

# IUCLID Feedback: Industry Perspective

Monika Bross (BASF), Andrew Whyte (ADAMA)

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# Feedback – Industry view



## IUCLID Software – Release of future versions

### – Release cycles:

- June – July 2022 (ECHA Cloud Services) - intermediate release
- 31<sup>st</sup> of October 2022 – service release
- 25<sup>th</sup> of April 2023 - major release, including format changes

### – Positive:

- Apr 2023: Early communication about intended changes in OHTs / EPS
- Commenting phase in Q 3 2022 announced

### – Concerns:

- More than 100 OHTs / EPSs will change:
  - Impact on validation rules in correlation with submitted dossiers unknown
  - Transition phase?

**Our expectation:** Early information of changes, comprehensive testing prior to official releases (with stakeholder involvement)

# Feedback – Industry view



## IUCLID Software - Data entry and reporting

- IUCLID requires significant changes before adding most of its potential value and being fit-for-purpose for crop protection submissions. For making IUCLID work, further changes are essential.
- One important goal would be to improve the user-friendliness for people entering data into IUCLID. E.g. by
  - **Improvement of Metapath**
  - **Electronic transfer of data into IUCLID (if needed and especially important for complex OHTs)**
  - Cross references between different datasets (e.g. Selection of GAPs)
  - Consistency of drop-down lists
  - Removal of character limitations in rich text fields
  - Removal of limitations in the selection of study types
- As subsequent step, the report templates should be improved. Besides the existing formats, other formats might be considered (\*.csv?)



# Feedback – Industry view

## IUCLID Software – Data entry: Metapath

- Further improvements of OHTs are required to produce high quality dossiers: Focus should be on the continued development of Metapath
- An industry subteam has identified several points for short and midterm improvement considering the major pain points.

### Composer



usability



data entry



time-consuming



error-prone



accuracy



text limitations

### MetaPath



data connection



compatibility



performance



interoperability

### Organizational



not centrally hosted



limited access



publication rules

# Feedback – Industry view



## IUCLID Software – Data entry: Metapath (cont.)

- Need of improvement is shared by other stakeholders: BfR Report on Metapath and a suggestion for Metapath II

### Our expectation:

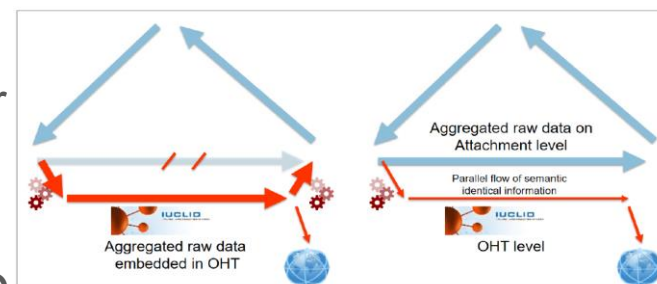
Timely bug fixing of known errors and pain points reducing efforts for composer file (Metapath) entries

Continued discussion on Metapath and successor with all stakeholders involved (MUG)

EFSA activity: Careful investigation (testing, impact, reporting) on the future purpose of IUCLID OHTs 85-2 and 85-3: Transport system or actual inclusion of data

OHT No	ENDPOINT_STUDY_RECORD name
OHT24	PhototransformationInAir
OHT25	Hydrolysis
OHT26	Phototransformation
OHT27	PhotoTransformationInSoil
OHT28	BiodegradationInWaterScreeningTests
OHT29	BiodegradationInWaterAndSedimentSimulationTests
OHT30	BiodegradationInSoil
OHT32	BioaccumulationAquaticSediment
OHT33	BioaccumulationTerrestrial
OHT34	AdsorptionDesorption
OHT56	BiotransformationAndKinetics
OHT58	BasicToxicokinetics
OHT59	DermalAbsorption
OHT85-1	MigrationOfResidues
OHT85-2	MetabolismInLivestock
OHT85-3	MetabolismInCrops
OHT85-8	NatureResiduesInProcessedCommod
OHT85-10	StabilityOfResiduesInStoredCommod

Source: ECHA



Source: BfR

# Feedback – Industry view



## IUCLID Software – Data entry: Complex OHTs

- Relevant information to be submitted in formats (OHTs and endpoint summaries) partly developed more than 10 years ago and never used in regulatory practice (e.g. residues)
- Today: Development of multiple work arounds: Generation of attachments files, use of free text fields (non structured data)
- The simple manual data entry into complex IUCLID OHTs is not feasible without providing a suitable upload functionality using human readable sheets.

