



**FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
28 MARCH 2023**

FEEDBACK FROM DE (BVL)

Encountered problems when working with IUCLID Cloud:

- Login accounts for EFSA DMS/ VPN are suddenly blocked for no apparent reason (password was used correctly). Germany kindly ask EFSA for the conditions under which the accesses are blocked.
- Access to the cloud is currently unstable: during work, users are logged out or even blocked for the day. The problem was especially encountered during the creation of the List of attachments.
- Sometimes necessary reports cannot be generated for days accompanied by error messages or logout from IUCLID (e.g. List of attachments, Documents L).



FEEDBACK FROM DE (BVL)

Questions regarding the availability and security of the dossiers in IUCLID Cloud:

- For how long will be the dossiers available in the Cloud?
- Is it planned to delete earlier versions of the dossiers, e.g. after the admissibility of a dossier is declared or after the assessment is closed?
- Is it possible to remove earlier versions of a dossier, if the newer versions were submitted in form of light-dossiers?
- Is it planned to archive the dossiers after the assessment is closed and if so, would it be possible for the MS to access the archived data?
- Is it guaranteed, that the dossiers after submission are unmodifiable in IUCLID-Cloud from all the parties involved?



FEEDBACK FROM DE (BVL)

Questions regarding the annotations function:

- What is the status and timeline of the introduction of the annotations?
- Will it be possible to turn off the function, e.g. when a commenting phase is over or when the assessment of a dossier is closed?

Other questions:

- Would it be possible in the future to search for a certain study in all submitted dossiers?
- Is a data base of all submitted studies planned in order to support the one substance – one evaluation concept? If yes, will it be open for MS?



FEEDBACK FROM FR

In the frame of the NoS Check for an MRL dossier we recently found the following comment:

*"Considering EFSA's legal obligation to publish a dossier upon admissibility and in order to ensure a smooth and robust process, a **teleconference between the RMS/EMS and EFSA is strongly recommended prior to the declaration of admissibility** with the aim of checking the key elements of the dossier and of the admissibility checklist to avoid issues at a later stage.*

*The RMS/EMS should contact EFSA (FDP@efsa.europa.eu) to **set up this teleconference prior to the declaration of admissibility.**"*



FEEDBACK FROM FR

•Remarks:

- This comment was written in a document called "comments" (format "blocnote").
- No other comments were listed.
- This blocnote was found on EFSA DMS after an update of the IUCLID dossier asked by the RMS (not available before)
- No other dossiers currently under assessment in France contain this comment.

Questions:

- Could EFSA clarify what kind of comments can be found in the document called 'comments'?
- Could EFSA clarify this specific comment on their strong recommendation to MSs to have telconfs prior to admissibility?



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