12th meeting of the PSN IUCLID sub-group
11-12 March 2025

IUCLID FORMAT PLANNING AND VALIDATION RULES

FDP, IDATA, PREV

EUROPEAN FOOD SAFETY AUTHORITY

INTRODUCTION

- IUCLID 6 v9 release and EU_PPP latest changes
- Validation Assistant rules – 2025 plan

IUCLID FORMAT RELEASE

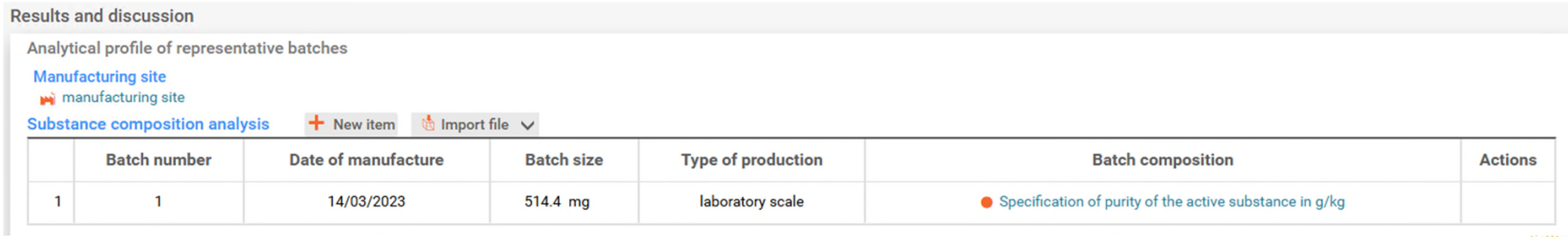
Next IUCLID format release scheduled on **26 May 2025**

- Below are some of the **planned highlights** for the upcoming release:
  - **User interface**
    - Simplifying the editing of fields in tables (delivered by OECD Activity 1)
  - **Performance improvement**
    - Continuing to improve the loading of the navigation tree in datasets
  - **Reporting**
    - Progressive transformation of providing reports in .docx format
  - **Access to ECHA repository**
    - Provide access to inventory of reference substances

https://iuclid6.echa.europa.eu/it/planned-releases

ANALYTICAL PROFILE OF BATCHES

- A new single Endpoint study record can be created for each manufacturing plant and/or for each 5BA submitted, including the administrative information related to the manufacturing plant (Link to point CA 1.2.1) and the production date and batch size (kg)
- A new endpoint summary can be created to collect the outcome of all the 5BA submitted for the active substance, sum up all the technical aspects and lead to a conclusion on the specifications
- **NEW repeatable block 'Substance composition analysis'**


Results and discussion

Analytical profile of representative batches

Manufacturing site

manufacturing site

Substance composition analysis + New item Import file

	Batch number	Date of manufacture	Batch size	Type of production	Batch composition	Actions
1	1	14/03/2023	514.4 mg	laboratory scale	Specification of purity of the active substance in g/kg	

