

13th meeting of the PSN IUCLID sub-group
12 June 2025

UPDATES ON CONFIDENTIALITY

LEGAL AFFAIRS UNIT

WHAT IS NEW

- Latest update of the [EFSA User Guide on confidentiality](#) (April 2025)

Focus on the parts relevant to this meeting:

- **Section A** (General Requirements) and
 - **Section C** (IUCLID)
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- New approach and modalities to exchange confidentiality-related documentation between EFSA and RMS



LATEST UPDATE OF THE EFSA USER GUIDE ON CONFIDENTIALITY

□ Section A (General Requirements)

This section has been entirely restructured with a robust focus on both **submission** (Applicant's side) and **processing** (Regulators' side) of CRs. This includes:

- an **updated glossary** of key concepts, including post-TR terminology;
- a revised and simplified explanation concerning **key confidentiality requirements**;
- **recommendations** on the submission of compliant CRs in relation to both **justifications** (minimum content) and **attachments** (confidential version and sanitised version for publication);
- **steps of the confidentiality decision-making process**, including the **implementation** of the confidentiality decisions and the **proactive publication** of the sanitised versions via the OpenEFSA portal.



LATEST UPDATE OF THE EFSA USER GUIDE ON CONFIDENTIALITY

□ Section C (IUCLID)

Clear separation between tool-related and legal requirements. This includes:

- **technical requirements** and tips to submit confidentiality requests in relation to the EU_PPP IUCLID format;
- **justification templates** and tips regarding claims on **personal data** and **CBI**;
- indicative examples of **confidential information** falling under **the legal grounds** (i.e. Art. 63(2) of PPP Reg.);
- an explanation as to **how** the confidentiality decision-making is **processed** and **implemented for IUCLID application dossiers**;
- a general overview of the decision-making cycle and **guidelines for the RMS** to process CRs **in the context of NAS/AMEND application dossiers**, in line with Article 7(3) of PPP Reg..



NAS/AMEND DOSSIERS: NEW APPROACH TO EXCHANGE DOCUMENTS BETWEEN RMS & EFSA

□ Linked to the guidelines for the RMS, EFSA has recently circulated an e-mail on the **newly-created dedicated folder “RMS confidentiality assessment” in the RMS dropbox** for each new active substance.

Through this new modality of transmission, the national authorities and EFSA can therefore share in a safely, structured and recorded manner:

- the **RMS’ draft confidentiality decision** for consultation
- **EFSA’s comments** on the RMS’ draft confidentiality decision
- the **RMS’ final confidentiality decision**
- the version of the **NoS extract** for publication (sanitised, if applicable)

EFSA Units to be notified by e-mail in relation to the upload of the above documents:

Legal Affairs Unit with **FDP Unit** and **RAL Unit** in cc.





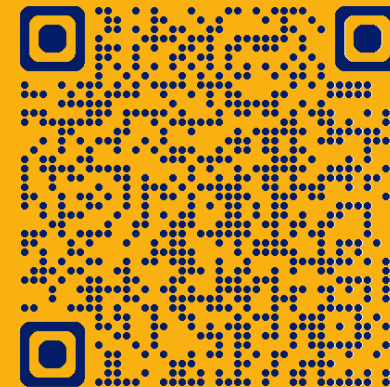
Enhanced User Guide on Confidentiality **NOW LIVE!**

Your **go-to resource on confidentiality**

just became even more user-friendly:

- Revamped General Section (A)
- Improved IUCLID Section (C)

Check it out and navigate confidentiality smoothly!



[link to User Guide](#)