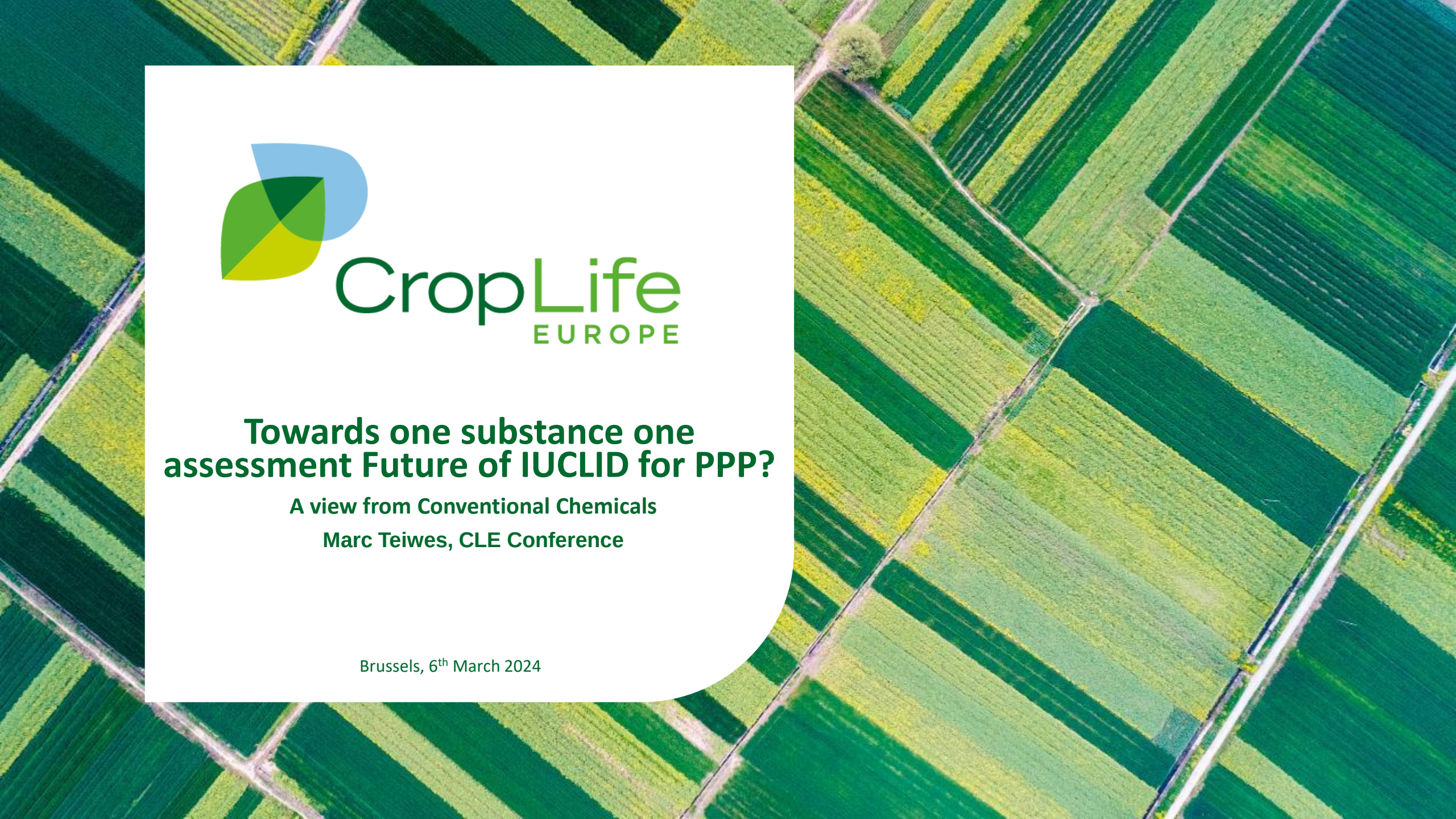


CropLife EUROPE

Towards one substance one assessment Future of IUCLID for PPP?

