

5th PSN ICULID subgroup meeting – 05 December 2022

Updates on confidentiality

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Trusted science for safe food

RMS confidentiality assessment (NAS) – mandatory consultation of EFSA on draft decision – 1



 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

RMS confidentiality assessment (NAS) – mandatory consultation of EFSA on draft decision – 2



 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

RMS confidentiality assessment (NAS) – mandatory consultation of EFSA on draft decision – 3



- 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

Useful information





Legal documents:

- General Food Law: <u>consolidated text of Regulation</u> (EC) No 178/2002
- Transparency Regulation: <u>Regulation (EU)</u> 2019/1381
- PAs on transparency and confidentiality: <u>Practical</u> <u>Arrangements concerning transparency and</u> <u>confidentiality</u>
- 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: <u>https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements</u>



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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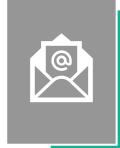
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