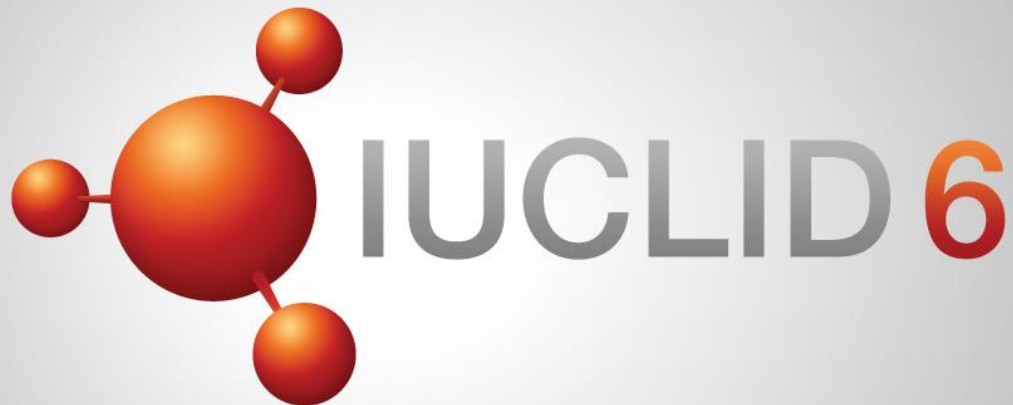


IUCLID 6

# Release notes

Version 8.0.3

13/06/2024



IUCLID 6 is developed by the European  
Chemicals Agency in association with the OECD



## TABLE OF CONTENTS

<b>1</b>	<b>INTRODUCTION .....</b>	<b>8</b>
<b>2</b>	<b>VERSION 8.0.3 (RELEASED ON 13 JUNE 2024).....</b>	<b>9</b>
<b>3</b>	<b>VERSION 8.0.2 (RELEASED ON 15 MAY 2024) .....</b>	<b>10</b>
<b>4</b>	<b>VERSION 8.0.1 (RELEASED ON 29 APRIL 2024) .....</b>	<b>11</b>
4.1	OECD Harmonised Templates .....	11
4.2	Other IUCLID harmonised documents.....	12
4.2.1	CORE .....	12
4.2.2	Domain .....	12
4.3	Changes linked to specific working contexts .....	12
4.3.1	Australia (AICIS) .....	12
4.3.2	EU BPR .....	12
4.3.3	EU CLP .....	13
4.3.4	EU DWD .....	13
4.3.5	EU ECHA.....	13
4.3.6	EU EFSA .....	13
4.3.7	EU PPP .....	13
4.3.8	EU REACH .....	14
4.3.9	New Zealand HSNO .....	14
4.4	Comparison.....	14
4.5	Data entry .....	14
4.6	Filtering .....	15
4.7	Migration .....	16
4.8	Public API .....	16
4.9	Report generator .....	16
4.9.1	SPC Product Family and Single Product, reports.....	17
4.9.2	GHS Classification and labelling report .....	17
4.9.3	Chemical Safety Report (CSR) .....	18
4.10	Updater .....	18
4.11	Validation assistant .....	18
4.11.1	REACH .....	18

4.11.2 EU_PPP .....	19
4.11.3 OFT .....	20
4.11.4 BPR .....	20
4.11.5 DWD.....	20
4.11.6 AICIS_AU .....	20
4.11.7 PCN.....	20
4.11.8 SCIP .....	21
4.12 Miscellaneous .....	21
<b>5 VERSION 7.12.6 (ECHA CLOUD SERVICES RELEASE 3 APRIL 2024) ...</b>	<b>22</b>
<b>6 VERSION 7.12.4 (PUBLIC RELEASE 5 FEBRUARY 2024) .....</b>	<b>23</b>
6.1 Data entry .....	23
6.2 Export .....	23
6.3 Report generator .....	23
6.4 Summary of Product Characteristics (SPC) under EU BPR.....	24
6.5 Validation assistant .....	25
6.6 Miscellaneous .....	25
<b>7 VERSION 7.12.2 (CLOUD RELEASE 11 DECEMBER 2023) .....</b>	<b>26</b>
7.1 Data entry .....	26
7.2 Filtering .....	26
7.3 Import.....	26
7.4 Report generator and Printing .....	26
<b>8 VERSION 7.10.3 (PUBLIC RELEASE 27 NOVEMBER 2023) .....</b>	<b>28</b>
<b>9 VERSION 7.10.2 (INTERNAL RELEASE 9 NOVEMBER 2023).....</b>	<b>29</b>
<b>10 VERSION 7.10.1 (PUBLIC RELEASE 30 OCTOBER 2023) .....</b>	<b>30</b>
10.1 Comparison.....	30
10.2 Data entry .....	30
10.2.1 Document layout update .....	30
10.3 Dossier creation .....	31
10.4 Export / import.....	31
10.5 Filtering .....	31
10.6 Installation / update .....	32
10.7 Migration .....	32
10.8 Report generator .....	32