### **Our expectation:**

Mandatory prerequisite: Development and availability of a user-friendly and manageable upload functionality either into IUCLID or in any other database without generation of multiple Excel files

Submission of complex information via attachment files (xml, agreed format) retaining only human-readable information on the level of the display of the OHTs in IUCLID

# Feedback – Industry view

## IUCLID Software – Reporting

- The IUCLID report generator is still insufficient, with MS requesting MCA/MCP dossier in parallel to meet their evaluation needs and for preparation of assessment / evaluation reports.

### Our expectation – mid / long term (after revision of OHTs / EPSs!):

It would be beneficial for each report to be accompanied by a mapping document stating the source of the information and how the report is compiled to identify issues

This would enable high quality IUCLID input in endpoint summaries such that the report may be useful for evaluation purposes

<b>Crop code</b> RIBSS (RIBRU)
<b>Crop variety</b> Rovada
<b>Date of planting</b> 2005-03-05
<b>Date of flowering (beginning)</b> 2020-04-30
<b>Date of flowering (end)</b> 2020-05-10
<b>Soil characterization</b> Loamy sand
<b>Plot description</b>
<b>Plot</b>
<b>Application</b>
<b>Application</b>
<b>Application no. (1, 2)</b> 1
<b>Growth stage code (BBCH) at application</b> 55-57
<b>Date of application</b> 2020-04-15
<b>Method of application</b> other:
<b>Applied test material</b>
<b>Test material information</b> SPU-02700-F
<b>Formulation type</b> SC Suspension concentrate (= flowable concentrate)
<b>Active ingredients (a.i.)</b>
<b>Related substance information</b> Copper dihydroxide / Copper (II) hydroxide or cupric hydroxide / 20427-59-2 / 243-815-9
<b>EC number</b> 243-815-9
<b>EC name</b> EC
<b>CAS number</b> 20427-59-2
<b>CAS name</b> Copper hydroxide
<b>IUPAC name</b> Copper (II) hydroxide or cupric hydroxide

# Feedback – Industry view

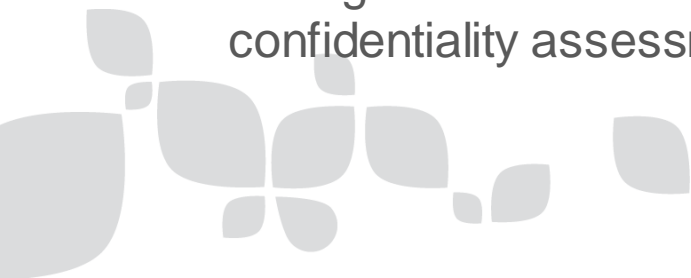


## IUCLID Software – Confidentiality checks

- Still a lot of unclarity around the process
- Confidentiality assessment poses high workload for industry and seemingly for regulators

### **Our expectation:**

- Simplification/Reduction of Confidentiality claims in IUCLID urgently needed
- Further examples would be beneficial to allow applicants to fully address EFSA requirements proactively
- Little experience to date with only one AIR dossier (of ~30 submitted) having been deemed admissible, published and have gone through the confidentiality assessment process





# Feedback – Industry view

## IUCLID – Admissibility and submission check

- Experience with the new process indicates that there are several checks
- Most dossiers required several updates due with NOS, scientific admissibility and validation alert updates updated separately
- Delays in the process and short deadlines are given (but so far no predictability as to when these may occur)
- The upload of revised dossier versions result in
  - Repetitions of the NoS ID checks
  - Validation errors in case of version changes
  - Questions from member states

### **Our expectation:**

We appreciate the commitment of EFSA to improve communication on timelines

Further guidance/experience is necessary for applicants to increase quality of IUCLID dossiers and reduce MS workload

# Feedback – Industry view

## IUCLID – Post Admissibility Phase

- After passing admissibility and during member state evaluation, industry typically addresses upcoming questions by submission of further argumentation, data or studies.
- The submission of such data is not resulting in the submission of full dossier updates.
- These data will be considered in the dAR and the updated dossier.

### CLE view – for discussion and alignment:

The process should be driven by the applicable Regulations

In the post admissibility phase, dossier updates (IUCLID) should be provided once (following the same process as for previous submissions)