A view from Conventional Chemicals

Marc Teiwes, CLE Conference

Brussels, 6th March 2024

Implementation of Standard Data Formats under the Transparency Regulation

Conventional Pesticides

IUCLID 6

Biopesticides

IUCLID 6

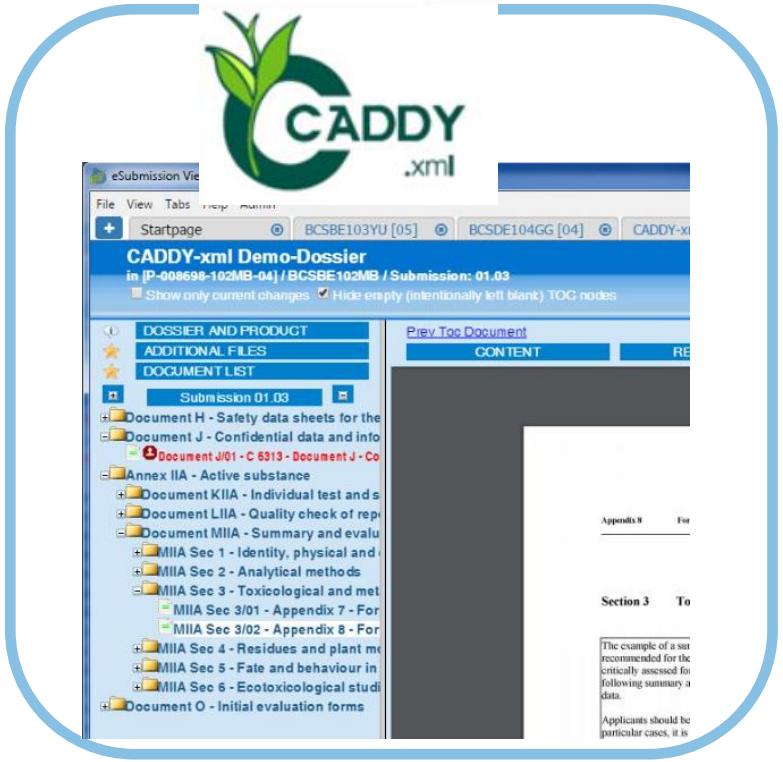
Plant Biotechnology

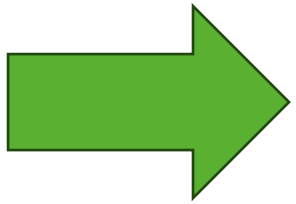
ESFC

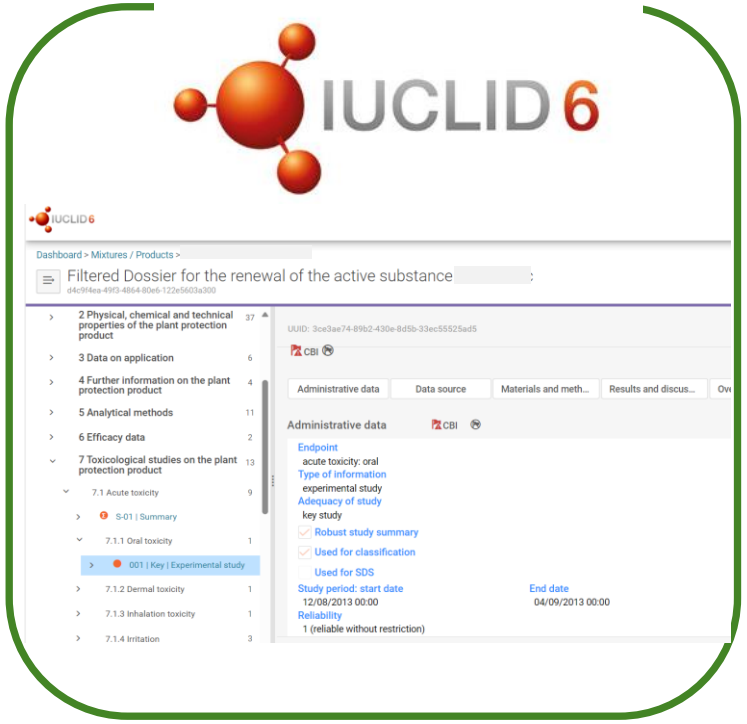
Digital and Precision Agriculture

N/A

IUCLID – not just a new tool for Dossier submissions







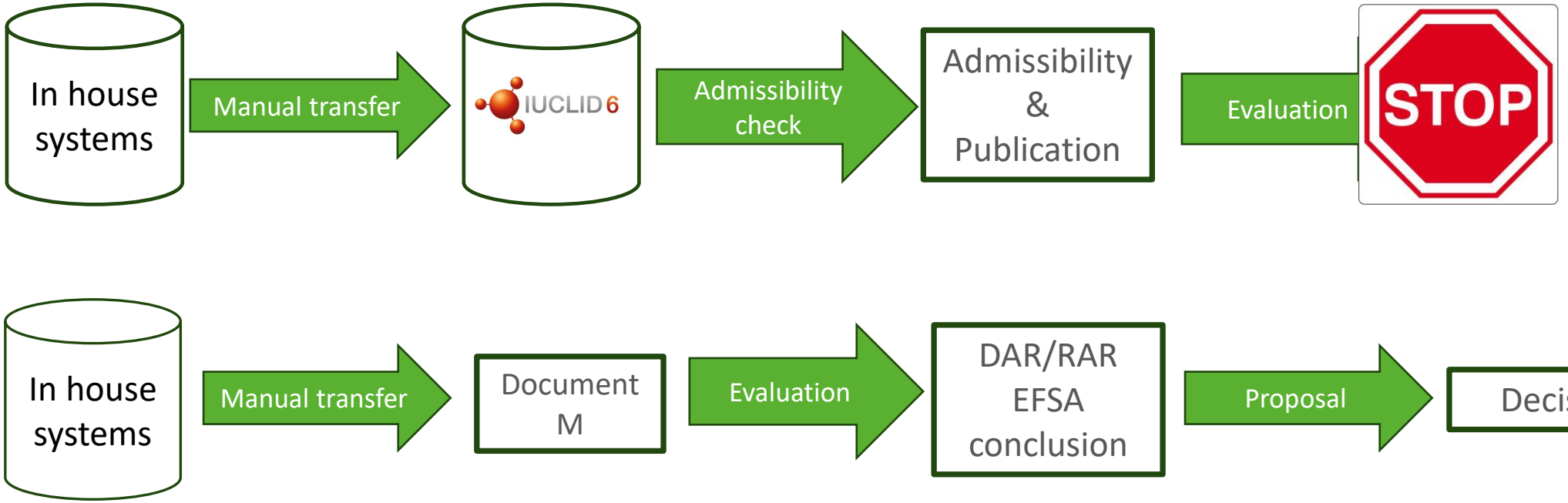
Paradigm Shift – from document-centric to data-centric submission

Promising move towards digitalisation

IUCLID Implementation

IUCLID has been implemented as **M**inimum **V**iable **P**roduct (MVP)

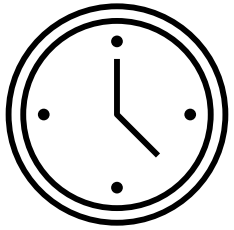
- Pure focus on filling of data for Dossier generation – manual work
- Not all data definitions available – some significant improvements made post-implementation