10.8.1	Chemical Safety Report .....	32
10.8.2	SPC Report.....	32
10.9	User management.....	33
10.10	Validation assistant.....	33
10.10.1	REACH .....	33
10.10.2	BPR (SPC).....	34
10.10.3	DWD .....	34
10.10.4	EU_PPP .....	34
10.10.5	PCN.....	35
10.10.6	SCIP .....	35
10.11	Miscellaneous .....	35
<b>11</b>	<b>VERSION 7.0.7 (PUBLIC RELEASE 19 JULY 2023, CLOUD USERS 21 JULY 2023).....</b>	<b>37</b>
11.1	Data entry .....	37
11.2	Data migration.....	37
11.3	Report generator .....	37
11.4	Validation assistant .....	37
<b>12</b>	<b>VERSION 7.0.5 (CLOUD RELEASE 03 JULY 2023) .....</b>	<b>38</b>
12.1	Data entry .....	38
12.2	Data migration.....	38
12.3	Report generator .....	38
12.4	Validation assistant .....	39
<b>13</b>	<b>VERSION 7.0.4 (PUBLIC RELEASE 12 JUNE 2023) .....</b>	<b>40</b>
13.1	Data migration.....	40
13.2	Data visualization .....	40
13.3	Validation assistant .....	40
<b>14</b>	<b>VERSION 7.0.2 (PUBLIC RELEASE 29 MAY 2023).....</b>	<b>42</b>
<b>15</b>	<b>VERSION 7.0.1 (PUBLIC RELEASE 22 MAY 2023).....</b>	<b>43</b>
15.1	Format changes .....	43
15.1.1	Introduction.....	43
15.1.2	Changes to harmonized Templates .....	43
15.1.3	Specific documents format changes .....	45
15.1.4	Technical changes.....	47

15.2	Annotations .....	47
15.3	Comparison.....	47
15.4	Data entry and view.....	47
15.5	ECHA Cloud Services .....	48
15.6	Export .....	48
15.7	Import.....	48
15.8	Installation / Upgrade .....	48
15.9	Report generator .....	49
15.9.1	Bug fixes.....	49
15.9.2	Extended functionality.....	49
15.9.3	Format changes.....	49
15.9.4	Updates to reports .....	49
15.9.5	Known issues.....	50
15.10	Validation assistant.....	50
15.10.1	EU REACH .....	50
15.10.2	EU PPP .....	50
15.10.3	EU BPR .....	52
15.10.4	EU CLP (PCN).....	52
15.10.5	EU WFD (SCIP).....	52
15.11	Miscellaneous.....	52
<b>16</b>	<b>VERSION 6.27.8 (PUBLIC RELEASE 2 MAY 2024).....</b>	<b>54</b>
16.1	Single sign on (SSO).....	54
<b>17</b>	<b>VERSION 6.27.7 (PUBLIC RELEASE 28 FEBRUARY 2023).....</b>	<b>55</b>
17.1	Updater .....	55
<b>18</b>	<b>VERSION 6.27.6 (INTERNAL AND CLOUD RELEASE 28 FEBRUARY 2023) .....</b>	<b>56</b>
18.1	Security.....	56
<b>19</b>	<b>VERSION 6.27.4 AND 6.27.5 (PUBLIC RELEASE 6 FEBRUARY 2023)..</b>	<b>57</b>
19.1	Data entry .....	57
19.2	Report generator .....	57
19.3	Updater .....	57
19.4	Validation assistant .....	57
19.5	Miscellaneous .....	57



---

25.7	Report generator .....	68
25.8	REST API.....	68
25.9	Search.....	68
25.10	User interface .....	69
25.11	Validation assistant.....	69
25.12	Miscellaneous .....	69
<b>26</b>	<b>VERSION 6.6.14.3 (26 APRIL 2022, PUBLIC RELEASE) .....</b>	<b>70</b>
26.1	Data entry .....	70
26.2	Dossier creation .....	70
26.3	File format validation .....	70
26.4	Import.....	71
26.5	Report generator .....	71
26.6	Validation assistant .....	71
26.7	Search.....	72
26.8	Server version management .....	72
26.9	User interface.....	72
26.10	Miscellaneous .....	72





## 1 INTRODUCTION

Please also refer to <https://iuclid6.echa.europa.eu/faq> for known issues, and if relevant, workarounds and advice on how to handle such issues.

The releases notes are highlighting changes compared to the previous published versions of IUCLID 6.

In the next sections, new features and improvements are identified with **NEW** and **IMP** respectively, and bug fixes with **FIX**.

Internal ECHA references are added next to each fix, improvement, or new feature; for example (Ref. 917499).

