

6th PSN IUCLID subgroup meeting

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# FEEDBACK FROM EFSA

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# OUTLINE

- Admissibility declaration
- Admissibility checklist
- Key messages
- Comparison tool
- Troubleshooting
- Bilateral meetings with MSs
- Workflow for public consultations
- Key posts in PSN channel



# ADMISSIBILITY DECLARATION – NOS INFORMATION

- The PPP Regulation establishes the RMS/EMS role in the declaration of the admissibility of PPP application dossiers.
- The Transparency Regulation has introduced the need for RMS/EMS to check the compliance with the obligation with the study notification within the admissibility step.
- EFSA is providing an extraction from the NoS database. However, EFSA will no longer provide comments on the NoS extractions. The NoS check is under the remit of the RMS/EMS, as defined in the TR.
- Once the RMS/EMS declares the admissibility of a dossier, EFSA will only check the presence of the set of documents indicated in the Administrative Guidance and proceed with the acknowledgment of the admissibility.



# ADMISSIBILITY DECLARATION - COMBINED NAS/AIR AND MRL APPLICATIONS

- When a NAS\* (or renewal) and MRL applications are submitted at the same time (the applicant should indicate the link between the two submissions in the dossier header)
- -> we recommend the MS to declare the admissibility of the two application dossiers at the same time: this ensures the confidentiality assessment will run simultaneously and EFSA will launch the public consultation on the two application dossiers simultaneously.
- When a renewal and MRL applications are NOT submitted at the same time (e.g. one of the two dossiers is received months later)
- -> the two applications can be processed independently.
- -> for efficiency reasons, the RMS might want to perform a combined evaluation (MRL application as part of the peer-review) and address the MRL evaluation with the DAR/RAR.

\* NAS and MRL are always declared admissible at the same time



# ADMISSIBILITY DECLARATION - JOINT SUBMISSION/INDIVIDUAL SUBMISSIONS FOR THE SAME ACTIVE SUBSTANCE

- In the case of Joint Submission/Task Forces for the same active substance approval (NAS) or renewal (AIR) -> we recommend the RMS to send the declaration of admissibility simultaneously for the lead dossier and all members of the joint submission/task forces (providing all UUIDs).
- In the case of individual submissions for the same active substance approval (NAS) or renewal (AIR) (no agreement on the JS/TF reached among the applicants) -> we recommend the RMS to send the declaration of admissibility simultaneously for the individual submissions.

-> this ensures the confidentiality assessment will run simultaneously and EFSA will launch the public consultation simultaneously.



# ADMISSIBILITY CHECKLIST

- The latest version of the **Admissibility Checklist** is available in the IUCLID PSN – All participants - folder “Resources”: [FINAL\\_Admissibility checklist for pesticide applications.docx](#)
- The admissibility checklist will be included as **Appendix to the EFSA Administrative Guidance**. The EFSA Administrative Guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure is currently under revision.
- We would like to highlight that EFSA is organising **pre-admissibility teleconference with Member States** to discuss any topic related to the admissibility check (dossier completeness, NoS information, light confidentiality check) and offer support. Please contact us via the FDP FMB (FDP@efsa.europa.eu) should you wish to receive such support.



# KEY MESSAGES

- Check that information in DAR/RAR/ER are compliant with the information in the IUCLID dossier.
  - Work is ongoing on the development of the use of the annotation tool that should support in the future the generation of ER and AR.
  - Dossier updates received during the admissibility trigger a new NoS check.
  - Dossier updates received during the scientific risk assessment by the RMS/EMS do not trigger a new NoS check --> No NoS assessment foreseen by the RMS/EMS at this stage.
- New document [Process and responsibilities for study notification of pesticide dossiers](#)



# COMPARISON TOOL

Video's on how to use the compare tool

- Comparison of Dossiers: [SPC Comparison tool demonstration - YouTube](#)
- Comparison of Documents: <https://www.youtube.com/watch?v=cUy6ahta3dE>





# TROUBLESHOOTING

- Supporting info for MSs organisations to access EFSA Agency is available in the IUCLID PSN – All participants: [Supporting info for MSs organisations to access EFSA Agency\\_v1.pdf](#)



Supporting information for Member  
States Organisations to access EFSA  
Agency IUCLID

European Food Safety Authority



# BILATERAL MEETINGS WITH MEMBER STATES

- EFSA has started a round of bilateral meetings with Member States to discuss relevant issues and challenges encountered during the evaluation of post-transparency applications.
- The topics discussed include problems with IUCLID access, admissibility check issues, technical IT problems, use of the report generator, specific topics on NAS/renewal/MRL application dossiers.
- We have had so far three meetings respectively with AT, DK and NL.
- We aim at reaching other MSs during the coming months
- Please express your interest in participating to these bilateral meetings. In any case please be reminded that you can contact us for any issues/questions related to the admissibility.



# KEY POSTS IN THE PSN CHANNEL

- [RICHARDSON Jane: How can I find something quickly if I have a UUID](#)
- [RICHARDSON Jane: Sometimes values are not visible in IUCLID](#)
- [RICHARDSON Jane: April 2023 IUCLID format release](#)
- [DELFINO Alessandro: Process and responsibilities for study notification of pesticide](#)
- [...](#)
- [SCARLATO Alessia Pia: New approach on Personal Data from 01 January 2023](#)



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