- No considerations on evaluation process – started post-implementation
- Parallel generation of „old“ summary Dossier still triggered



IUCLID for PPP
Current Status

CropLife EUROPE

IUCLID – Problems for applicants

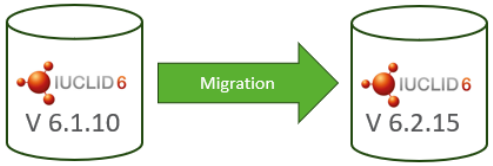


Performance of the software

- Time needed to compile an IUCLID Dossier more then 2000 hours on average partially due to long loading times and errors

Interoperability of IUCLID

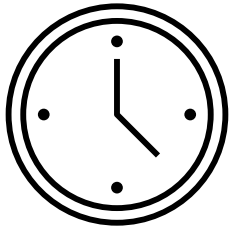
- IUCLID does not allow for smooth integration with existing systems
- Manual data transfer inefficient and error-prone



Transparency on changes and integrity of the dossiers

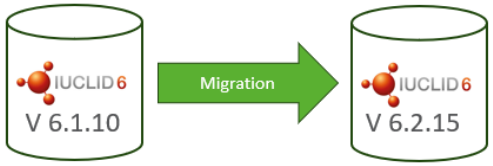
- New versions released 3-4 times per year with only partial data migration
- Need to constantly update the Dossier (not foreseen by Reg. 1107/2009)

IUCLID – Basis for evaluation?