For information about older versions of IUCLID, go to: <https://iuclid6.echa.europa.eu/archive>

## 2 VERSION 8.0.3 (RELEASED ON 13 JUNE 2024)

This version contains the following fixes:

**FIX** Users cannot install IUCLID desktop on Windows 11: UserPrincipalNotFoundException (Ref. 969922)

**FIX** Tagging / Filtering engine: performance issue with large dossiers containing thousands of documents (Ref. 972220)

### 3 VERSION 8.0.2 (RELEASED ON 15 MAY 2024)

This version contains minor fixes, as listed below:

**FIX** IUCLID Migrator: Fails in some cases due to Definition not found error. Warning appeared in the log files in some migration cases without impacting the functioning of the application (Ref. 966608)

**FIX** Update of REACH messages for the validation assistant, see [known issue #124](#) (Ref. 966785)

**FIX** New and updated translations to be used in the context of the EU BPR for Summary of Product Characteristics, see [known issue #123](#) (Ref. 967340, 968206)

**FIX** Update of the EU BPR active substance configuration, including messages, for the validation assistant (Ref. 967837, 967843)

**FIX** Update of the Chesar IUCLID plug-in, see [known issue #125](#) (Ref. 968329)

**FIX** update of the user synchronisation for ECHA IUCLID instances (Ref. 965277)

## 4 VERSION 8.0.1 (RELEASED ON 29 APRIL 2024)

This IUCLID version contains update to the format. A summary of the main changes is given below. Details about the changes and the format configuration can be found on the IUCLID website: <https://iuclid6.echa.europa.eu/format>

### 4.1 OECD Harmonised Templates

- Implementation of the [OECD QSAR Assessment Framework](#)
- Alignment of result reporting in environmental fate study summaries
  - o OHT 25 Hydrolysis
  - o OHT 26 Phototransformation in water
  - o OHT 27 Phototransformation in soil
  - o OHT 30 Biodegradation in soil
  - o OHT 29 Biodegradation in water and sediment: simulation tests
- Evolution of OECD Test Guidelines
  - o OHT 29 Biodegradation in water and sediment: simulation tests (new TG 320)
  - o OHT 48-2 Endocrine disrupter testing in aquatic vertebrates - in vivo/embryo (TG 240, new TG 251)
  - o OHT 49 Sediment toxicity (TG 218, TG 219)
  - o OHT 65 Eye Irritation (new TG 467, new TG 492B, TG 496)
  - o OHT 71 Genetic toxicity in vivo (new TG 470, TG 488)
  - o OHT 105 Nanomaterial specific surface area changed into Nanomaterial specific surface area and skeletal density (new TG 124)
  - o OHT 107 Nanomaterial surface chemistry (new TG 126)
- Use and exposure information: alignment between the REACH and OECD templates
- Other smaller maintenance updates and alignment between documents, for example on the following documents:
  - o Explosiveness (endpoint summary)
  - o Field studies (endpoint summary)
  - o Repeated dose toxicity (endpoint summary)
  - o OHT 201 Intermediate effects - mechanistic information

## 4.2 Other IUCLID harmonised documents

### 4.2.1 CORE

- Use and exposure information: replacement of the templates used under REACH by the updated OECD harmonised templates
- Classification and Labelling information
  - o extension of the GHS document in order to include new hazard classes introduced under EU CLP
  - o addition of a field 'reason for classification'
  - o new fields to store Acute Toxicity Estimates
- Toxicological information: relevant units applied for the dermal route doses
- Mixture composition: indication for 'Authorised co-formulant'
- Measures to protect humans, animals and the environment: new field for 'Control measures of repellents or poison included in the product, to prevent action against non-target organisms (relevant for products only)'

### 4.2.2 Domain

- Category: update of the path for the field 'Category members'
- Reference substance: new field 'InChIKey'

## 4.3 Changes linked to specific working contexts

### 4.3.1 Australia (AICIS)

- Update of the relevant Table of Contents to use the new version of the OECD Harmonised Templates on Use and Exposure information

### 4.3.2 EU BPR

- Several improvements for the Summary of Product Characteristics and Biocidal Product Authorisation working contexts
- Picklist added for Risk mitigation measures, based on the document 'Frequently used sentences' in the SPC available from the ECHA website
- New document for 'Use-specific instruction for use'
- Active substance approval: new picklist to indicate the 'Purpose of the application'

### 4.3.3 EU CLP

- Poison Centres Notifications
  - o for group submissions, possibility to link a product to several mixtures (instead of only one)
  - o new update justification added

### 4.3.4 EU DWD

- Finalisation of the Minimal Viable Product for the following working contexts:
  - o DWD Notification of intention (dossier)
  - o DWD application (dossier)
  - o DWD Data for relevant chemical species (sub tree in DWD application, in section 1.5)
- Updates of existing documents and new documents created:
  - o Melt flow index (record and summary)
  - o Data on electrochemical test and passivation tendency of a metallic material
  - o Data on migration of the substance (summary)
  - o Assessment by other authorities
  - o Risk acceptance
  - o Human health hazard characteristics

### 4.3.5 EU ECHA

- Indicator for registration dossiers 'Filtered as NONS'

### 4.3.6 EU EFSA

- New documents to test possible changes to the corresponding OECD Harmonised Templates
  - o Magnitude of residues in processed commodities – new
  - o Residues in crops (field trials) and in rotational crops (limited field studies) – new
  - o Magnitude of residues in plants – new (summary)
  - o Nature and magnitude of residues in processed commodities – new (summary)