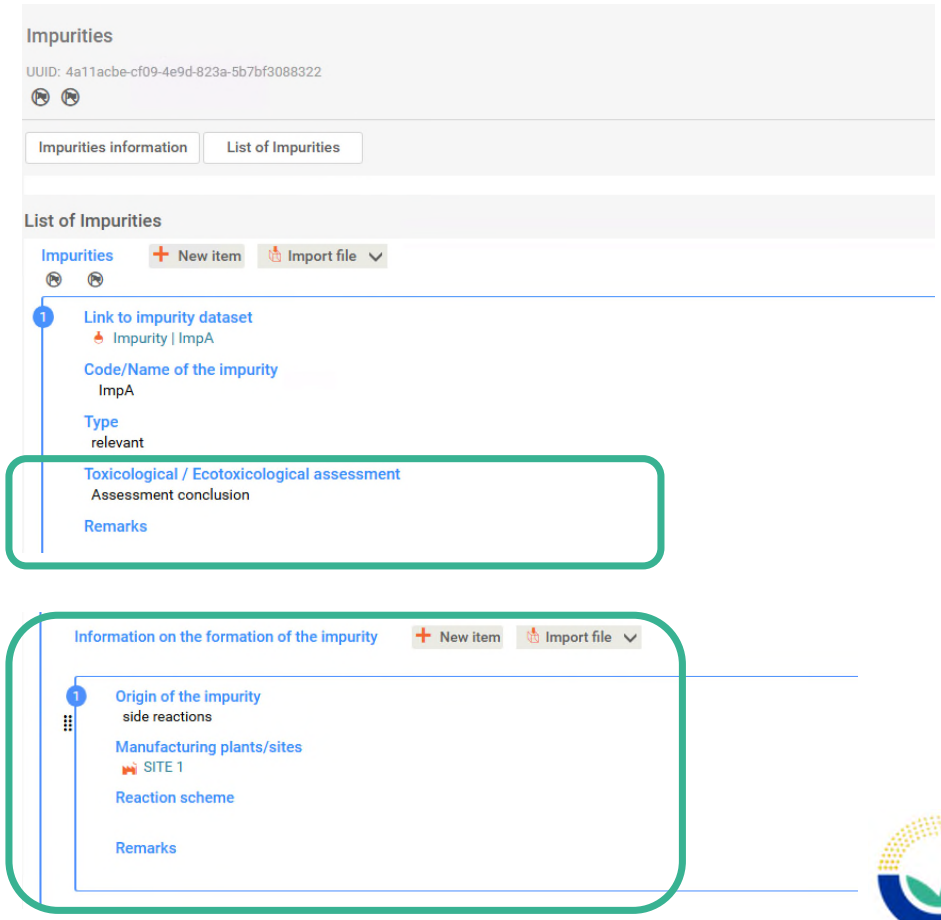
IMPURITIES

Document to list all types of impurities included in the dossier, either as substance dataset (if studies provided) or reference substance (no studies).

As from IUCLID 6v9 **NEW** nested repeatable table in the **IMPURITIES document** to report data on each impurity:

- Origin of the impurity
- Manufacturing plants/sites (Link to SITE → used to link to manufacturing and 5BA docs)
- Reaction scheme (Chemical reaction)
- Remarks

New field ***Toxicological / Ecotoxicological assessment*** to provide a high-level toxicological and ecotoxicological assessment and conclusion for the impurity



MICROBIAL TABLE OF CONTENT

- New four implementing Regulations are applicable as of 21 November 2022
- EFSA has updated the IUCLID Table of Content (ToC) in April 2023 to allow applicants comply with the new data requirements
- IUCLID documents that no longer comply with these data requirements were moved in section 'Previously used documents now obsolete, kept until April 2024'
- EFSA **intends to retain these documents**. Applicants who submitted their dossiers before November 2022 can still generate these documents to comply with the former applicable data requirements
- The section 'Previously used documents now obsolete, kept until April 2024' will be **renamed to 'Documents applicable to the former data requirements'**

SCOPE IUCLID 6.9 – VALIDATION RULES

- 7 new QLT warnings
- 2 QLT update
- 2 message update (QLT_155&156)

