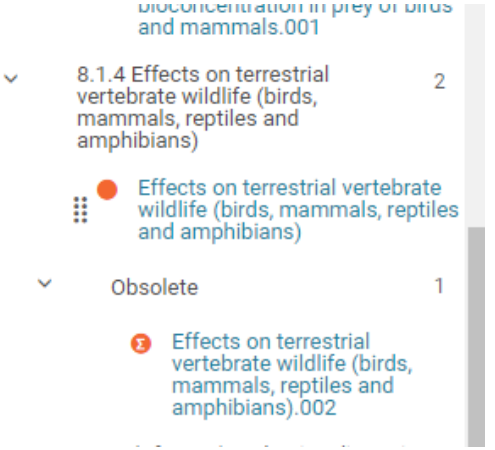
IUCLID: PSN Meeting March 2023

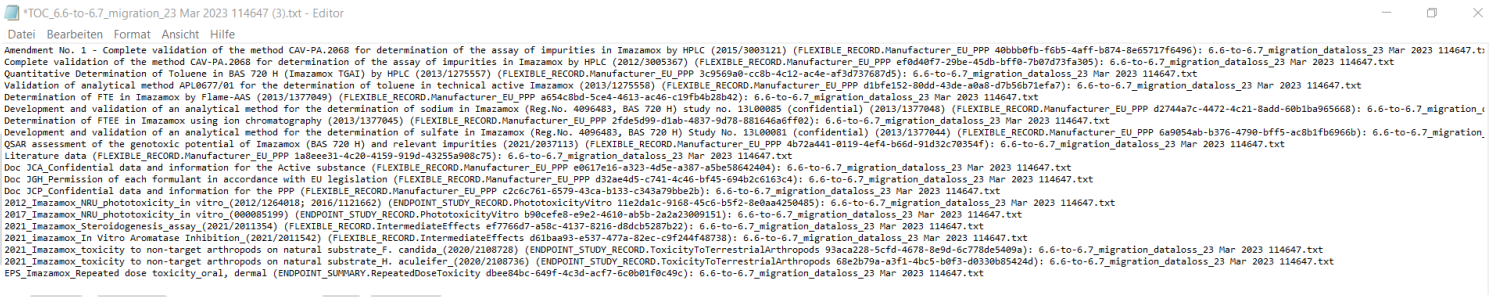
CropLife Europe

Migration to IUCLID 6.7

- **IUCLID format changes are necessary and overall welcome**
- **Data Migration is a difficult task and can never achieve 100 %**



- **IUCLID 6.7 situation**
  - About 300 documents changed
  - Migration impact massive
    - All PPP EP summaries moved to obsolete
    - Long List of individual documents where complete data loss occurs



Migration to IUCLID 6.7

Impact

- Submitted and Published Dossiers will be altered
- Several required Data will be gone completely

Solution ?

- No adhoc solution, manual rework needed
  - Resource intensive and time consuming (> 6 months for ai Dossier realistic considering number of Dossier submitted)
  - In line with applicable regulations?
  - Mistakes and data inconsistencies are given
  - Additional delays of regulatory processes triggered

Better Solution Going Forward

- IUCLID needs a toolbox for enabling parallel version support keeping submitted Dossiers stable for as long as required

IUCLID and Parallel Process

- **Issue**
  - Industry now have several dossiers using the same dataset in different stages of the process
    - Renewal (AIR) dossier, Art 12 MRL Confirmatory Data, Art 10 MRL Application
      - Pending admissibility, Admissible, Admissible respectively
    - The underlying dataset in these cases uses the same study reports and is “live”, needing to be updated as requested by the different stakeholders (RMS, eMS, EFSA)
    - Within the confidentiality stage EFSA have indicated that the dossier should not be modified, but resulting questions from the RMS on yet-admissibe applications, or version changes prohibit this.
    - This could be future complicated with submissions via a LoA by a 3rd party, or different MS for MRL v Renewal
  - **It is therefore not possible within the same dataset to amend according to these requests and resubmit <u>without changing the dossier in all processes</u>**

IUCLID and Parallel Process

Current Workaround

- Industry are in many cases forced to ***duplicate datasets*** to overcome these issues;
  - This results in many versions of the same information
  - Is increasingly impossible to administratively manage what data is in what process, what is the “approved” version and what version should be used moving forward, this will get increasingly difficult over time
  - Goes against the one substance, one assessment principle
  - Will prevent a succinct overview of data for any useful purposes within agency IUCLID as the same molecule, study reports with differing UUIDs and contents will be available

Request

- IUCLID should have sufficient data management tools and lifecycle management across competing processes to enable one substance, one assessment principles and allow for datasets to not require duplication to achieve stakeholder requests across projects.