### 4.3.7 EU PPP

- New documents
  - o Definition of the residue (biomonitoring) (summary)

- Impurities (summary)
- Dossier headers: update of the way the 'Role in the Joint Submission' is recorded
- Update of the following documents
  - Assessment from other authorities
  - 'Good Agricultural Practices (GAP)'
  - Expected exposure
  - Definition of the residue (fate) (summary)
  - Information on metabolites of toxicological concern
  - Metabolites
  - Toxicological reference values

#### 4.3.8 EU REACH

- Dossier header 'REACH Downstream user notification of authorised uses', confidentiality claims removed

#### 4.3.9 New Zealand HSNO

- Phrase group updates in the following documents
  - Hazardous substance controls
  - Intended exclusive economic zone uses
  - Intended general uses
  - Intended pesticide uses
  - Intended veterinary medicine uses
  - Regulatory history

### 4.4 Comparison

**FIX** HTML report does not display the false value when creating dossiers and comparing them directly (Ref. 666547)

**FIX** Comparison tool shows difference when the legal entity is identical (Ref. 956097)

**FIX** Comparison report does not reflect the order-based comparison logic correctly (Ref. 960331)

### 4.5 Data entry

**FIX** Reordering document on navigation tree does not work properly (Ref. 928461, 939908)

**FIX** Documents of template appearing in wrong ordering after saving a document (Ref. 941921)

- FIX** Document name and confidentiality claim in the sliding window can be edited for a dossier, but not saved (Ref. 810176)
- FIX** For REACH registration dossiers for members of a joint submission, the opt-out documents settings for dossier creation are respected (Ref. 933727)
- IMP** Bulk document delete: no indication of ongoing operation after user selects to remove existing references (Ref. 956175)
- IMP** Support parameterized phrases in multi picklists (Ref. 957093)
- FIX** Inherited template are not ordered chronologically in the sliding window (Ref. 953615)
- FIX** The order of Referenced documents in sliding window is not correct (including in document selection step) (Ref. 689667)
- IMP** Display pictograms for each Classification record retrieved from ECHA's C&L Inventory (Ref. 941712)
- FIX** Insert into Modification fails for working LE with long name, town and country (Ref. 955179)
- FIX** Legal Entity country not being displayed properly upon user selection "other" in LEGAL\_ENTITY.GeneralInfo.ContactAddress.Country (Ref. 955622)
- FIX** Clone functionality fails when trying to clone an entity that its name reaches maximum length (Ref. 955626)
- IMP** Improve additional text display when editing and viewing a picklist (Ref. 773118 and 950369)
- IMP** User should be able to search picklist by additional text (Ref. 927788)
- IMP** Ordering of Referenced Documents now follows the order of the links in the document (Ref. 692135)
- FIX** Document creation selection list is not displayed correctly at the bottom of the screen (Ref. 962019)
- FIX** Working context is not selectable after the related dataset is cloned (Ref. 955794)

## 4.6 Filtering

- FIX** Filtering engine should follow the configuration for removing attachments (Ref. 916085)
- FIX** Nomenclature error - filtered name displayed is not correct for use and exposure information (Ref. 931685)
- FIX** Missing Document names from Filtered Dossier in specific document types – entities (Ref. 940490)
- NEW** Filtering logic for EU PPP summary on impurities (Ref. 955223)

For Relevant Impurities all information will be PUBLISHED by default except the Manufacturing plant (if CBI flag is set). For all other impurities (Significant, Not significant & Theoretical) and which are set as confidential, all the information is set to UNLESS\_CONF



**NEW** Filtering logic for Analytical methods information under EU PPP (Ref. 951655)

The rule impacts data in the “Materials and Methods” and “Results and Discussion” sections of the Endpoints listed below.

They will be subject to the new rule whereby if the CBI flag is set **in the Admin block** (i.e. at the top of the document) and a justification is provided, the data from the fields subject to this rule will be redacted. For all other Endpoints the filtering is PUBLISHED/UNLESS\_CONF as listed in the configuration file.

Analytical methods subject to this rule:

- analysis of the micro-organism as manufactured (QC)
- analytical profile of batches
- methods for providing information on possible variability of seed stock/active micro-organism
- methods for providing information on purity of seed stock/active micro-organism
- methods for the analysis of the (formulated) product
- methods for the analysis of the active substance as manufactured (QC)
- methods to differentiate a mutant of the micro-organism from the parent wild strain
- methods to identify and quantify contaminating micro-organisms
- methods, procedures and criteria used to establish the presence and identity of the micro-organism, analysis of the micro-organism as manufactured
- methods for significant impurities

## 4.7 Migration

**FIX** Handle unmigrated draft dossier header (CUSTOM\_SECTION.\*\*\*) (Ref. 960006)

**FIX** Reinsert data in fields instead of attachments created during migration, cf. known issue #116 (Ref. 938161)

## 4.8 Public API

**IMP** Improve DataProtection representation in JSON representation of document definitions (Ref. 263293)

**IMP** Document definition of dossier header should contain the missing fields: Name, Version, Submission Type, Submitting Legal Entity (Ref. 914084)

**FIX** URLs for printing DOCX raw and dossiers requires the type in the URL, it should also support the Accept header for that (Ref. 951019)

## 4.9 Report generator

Reports have been updated to reflect, where relevant, the latest IUCLID format.

