



**IUCLID PSN meeting
05th December 2022
Feedback/stakeholder Issues**

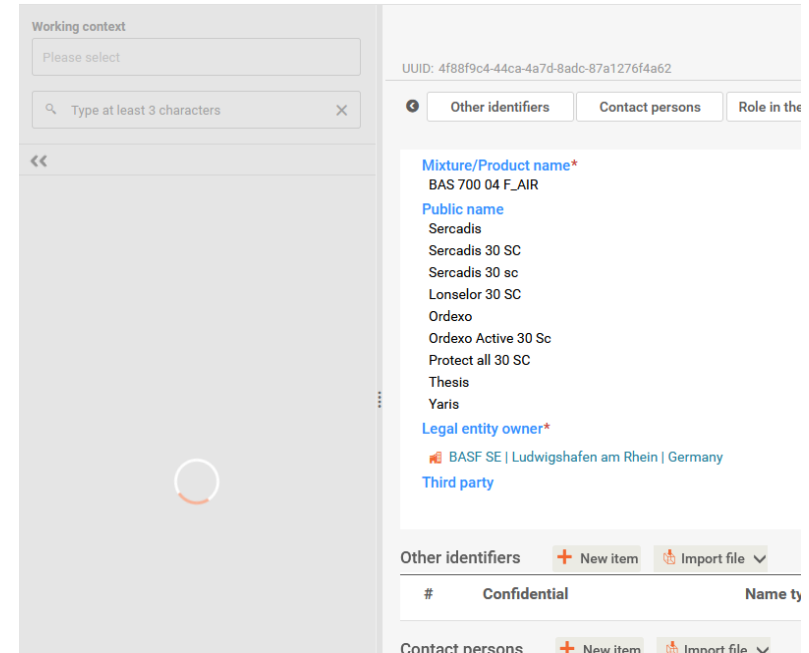
IUCLID

Recent Technical issues

Several Applicants face severe technical problems with complex data sets as required for PPP submissions

- In some cases, with 6.6.27, in others already with 6.6.19
 - Data sets do not open
 - Dossier creation fails

=> Overall continuous operability of IUCLID could not be ensured in all cases



Working context

Please select

Type at least 3 characters

UUID: 4f88f9c4-44ca-4a7d-8adc-87a1276f4a62

Other identifiers Contact persons Role in the

Mixture/Product name*
BAS 700 04 F_AIR

Public name
Sercadis
Sercadis 30 SC
Sercadis 30 sc
Lonselor 30 SC
Ordexo
Ordexo Active 30 Sc
Protect all 30 SC
Thesis
Yaris

Legal entity owner*
BASF SE | Ludwigshafen am Rhein | Germany

Third party

Other identifiers + New item Import file

#	Confidential	Name ty
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Contact persons + New item Import file

Our Expectation:

- ❖ Next IUCLID update to focus on functionality, usability, scalability and robustness improvements even if at cost of delaying necessary format changes etc.
- ❖ IUCLID to be used **solely** for active substances and MRL submissions, at least until the technical issues are solved, and NOT for Product Authorisations.

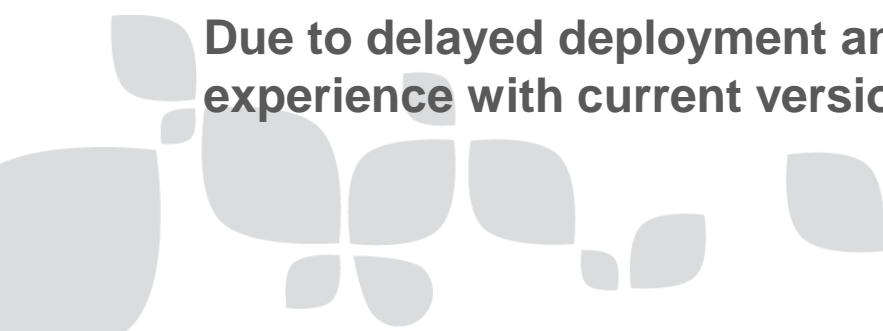
IUCLID Release of future versions



- **Release cycles:**
 - 31st of October 2022 – “service release”
 - 25th of April 2023 - major release, including format changes

- **Positive:**
 - Oct 2022: Validation rules early communicated
 - Apr 2023:
 - Communication about intended changes in OHTs / EPS
 - Draft versions published on the Internet (link ECHA webpage)
 - Commenting phase in Q 3 2022 initiated via OECD

Due to delayed deployment and severe technical issues: Limited experience with current version