SCOPE IUCLID 6.9 – VALIDATION RULES

Section: Physical and chemical properties of the substance

Applicable to AS_Chemical working context. Only the AS dataset is checked

Target document	Specifications	Message
Appearance (ENDPOINT_STUDY_RECORD.GeneralInformation)	The rule checks that if an endpoint study record has been indicated as a 'key study' or 'weight of evidence' in the field 'Adequacy of study', then the fields **'Physical state at 20ºC and 1013 hPa**' and **''form/colour/odour**' must not be empty.	Results and discussion is not complete. For each record marked as 'key study' or 'weight of evidence', the fields 'Physical state at 20\u00B0C and 1013 hPa' and ''form/colour/odour' must be filled in
ENDPOINT_STUDY_RECORD.Partition	This rule checks that if an endpoint study record has been indicated as a 'key study' or 'weight of evidence' in the field 'Adequacy of study', then the table **'Partition coefficient**' must fulfil both of the following: 1. Complete means that at least one of the below is true:-All of the fields 'Type', 'Partition coefficient', 'Temp.' and 'pH' have been filled in, with unit.-	'Results and discussion' is not complete. For each record marked as 'key study' or 'weight of evidence', under the 'Partition coefficient' heading, the fields 'Type', 'Partition coefficient', 'Temp.' and 'pH' must be filled in with the unit where such a field is available. Each created entry must be complete. **In addition, The Partition coefficient at 20 °C or 25 °C shall be reported.** If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'. If 'other:' was selected in any of the picklists, the below field 'other' must be filled in.

SCOPE IUCLID 6.9 – VALIDATION RULES

Applicable to AS_Chemical working context. Only the AS dataset is checked

Target document	Specifications	Message
ENDPOINT_STUDY_RECORD.BoilingPoint **ENDPOINT_STUDY_RECORD.FlashPoint** **ENDPOINT_STUDY_RECORD.Melting** **ENDPOINT_STUDY_RECORD.Partition** **ENDPOINT_STUDY_RECORD.SurfaceTension** **ENDPOINT_STUDY_RECORD.Vapour** **ENDPOINT_STUDY_RECORD.WaterSolubility**	The rule checks that if an endpoint study record in the following sections has been indicated as a 'key study' in the field 'Adequacy of study', then the field 'Type of method' must be provided. Endpoint study records where the field 'Type of information' set to one of the following are not checked: experimental study planned experimental study planned (based on read-across) (Q)SAR calculation (if not (Q)SAR) read-across based on grouping of substances (category approach) read-across from supporting substance (structural analogue or surrogate)	'Materials and methods' is not complete. For each endpoint study record in this section marked as 'key study' the 'Type of method' must be provided. If 'other:' was selected the below field must be filled in.

SCOPE IUCLID 6.9 – VALIDATION RULES

Applicable to AS_Chemical working context. Only the AS dataset is checked

Target document	Specifications	Message
ENDPOINT_STUDY_RECORD.Vapour	The rule checks that if an endpoint study record has been indicated as a 'key study' or 'weight of evidence' in the field 'Adequacy of study', then the table **'Vapour pressure**' must fulfil both of the following: 1. At least one row must exist in the table. 2. Each created row must be complete. Complete means that at least one of the below is true: -Both of the fields 'Vapour pressure' and 'Temp.' have been filled in, with unit.	'Results and discussion' is not complete. For each record marked as 'key study' or 'weight of evidence', under the 'Vapour pressure' heading, the fields 'Vapour pressure' and 'Temp.' must be filled in with the unit where such a field is available. Each created entry must be complete.**In addition, The vapour pressure at 20 °C or 25 °C shall be reported.** If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'. If 'other:' was selected in any of the picklists, the below field 'other' must be filled in.
ENDPOINT_STUDY_RECORD.SolubilityOrganic	The rule checks that if an endpoint study record has been indicated as a 'key study' or 'weight of evidence' in the field 'Adequacy of study', then both of the following must be fulfilled: 1. the table **'Solubility in organic solvents / fat solubility**' must contain at least one row; 2. Each created row must be complete. Complete means that at least one of the below is true: -All of the fields 'medium', 'solubility' and 'Temp.' have been filled in, with unit.	Results and discussion' is not complete. For each record marked as 'key study' or 'weight of evidence', under the 'Solubility in organic solvents / fat solubility' heading, the fields 'medium', 'solubility', and 'Temp.' must be filled in with the unit where such a field is available. Each created entry must be complete. In addition, if the solubility is less than than 250 g/L, also the solubility at 20 °C or 25 °C shall be reported. If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'. If 'other:' was selected in any of the picklists, the below field 'other' must be filled in.
ENDPOINT_STUDY_RECORD.DissociationConstant	The rule checks that if an endpoint study record has been indicated as a 'key study' or 'weight of evidence' in the field 'Adequacy of study', then under 'Results and discussions' a selection must be made in the field **'Dissociating properties**'. In addition, if the value 'yes' is selected in the field 'Dissociating properties', then both of the following must be true: 1. At least one row must exist in the table 'Dissociation constant'; 2. Each created row must fulfil at least one of the following:-the fields 'pKa' and 'Temp.' have been provided, with unit; -	Results and discussion' is not complete. For each record marked as 'key study' or 'weight of evidence', the field 'Dissociating properties' must be filled in. If the value 'yes' is selected in the picklist, then at least one entry must be created under the 'Dissociation constant' heading with the fields 'pKa' and 'Temp.' with the unit where such a field is available. Each created entry must be complete. **The Dissociation Constant at 20 °C shall be reported.**