**FIX** File name issue when using & (Ref. 939719)

**FIX** When same ref. substance is in section 1.1 and 1.2, and extracted in a report, the report fails (Ref. 957717)

#### 4.9.1 SPC Product Family and Single Product, reports

##### Improvements

- To condense the report, the Table of Contents has been removed
- The Reference substance name in the Active substance is now displayed to represent the Active Substance in the 'Manufacturer(s) of the active substance(s)' table, and not the Common name of the Active Substance
- The Reference substance name in the Active substance is now displayed for components indicated as Substances of Concern in the respective tables listing the components of the Family, Meta SPC and/or Product
- The Family and Product name in the Cover page of the SPC Reports is no longer taken from the 'Family or single product SPC name' in the main mixture, but from the 'Family or meta SPC identifier' or 'Product name' fields under 'Family, meta SPC, product', respectively
- If a user has selected a Reference Substance component and used the Approved list of BPR Active Substances, the translated name of this Reference substance is now displayed (previously, this was only displayed for Substance components).

##### Fixes

- When using '&' in the name of the Supplier or Site details, this will now display '&' and no longer '&amp;'
- The Maltese version of the SPC report now includes the correct Cover page and Header details
- The Composition tables for Meta SPCs and Products should now include all the relevant components (unless they are 0-0% and Substance of Concern)

#### 4.9.2 GHS Classification and labelling report

**IMP** This report, which extracts the classification and labelling information of a Substance or Mixture, is now available in a .docx and .html output (previously available in .rtf and .pdf) output

**Note:** that in future a PDF version will also be available. Until then, the HTML report can be Printed as a PDF by the user if needed

**IMP** The report can also be generated from the sub entities of a Mixture (e.g. a Substance component of the Mixture)

### 4.9.3 Chemical Safety Report (CSR)

**IMP** The CSR can now be generated from a main Mixture entity, and will display that main Mixture entities information (excluding the Substance identity information and Use and Exposure) (Ref: 964817 / #2927)

**Note:** The CSR has not been made available for specific working contexts. Therefore, to generate from a Mixture, upload the CSR templates as provided on the IUCLID website

**IMP** The Summary 'ENDPOINT\_SUMMARY.ExposureRelatedObservationsHumans' has been re-positioned in the CSR, at the beginning of Chapter 5. This summary is potentially relevant to many different Toxicological endpoints and cannot be explicitly linked to a relevant Endpoint. Therefore, if this summary contains information, the user is then re-distribute this information as needed inside the generated CSR (Ref: 961629)

**FIX** The field information for "Mode of Action" for the Summaries on Repeated dose toxicity and Toxicity to Reproduction, is now re-included in the report (Ref: 960237)

**FIX** The field information for "Justification for classification or non-classification" is now re-included for Summaries on Acute Toxicity (all routes) and Repeated dose toxicity (Ref: 960238)

## 4.10 Updater

**FIX** IUCLID Updater Tool gives error related to IUCLID Drive (Ref. 961998)

## 4.11 Validation assistant

### 4.11.1 REACH

**NEW** set of QLT rules checking section 2.1\_GHS following the CLP Regulation amendment in 2023. More information can be found on the ECHA website: <https://echa.europa.eu/new-hazard-classes-2023>.

**IMP** update of existing rules checking section 2.1\_GHS due to addition of new hazard classes.

**NEW** Business rule for REACH Downstream user notification of authorised uses checking that a reference number is provided for a spontaneous update.

**IMP** update of rules checking the documents under the section 7.3.2\_Eye irritation following format updates.

**IMP** update of rules checking study results information under the sections 5.1.2\_Hydrolysis and 5.2.2\_Biodegradation in water and sediment simulation tests documents following format updates.

**IMP** update of rules checking the field '*Product category (PC) / Product category used*' under the relevant documents in section 3.5\_Use and exposure information.

**IMP** two rules were reactivated (TCC\_070602\_A01, TCC\_070602\_A02) to improve the check of the sections 7.6.1\_Genetic toxicity in vitro and 7.6.2\_Genetic toxicity in vivo.

#### Known issues and future improvements:

- Issue with TCC\_030502\_01, TCC\_030503\_01 rule messages. The message refers to incorrect label instead of 'Registration / Report status' the message specifies 'Registration/Notification status for the use'. The correct message is the following:
  - (...) Note that a use description is required for all uses registered under REACH Article 10. When reporting another type of use, this should be indicated in the field 'Registration / Report status'.
- Issues with TCC\_050102\_02 rule message. The message refers to incorrect label instead of 'Disappearance time (DT) of parent compound' the message specifies 'Dissipation DT50 of parent compound'. The correct message is the following:
  - (...) If a preliminary study was carried out, the results must be described in the field 'Preliminary study'. If the preliminary study indicates that the substance is hydrolytically stable and no further study was performed, this must be indicated under the 'Disappearance time (DT) of parent compound' heading in the field 'Remarks on result'. Each created entry must be complete. (...)