IUCLID Release of version 6.6.27

IUCLID – Changes in Validation Rules

Validation Assistant: October release

➤ Completeness check of **Flexible and Endpoint Summaries**

Rules	Description	Flexible summary
QLT_PPP_116	FLEXIBLE_SUMMARY.ResiduesInLivestock must be provided in case KS, WoE is present in the section Feeding studies (ENDPOINT_STUDY_RECORD.ResiduesInLivestock)	FLEXIBLE_SUMMARY.ResiduesInLivestock
QLT_PPP_124	Flexible Summary Endocrine disrupting properties must be provided	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest
QLT_PPP_125	Flexible Summary MRL Proposal must be provided	FLEXIBLE_SUMMARY.MRLProposal
QLT_PPP_126	Flexible Summary Expected Exposure must be provided	
QLT_PPP_127	Flexible Summary Residue Definition Fate must be provided	
QLT_PPP_131	Flexible Summary Ecotoxicology Risk Assessment must be provided	
QLT_PPP_128	Flexible Summary Effects on aquatic organisms must be provided	
QLT_PPP_129	Flexible Summary Relevance of metabolites in general must be provided	
QLT_PPP_057	Flexible Summary Toxicological reference values must be provided	
QLT_PPP_132	Flexible Summary Data on exposure must be provided	
QLT_PPP_133	Flexible Summary Information on metabolites must be provided	
QLT_PPP_134	Flexible Summary Estimation of concentrations in general must be provided	
QLT_PPP_135	Flexible Summary Estimation of concentrations in general must be provided	
QLT_PPP_136	Flexible Summary Estimation of concentrations in general must be provided	

Validation Assistant: October release

➤ Completeness check of **Flexible and Endpoint Summaries**

☐ QLT_PPP_53-56 → *ENDPOINT_SUMMARY.ResidueFood*

Rules	Description
QLT_PPP_053	Proposed residue definitions. A Residue definition for enforcement for unprocessed plant/animal products must be provided
QLT_PPP_054	Proposed residue definitions. A Residue definition for risk assessment for unprocessed plant/animal products must be provided.
QLT_PPP_055	Proposed residue definitions. A Residue definition for risk assessment for processed crops must be provided.
QLT_PPP_056	Proposed residue definitions. A Residue definition for risk assessment for rotational crops must be provided

☐ QLT_PPP_58-61 → *FLEXIBLE_SUMMARY.ToxRefValues*



Rules	Description
QLT_PPP_058	Toxicological reference values document the AOEL must be completed (MO, MRL, Active sub app)
QLT_PPP_059	Toxicological reference values document the ADI must be completed (MO, MRL, Active sub app)
QLT_PPP_060	Toxicological reference values document the ARfD must be completed (MO, MRL, Active sub app)
QLT_PPP_061	Toxicological reference values must be complete, AAOEL (MO, MRL, Active sub app)

IUCLID Release of version 6.6.27

IUCLID – Changes in Validation Rules

Observation:



- New validation rules apply to already submitted dossiers prepared according to guidance received during the HyperCare programme
- Upload of revised dossiers (e.g. driven to address questions during admissibility / confidentiality check) results in multiple validation errors (quality rules)
- Validation rules seem to apply to all components of a mixture data set.

 5 Toxicological and metabolism studies on the substance ( Polysaccharide)



Toxicological reference values have not been provided. Flexible Summary, Toxicological reference values must be completed.

 6.7.2 Proposed maximum residue levels ( Polysaccharide)

The Flexible Summary MRL Proposal must be provided in the Active Substance dataset.

 6.9 Estimation of the potential and actual exposure through diet and other sources ( Polysaccharide)

The Flexible Summary Expected Exposure must be provided in the Active Substance dataset.

 7.4 Residue definition for risk assessment and environmental monitoring ( Polysaccharide)

The Flexible Summary Residue definition for risk assessment and environmental monitoring must be provided in the Active Substance dataset.

Our expectation:

- Validation rules must be carefully tested prior to deployment

IUCLID Release of future version 6.7



IUCLID – Changes in OHTs and EPSs

CLE feedback on updates of OHTs / EPSs:

- Submission of extensive comments to OECD for phys/chem, environmental fate and residue sections (OHTs, EPSs)
- If accepted by OECD / EFSA / ECHA: Considerable changes – also in data structure within OHTS
- Migration of current data not clear, obviously not all data can be migrated 1:1

Concerns:

- Apr 2023: More than 300 OHTs / EPSs will change; potential impact:
 - Dossier modification driven by software updates?
 - “Empty” OHTs in dossiers already under evaluation??
 - Overall: Admissible and published Dossiers are altered with no option to retrieve the “admissible state” ???



IUCLID Release of future version 6.7



Our expectation:

- Proper migration rules to be developed and communicated by ECHA / EFSA
- Any software updates to be tested by ECHA with real case scenarios (realistic dossier size and complexity, end-to-end testing, both in functionality and performance).
- Revisit priorities: Focus on functionality, usability, scalability and robustness improvements (if in conflict with format changes)
- Improvements in lifecycle management and parallel format support to avoid legal issues when changing already submitted dossiers during release updates