Legal timelines

- New processes needed adaptation and increased pressure on timelines
- New processes triggered additional huge delays (this starts to significantly improve)



Transparency on changes and integrity of the dossiers

- Difficulty to make use of data in the evaluation process because Dossiers are altered with each Major release
- Depicting data loss and changes subject to high workload

Report generator

- Good functionality providing exerts of data (-> Document M, L, etc.)
- Often lacks information as targeted fields in IUCLID are not filled
- Alignment to DAR/RAR not finalised

IUCLID Outlook

IUCLID for one substance, one dataset, one evaluation ?

One example from PPP Domain alone: 5 different Dossiers for one active substance submitted so far

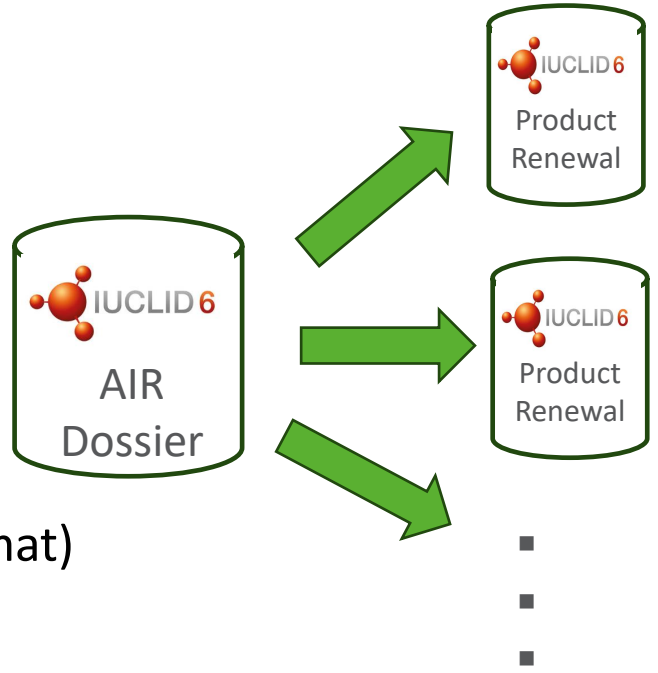
- For each submission an independent data set exists within applicant IUCLID to comply with the **valid** provision not to change anything to the data in evaluation process
- Submissions follow different legal processes with overlaying timelines
- Data are partially redundant and in different states of maturity due to IUCLID updates applied in between

  - **Currently it is not possible to re-use IUCLID entries within one regulated domain**
  - **Version control in IUCLID missing to bring the concept of one data set – many submissions to life**

IUCLID for national Product authorisation?

Logical step BUT intense preparation needed before implementation

- Implementation of missing data definitions (e.G. for efficacy, RAs, etc.)
- Enablement of Re-use of active substance data (incl. Peer Review outcome)
- Version control
- Support and considerance of the zonal process from the beginning
- National Requirements
- A real-case Pilot should be run prior to full implementation (as for dRR Format)



- **A prerequisite should be an end to end solution for the EU process**
- **A ten-year time frame foreseen for realisation**

Conclusion

Move to structured data welcome and fully supported as it bears huge potential

- ❖ Increase transparency and data clarity
- ❖ Reduction of administrative burden

Several steps needed to ensure efficiency and transparency of the RA process prior to considering IUCLID to be expanded further:

- ➢ Version control to enable re-use of data throughout the Regulatory Life Cycle of a molecule
- ➢ Full implementation of evaluation processes using IUCLID data
- ➢ Implementation of missing data definitions
- ➢ Improvement of IUCLID Performance

Thank You!

CropLife EUROPE