#### 4.11.2 EU\_PPP

**NEW** business rule checking that Dossier name in the dossier header is provided.

**NEW** set of quality rules checking presence of EU\_PPP flexible summaries and flexible records.

**NEW** QLT rule checking that exactly one Proposed residue definitions summary is provided in the Active substance dataset.

**NEW** QLT rule checking completeness of the GAP document.

**NEW** QLT rule checking that concentration unit of the active substance is set to CFU/g for Microorganisms working context

**NEW** QLT rule checking that the 'Additional information on data requirements' field is filled in for the MRL working context.

**NEW** QLT\_PPP\_126 checking that at least one Expected Exposure Flexible Summary is provided for Microorganisms working context.

**NEW** disclaimer message in VA report for EU\_PPP.

**IMP** update to business rules (BR\_PPP\_039, BR\_PPP\_052, BR\_PPP\_115, BR\_PPP\_159) due to format changes.

**IMP** update to quality rules (QLT\_PPP\_155-157, QLT\_PPP\_059-060, QLT\_PPP\_026B) due to format changes. In case of numeric range check, the rules were updated to check that at least the lower bound is provided.

**IMP** update to the mandatory documents being checked for the Microorganisms working context (BR\_PPP\_011, QLT\_PPP\_012, BR\_PPP\_015, BR\_PPP\_016)

**IMP** update to QLT\_PPP\_077 to exclude feed commodities from the check.

**IMP** QLT\_PPP\_125 is removed for Microorganisms working context.

Known issue and future improvement:

Rule ID displayed in the submission portal e.g., QLT\_PPP\_004\_multi, QLT\_PPP\_004\_study need to be fixed to exclude characters after the ID number. The correct rule ID to be displayed is QLT\_PPP\_004.

### 4.11.3 OFT

**NEW** set of rules checking substance identity and composition for EFSA Chemicals database working context (OpenFoodTox).

### 4.11.4 BPR

**NEW** set of rules checking BPR Active substance application (representative product) working context.

**IMP** set of rules were reconfigured to quality checks for working context BPR Summary of product characteristics (SPC).

**IMP** update on BR\_SPC\_021 which checks mixture composition components being complete under the BPR Summary of product characteristics (SPC) working context.

**IMP** the messages were improved for the following quality checks (SPC): QLT\_SPC\_014, QLT\_SPC\_015, QLT\_SPC\_025.

**IMP** BR\_SPC\_035 is removed for BPR Summary of product characteristics (SPC) working context.

**FIX** the issues (Ref.#926912) with the rules checking completeness of the Manufacturers of the active substance and Location of manufacturing site documents under the Active substance datasets linked under Mixture and Product summary compositions (BR\_SPC\_016, -017, -024, -025) have been resolved. The rules were incorrectly passing in case more than one active substance dataset is provided and incomplete.

### 4.11.5 DWD

**NEW** set of rules checking DWD Application working context.

### 4.11.6 AICIS\_AU

**FIX** of two rules TCC\_AU\_0002 and TCC\_AU\_0004. The rules were updated due to change to the documents' relevant paths.

### 4.11.7 PCN

**IMP** QLT1000: 'There should be only one trade name per 'Trade name' field.' This rule was previously triggered if the provided trade name contained ; or : character. It was modified not to fail if trade name contains : character.

#### 4.11.8 SCIP

No changes in Validation rules

#### 4.12 Miscellaneous

**IMP** Compatibility with Windows Server 2022 confirmed (Ref. 946159)

**FIX** Remove "Export to Cloud Drive" button from IUCLID cloud instances as the feature is not in use (Ref. 956585)

**IMP** New version of the user manual embedded (Ref. 960218)

## 5 VERSION 7.12.6 (ECHA CLOUD SERVICES RELEASE 3 APRIL 2024)

**FIX** Remove "Export to Cloud Drive" button from IUCLID cloud instances (Ref. 956585)

**FIX** SPC Import of an xml file: Text is truncated to 255 characters even if the target field accepts 2000 characters (Ref. 959347)

**FIX** SPC report does not display the correct META SPC compositional information (Ref. 959711)

## 6 VERSION 7.12.4 (PUBLIC RELEASE 5 FEBRUARY 2024)

Warning: this version of IUCLID introduces an incompatibility with the data extractor. A new version of the data extractor, compatible with this IUCLID version will be made available as soon as possible on the IUCLID website: <https://iuclid6.echa.europa.eu/data-extractor>

### 6.1 Data entry

**FIX** Information about "Other" identifier not saved in reference substance synonyms for other languages than English (Ref. 929260)

**FIX** Poison Centres Notifications: incorrect sub-Table of Contents is displayed in the dataset view for ICG and Standard Formula mixture composition components (Ref. 947317)

**FIX** CLP notification dossier preparation: fetching GHS records from ECHA web services fails with 404 error (Ref. 949656)

