

5th PSN ICULID subgroup meeting – 05 December 2022



Updates on confidentiality

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- **Not one single consultation request yet received by EFSA from RMS** in context of NAS confidentiality assessment
- **Reminder - PAs concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 107/2009 (Article 7(6)) require RMS to consult EFSA (confidentialityrequestassessment@efsa.europa.eu) on draft confidentiality decision on NAS dossier**

- **Objective:** ensuring **consistency** between EFSA's & RMS' confidentiality assessments on identical or similar items included in pesticide dossiers

- **Common position between MS & EFSA is essential:** otherwise, the respective confidentiality decisions adopted by EFSA & the RMS may undermine each other

- Scenario where use of mandatory consultation is particularly important – **NAS dossier with cross-referenced MRL dossier** concerning intended uses specified in NAS dossier
- Risk assessment for NAS and related MRL are **closely interlinked** (e.g. publication consultation for NAS and related MRL are launched simultaneously & there is one common EFSA output)
- RMS and EFSA shall **make every effort** (above & beyond the mandatory consultation mechanism) to **coordinate respective confidentiality assessments**. This concerns also the **timing** of the respective confidentiality assessments which shall to the extent possible be **aligned**



Legal documents:

- General Food Law: [consolidated text of Regulation \(EC\) No 178/2002](#)
- Transparency Regulation: [Regulation \(EU\) 2019/1381](#)
- PAs on transparency and confidentiality: [Practical Arrangements concerning transparency and confidentiality](#)
- PA on confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009: [Practical Arrangements on confidentiality in accordance with Articles 7\(3\) and 16 of Regulation \(EC\) No 1107/2009](#)
- Q&A on Practical arrangements: <https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements>



Guidance/training material:

- [User guide for the submission of confidentiality requests](#) **NEW March 2022!**
- [Webpage on confidentiality assessment and content sanitisation](#) **NEW – September 2022!**
- [Toolkit for applicants](#) – overview of all EFSA portals
- [IUCLID](#)
 - [EFSA: IUCLID Training for applicants](#)
 - [IUCLID videos on most common mistakes \(part 1\)](#)
- [Webinar on confidentiality assessment and content sanitisation in the context of the Transparency Regulation](#) – **NEW September 2022!**



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