

***Pesticides Steering
Network***

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Confidentiality - Lessons learnt & next steps

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Legal & Assurance Services

Trusted science for safe food

- Subject to proactive disclosure requirements under the Transparency Regulation
- Transparency is the rule, confidentiality is the exception
- in **the absence of confidentiality requests** submitted with regard to information, documents or data supporting the application, **EFSA will make proactively available to the public the entire dossier including** all information, documents and data submitted once an application is considered admissible
- **EFSA publishes the application as received once declared admissible**
- **Confidentiality** decision making starts ***after* admissibility**

RMS / EMS proactive role key in admissibility phase to verify:

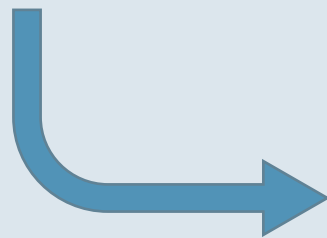
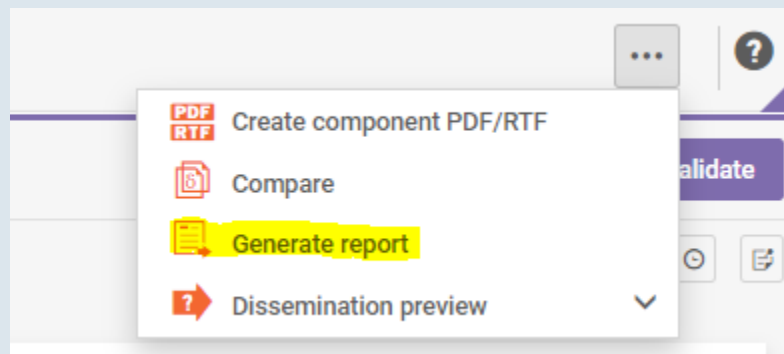
- A. Correct submission of attachments
- B. Personal data claimed confidential and sanitised
- C. Identification of the information claimed confidential
- D. Compliant justifications

0. Preliminary step

How to verify confidentiality requests

How to generate the Confidentiality Report?

- The Confidentiality Report is available under the 'Uploaded IUCLID reports':



2. Confidentiality requests

Table 2.1. Confidentiality requests

#	Entity	IUCLID section	Document	Doc. section	Justification	Accept Y/N
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The Confidentiality Report allows the applicant / MS / EFSA to identify:

- 1) the IUCLID sub-sections and/ or fields where a confidentiality flag has been set (with hyperlink)
- 2) the corresponding justification provided

If there is no confidentiality request

- For each attachment submitted, there must **always be a public version** under '*Attached (sanitised) documents for publication*'
- If no CRs are submitted, no other version of the attachment than the public version is to be submitted
- The field for confidential attachments ('*Attached confidential document*') is to be used **only** if the applicant submits a corresponding CR

If there is one or more confidentiality request(s)

- In addition to the public version, a **confidential version** must be submitted for each document including at least a confidentiality request,
- Applicants should **box or earmark** all information claimed confidential in the confidential version of attachments

- Applicant must submit CRs for **any personal data** contained in the information, documents and data submitted [except Art 39e(1) GFL]
- When submitting CRs based on Article 39e(3) GFL, the applicant is expected to confirm **whether the data qualify as personal data** as defined under Article 3(1) of Regulation (EU) 2018/1725

- The justification must contain a **clear identification of the precise field or attachment** subject to the request referring to the exact page, paragraph and line or part, as appropriate, where the piece of information claimed confidential is located (for attachments)
- Otherwise, EFSA / MS will not be able to assess the claim

Indicating the legal basis (ground) for the claim
[Art 39(2) and 39e GFL and, as appropriate, Art 63(2)(b) to (d) PPPR]

Justifying why the item should be kept confidential based on all below elements (except for personal data):

- Information not publicly available
- Potential harm to a significant degree
 - Information acquired legitimately
 - Negligible harm – rebuttable presumption
 - Novelty – rebuttable presumption
- Environmental information?

- Proposal for confidentiality assessment workflow for EFSA to be proposed to process requests received via IUCLID
- Changes on filtering rules to ease submission and assessment of certain Personal Data
- Business case to look into possibility for further adapting filtering and flagging features

Timeline: by 16 October

- PSN members screening applications kindly asked to perform a light check on the presence of key elements in confidentiality requests
 - a. Personal data sanitised
 - b. For confidentiality requests submitted, background documents and
 - c. a justification should be present
- PSN members to share their suggestions in improving the confidentiality justification template currently available in IUCLID
- PSN members to share feedback regarding current filtering and flagging scheme

Legal texts

- Transparency Regulation 2019/1381: [here](#)
- General Food Law Regulation No 178/2002: consolidated text [here](#)
- Pesticides Regulation No 1107/2009: [here](#)
- Practical Arrangements concerning transparency and confidentiality: [here](#)
- Practical Arrangement concerning confidentiality for decisions under Article 7(3) and 16 or Regulation 1107/2009: [here](#)

Guidance/training materials

- Q&As on EFSA's Practical Arrangements: [here](#)
- EFSA's administrative guidance for regulated products: 2021 update [here](#)
- EFSA's administrative guidance for pesticides active substance and MRL applications: 2021 update [here](#)
- IUCLID filter rules: [here](#)
- Relevant IUCLID manuals: [here](#)
- Training material under the *Transparency Regulation Implementation Training Programme* [page](#)