### 6.2 Export

**FIX** [Bulk Export Dossiers] Download of .zip is not starting after export completes (Ref. 942009)

### 6.3 Report generator

**IMP** Unify the parameters used in function 'iuclid.text' for reports using localizations (Ref. 937499)

**FIX** Rich text fields in reports: invalid XML format caused by special characters (Ref. 938153)

**FIX** Reports fail due to XML invalid error: "A table-cell is spanning more rows than available in its parent element" (Ref. 942548)

**FIX** Modification history is not fetched in reports from dossiers (Ref. 942974)

#### Report-specific updates

**NEW Test Materials Report:** A new report names 'List of Test Materials' can be generated. This report lists all test materials found in a Substance or Mixture together with the key information of the test material

#### **IMP/ FIX Chemical Safety Report:**

- Respiratory / Skin Sensitisation now included in the list of DNEL information (Section 5.11)
- The hardcoded table titles for each (Eco)Tox and Fate and Behaviour study now dynamically fetches the name of the study from the IUCLID section tree

#### **IMP / FIX Summary of Product Characteristics Reports' (SPC)**



- The finalised versions of the SPC Product Family and SPC Single Product reports was delivered, including;
  - an update to the styling and layout;
  - an update to some of the translations and report-specific terminology;
  - the possibility to include R4BP injected values, such as the authorisation number and Meta SPC suffices;
  - the display of the translated reference substance name if a user is preparing a non-EN SPC dossier and has selected a reference substance from the List of BPR Active Substances;
  - the removal of Product components which are concentration “0” and are not an active substance

### Report-builders

**IMP** Note that the following common modules have been updated so that the majority of the endpoint study and summary tables, are now called with a common macro call which requires the *documentType* and *documentSubType* as minimum parameters:

- `common_module_human_health_hazard_assessment`
- `common_module_environmental_hazard_assessment`
- `common_module_environmental_fate_properties`

The macro call for studies:

- `@<module_variable_name>.studyTable`

The macro call for summaries:

- `@<module_variable_name>.summaryTable`

For more information, contact the ECHA Helpdesk

## 6.4 Summary of Product Characteristics (SPC) under EU BPR

**IMP** Update SPC XML import component: "empty" Function value from XML should be mapped to "not applicable" value (Ref. 948621)

**FIX** No rule error during the aggregation execution when merging SPC dossiers (Ref. 941923)

**IMP** SPC XML mapping: generate random UUIDs for ProductSummaryComposition (Ref. 945621)

**FIX** ECHA Cloud Services: when refreshing the application page, the selection of the language is reset to English (Ref. 941458)

## 6.5 Validation assistant

**IMP** Update of the Candidate list update (CSV file) - January 2024, taken into account for the validation of Article dossiers under SCIP (Ref. 942814)

## 6.6 Miscellaneous

**FIX** Error when running updater on PostgreSQL (Ref. 946064)

## 7 VERSION 7.12.2 (CLOUD RELEASE 11 DECEMBER 2023)

### 7.1 Data entry

**FIX** Check icon is not displayed in multiselect lists (Ref. 914337)

**NEW** REACH Downstream users notification of authorized uses

- User views authorised uses relevant to the reference substance they have selected (Ref. 919725)

**NEW** CLP notifications

- User views and selects C&L entry from ECHA's C&L Inventory (Ref. 928774)
- User views C&L entries relevant to the reference substance they have selected (Ref. 933736)

**IMP** Bulk delete of entities: inform user properly in case of an error (Ref. 931599)

**FIX** Bulk delete: the documents are not listed in the order of the navigation tree (Ref. 934072)

**IMP** User should be able to add new rows in repeatable tables/lists via 'Actions' (Ref. 936967)

**FIX** [EU PPP Summary and evaluation] - Delete with bulk delete operation (Ref. 937781)

### 7.2 Filtering

**IMP** Change naming rule for FIXED RECORDS (Ref. 929687)

**IMP** Update of labels in ECHA Dossier Publication dossier header (Ref. 933476)

### 7.3 Import

**FIX** Specific SPC XML fails import (Ref. 936097, 938828)

### 7.4 Report generator and Printing

**IMP** Reporting API: support the retrieval of all entities/documents from a working context of an entity (Ref. 913965 and 2621)

**FIX** Reporting engine - Error during pdf/rtf creation for specific dossiers (BPR SPC) (Ref. 931932)

**FIX** Include fields with no values not working in Print to RTF/PDF (Ref. 932850)

**FIX** [Create PDF/RTF] -Create document PDF includes unnecessary references (Ref. 935907)

#### Reports updated:

- SPC Product Family report
- SPC Single Product report

- Chemical Safety report
- Common modules

## 8 VERSION 7.10.3 (PUBLIC RELEASE 27 NOVEMBER 2023)

This patch release addresses the following fix:

**FIX** Report generator: content of inherited templates linked to a parent entity is not taken into account in the generation of a report. This also affects Create PDF and Create RTF (Ref. 941637)

**FIX** Series of fixes made to EFSA report templates, update of common templates and update of the SPC report templates (Ref. 938593)

## 9 VERSION 7.10.2 (INTERNAL RELEASE 9 NOVEMBER 2023)

This patch release addresses the following fix:

