Questions on IUCLID - DE

Generally:

- In which procedures will IUCLID be mandatory as the standard data format in the future?
- When will IUCLID become mandatory for the respective procedures?
- Which features and functions in IUCLID need to be handled by the RMS? E.g. is the use of annotations or the use of the report generator mandatory?

With special regard to the transparency:

- How does the implementation of IUCLID contribute to an increased transparency?
- Will there be a public access to the IUCLID cloud?
- Does the implementation of IUCLID fully cover the requirements of the Transparency Regulation or does EFSA consider that also the product evaluation procedures for plant protection products need to be included? If so, could you please specify the timeframe and the responsibilities, especially with regard to the planned use of PPPAMS from the European Commission.

Organisational:

- Will the implementation of IUCLID change the format of the assessment reports?
- What is the (actual) template behind the report generator and is it editable for RMS?
- How are revised dossiers reflected in IUCLID and how does EFSA ensure that MS always use the latest version of the dossier as a source of information?
- When submitting a revised dossier, are applicants expected to provide a cover letter with a summary of the relevant changes? If so, where can these cover letters be found?
- How can the RMS easily identify relevant differences between subsequent dossiers?
- How is a consistent presentation of different revised dossiers in IUCLID ensured?
- How can literature that is not part of the dossier, but considered relevant by the RMS, be included in the dossier?

Special technical questions:

- IUCLID is not a Document Management and File Processing System. For this reason, R4BP is used in the biocidal area. How will EFSA make the assessment processes transparent for applicants and MS?

- Do personal RSA keys as in the biocidal and REACH processes guarantee the safe access to IUCLID?

- When will the individual roles and rights for the access of IUCLID be organised?

- Is there any link of the studies in IUCLID to the "Notification Register of Studies" planned? Is it planned that the RMS need to use this source of information?

- What about the implementation of a software used for the sanitisation?

- Will ECHA's technical support for IUCLID be expanded by the introduction of the plant protection processes?