PSN - IUCLID Commission feedback

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5.12.2022

Challenges - General

- Severe delays on admissibility due to:
    - Steep learning curve
    - NoS checks – moving targets
    - Confidentiality/Personal data/Intellectual property checks
    - Connection (VPN) issues
    - Finding documents in the template structure
    - Different numbering/titles than data requirements

- MS still often requesting dossiers also in the pre-TR format

- Building up knowledge of the IT system and keeping up with upgrades

- Populate IUCLID with pre-IUCLID submitted data (who, when, how)

Challenges – basic substances

Experience based on the few dossiers submitted so far

- Applicants experience difficulties in completing the dossier correctly
  In particular:
- GAP table is filled in incorrectly (point to consider: revise the manual to make it easier)
- Information related to notification of studies is not correctly provided
- General problems with getting the dossier submitted:
  - applicants contacted COM to ask if they can send the dossier by e-mail because of general difficulties with IUCLID
  - applicants contacted COM to ask for confirmation whether the dossier was received in IUCLID (no clear information from the system following submission?)
  - applicants informed on the need to employ consultant for assistance with IUCLID (whereas the submission was meant to be simple for basic substance applicants)

- The majority of the options in report generator are not applicable to basic substances

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Advantages

- Dossier availability for authorities and stakeholders

- Ensure interoperability and dossier to be submitted, searched, copied and printed

- Centralised communication/notifications

- Centralised help desk and training materials

- Building up data repositories for future processes

Recommendations

- More agreed rules/checks (quality/business) are needed to avoid delays in the admissibility checks

- Better coordination between NoS information, checks and re-submission

- Early checks on confidential/personal data requests are needed to avoid delays in the admissibility check and publication of the content of the dossiers

- More report templates are needed also in less frequently used application types

- Users should collaborate with EFSA to refine report templates and then use them.