification of study information to be published
  - **List of Confidentiality claims**

Important clarification:

The **List of Confidentiality Claims** must be generated for the RMS with the sole purpose of ensuring that the applicant has made confidentiality requests in the dossier and that the report is not empty. The actual confidentiality request assessment is to be performed after the dossier has been declared admissible.

The above comment will be included as a footnote in the upcoming updated to the Administrative guidance

FILTERING CONFIGURATION

- Filtering rules were assigned to all the new fields included in IUCLID 6 v.10 → the Filtering WP was consulted in writing between 16 – 23 March and no comments were received on EFSA's proposal
- The updated filtering file will be published (and accessible from the Toolkit) when the release goes live
- As agreed at the last PSN, the field on animal strains (MaterialsAndMethods.TestAnimals.Strain) will be changed from PUBLISHED to UNLESS_CONF and the associated confidentiality request will be assessed on a case-by-case basis

DISSEMINATION PREVIEW

- Two issues with Dissemination Preview were flagged to EFSA:
  - Incorrect behaviour in “composition tables” (e.g. mixture composition and test material composition)
    - The data appeared not to be filtered out unless the individual Reference substances were claimed confidential (which is NOT a suggested way forward)
    - The filtered dossier was generated correctly
    - The issue was recognised as a bug and will be fixed in IUCLID 6 v.10
  - Failure in generating the Dissemination preview with a complex dossier
    - Issue currently under joint investigation by ECHA and EFSA
    - A short-term solution has been identified (*the dissemination preview will be made available as a CSV in IUCLID 6 v.10*) and we are investigating changes to the Dissemination preview for implementation in October/April

TEST MATERIAL ENTITY

- In IUCLID 6 v.10 the TM_DETAILS filtering rule will be replaced with TM_PPP with reference to the filtering of the composition table in the Test Material Entity
- TM_DETAILS relied on the flagging in the Administrative data block of the associated endpoint study record and removed the full TM composition table
- TM_PPP will read the flags in the rows of the TM composition table and will remove data accordingly, with the exception of the active substance which will always be published

TEST MATERIAL ENTITY

- N.B. TM_PPP will only be applied to NEW dossiers with initial submissions **as from 1 July 2026**. Previously submitted dossiers will continue to be filtered using TM_DETAILS as the confidentiality flags were set accordingly
  - All details provided in EFSA's dedicated communication

Mixture composition table

Components

	Component flag	Name	Function
1		Different ref sub | 123	active substance
2		Dossier 1 | test | 00100	adsorbent

Test material composition

Name*
Dossier 1

Composition

Composition

	Component flag	Type	Reference substance
1	CBI	constituent	Different ref sub | 123
2	CBI	constituent	Dossier 1 | test | 00100

Filtered test material

Name*
Dossier 1

Composition

Composition

	Component flag	Type	Reference substance
1	CBI	constituent	Different ref sub | 123

STAY CONNECTED

SUBSCRIBE TO
efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
Careers.efsa.europa.eu – job alerts

LISTEN TO OUR PODCAST
Science on the Menu –Spotify, Apple Podcast and YouTube

FOLLOW US ON BLUESKY
@efsa.bsky.social
@efsa-animals.bsky.social @efsa-plants.bsky.social

FOLLOW US ON LINKEDIN
Linkedin.com/company/efsa

FOLLOW US ON INSTAGRAM
@onehealth_eu

CONTACT US
efsa.europa.eu/en/contact/askefsa

efsa
EUROPEAN FOOD SAFETY AUTHORITY