SCOPE IUCLID 6.9 – VALIDATION RULES

Section: Further information on the substance

Applicable to AS_Chemical working context. Only the AS dataset is checked

Target document	Specifications	Message
ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms	The rule checks that if an endpoint study record has been indicated as a 'key study' or 'weight of evidence' in the field 'Adequacy of study', then the fields **- function addressed** **- product type** **- Field of use envisaged / User** **- effect on target organisms** **- mode of action** **- (Possible) Occurrence of resistance** must not be empty.	General Information' is not complete. For each record marked as 'key study' or 'weight of evidence', under the 'Effects in harmful organisms' heading, the fields - function addressed - product type - Field of use envisaged / User - effect on target organisms - mode of action -(Possible) Occurrence of resistance must be filled in. If '(Possible) Occurrence of resistance' is not available, provide a justification. If 'other:' was selected in any of the picklists, the below field ‘other’ must be filled in.

SCOPE IUCLID 6.9 – VALIDATION RULES

Target document	Specifications	Message
Update QLT_171 ENDPOINT_STUDY_RECORD_ALL	In the linked 'Test material information' document, at least one created row entry in the table 'Composition' has the selection 'Constituent' under the field Type For each created row entry with Type = 'Constituent', the range field Concentration (TEST_MATERIAL_INFORMATION.Composition.CompositionList.Concentration) must be provided. When range fields are checked, it is sufficient that at least one of the two range values is given, with a unit. Qualifiers are not required. Target documents: EU_PPP_endpoints_all	Materials and methods' is not complete. the test material (to be) used in the study should contain sufficient information to allow the understanding of the identity of the tested substance. Under 'Composition' each created component must contain the concentration and at least one 'Constituent' must be reported.
Update QLT_077 ENDPOINT_SUMMARY.MagnitudeResiduesPlants	Rule specs: the rule checks that at least one common block 'Summary of residues data from the supervised residue trials' is created in document ENDPOINT_SUMMARY.MagnitudeResiduesPlants. The rule also checks that for each common block item created the following fields are filled in: - 'Study name/type' - 'Relevant gap', - Commodity' Data selection: any substance linked to main	Description of key information is incomplete: At least one item must be created for each 'Summary of residues data from the supervised residue trials'. In addition, for each item created the following fields must be filled in: - 'Study name/type' - 'Relevant gap', ' - Commodity'

SCOPE 2025 – VALIDATION RULES

IUCLID 6.9 release

- More details on the proposed QLT warnings for the next IUCLID 6 v.9 release are available here
  - All proposed rules align with data requirements however, if you have major objections, please submit your feedback by 26 March in the above excel file (worksheet '*Scope IUCLID 6v9 May2025*')

IUCLID service release (Oct)

- The draft scope of the IUCLID service release (October 2025) is available here
  - Please submit your feedback by 30 May 2025, in the above excel file (worksheet '*Scope October2025*')
  - Suggestions for new VA rules are encouraged. EFSA will prioritise the feedback received in collaboration with ECHA

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