**FIX** Filtered dossiers cannot be imported due to missing attachment references (Ref. 937792)

## 10 VERSION 7.10.1 (PUBLIC RELEASE 30 OCTOBER 2023)

All fixes and improvements included in v7.10.1 were also available in v7.10.0 of IUCLID which has been deployed to the ECHA Cloud Services, except for the following fix introduced exclusively since v7.10.1:

**FIX** The following error occurs for PostgreSQL and Oracle databases when deleting documents in a dataset: ClassCastException: Long cannot be cast to Integer (Ref. 936047)

### 10.1 Comparison

**NEW** Comparison report: filter only for differences (Ref. 917499)

**IMP** Extract to dataset: performance improvement at the comparison step (Ref. 924756)

### 10.2 Data entry

**FIX** The dossier header label is missing for the dataset extraction view page (Ref. 806860)

**FIX** When a remarks field is displayed for a picklist, it should be displayed for all picklist selections (Ref. 809403)

**IMP** Allow user-entered "Inventory number" value in the Reference Substance form (Ref. 775941)

**IMP** Dynamic content rule in "Genomic characterisation of the microorganism" updated to include 'mixed' (Ref. 809402)

**FIX** Keyboard navigation in sliding windows (Ref. 776088)

**NEW** Notification of downstream uses for authorized substances under REACH (Art. 66): possibility added under the relevant working context to retrieve substance and use information from ECHA's repository (Ref. 846064, 806841, 806842, 912731, 930793)

**FIX** One section is not displayed in two DWD tables of contents (Ref. 806154)

**NEW** Select reference substance from ECHA's repository of Biocidal active substances (Ref. 927862)

**IMP** Default name of a document created from another document (in sliding window) is incorrect in the field 'Edit' (Ref. 913601)

**FIX** When editing a document via a custom definition, the contents of the repeatable blocks not part of the custom definition are removed (Ref. 675171)

**FIX** Hierarchical multi-select picklist, issue with entering 'other:' value (Ref. 924840)

**FIX** Copy data from' and 'clone' not working with cyclical / circular references (Ref. 360593)

**IMP** 'Copy data from' supports copying documents into sub-Table of Contents (e.g., for mixture components) (Ref. 913937)

#### 10.2.1 Document layout update

**IMP** Changes to the dossier header 'ECHA dossier publication' (Ref. 922453)

**IMP** Update of field-level help text in SPC documents (Ref. 926174)

**IMP** 'Site flags' and 'Contact address' flag inside 'Sites' document should be hidden for DU66 (Ref. 917660)

**IMP** Confidentiality flag and 'Substitution activities' field for authorised uses should be made available for DU66 (Ref. 917668)

**IMP** Custom section update: add mixture component to 'SPC Mixture Composition' (Ref. 927861)

**IMP** Make field 'Substitution activities' visible in the DU66 use documents in Section 2 'Authorised uses notified' (Ref. 917635)

**IMP** Add mixture component to SPC product summary composition (Ref. 930800)

**IMP** SPC working context, hide 'Additional text' under the GHS custom section (Ref. 930902)

**IMP** Adjusting the Legal Entity mandatoriness for SPC documents (Ref. 931318)

### 10.3 Dossier creation

**FIX** BPR SPC dossier cannot be created with Authorisation holder (Ref. 874855)

### 10.4 Export / import

**FIX** Error during creating i6z file when excluding Templates: NullPointerException (Ref. 808436)

**FIX** Export i6z of SPC dossier loses authorization holder data (Ref. 874857)

**IMP** SPC XML import fixes: link to active substance manufacturer, link to other information (Ref. 809865)

**FIX** Literature Reference cannot be imported with title more than 255 characters (Ref. 919017)

**NEW** Support import from / export to shared folders, 'IUCLID Drive'. This new feature can be activated by administrators of IUCLID servers. It is not available for Desktop or ECHA Cloud Services installations (Ref. 917301)

**IMP** Export performance improvement at the level of the download mechanism (Ref. 924583)

### 10.5 Filtering

**NEW** Naming convention for IUCLID document names (and automatic generation of default names) (Ref. 700223, 927090)

**IMP** Filtering: apply the new dossier header defined for ECHA dissemination for REACH registrations (Ref. 917647)

**NEW** Keep the document UUIDs during filtering (Ref. 917648)

**IMP** Entry in modification history and creation date to be set in filtered documents (Ref. 927736)

**Known issue:** exported filtered dossiers cannot be imported to IUCLID due to missing references to attachments (issue with the post-filtering cleaning operations). (Ref. 937792) See also <https://iuclid6.echa.europa.eu/faq?#q117>



## 10.6 Installation / update

**FIX** Desktop version: startup fixer tool does not work (Ref. 805788)

**FIX** The Updater tool should not install server scripts into a desktop installation (Ref. 805553)

**FIX** Cannot identify connection parameters for 'External Derby' (Ref. 806654)

## 10.7 Migration

**FIX** Missing backwards migrations:

ENDPOINT\_STUDY\_RECORD.BiodegradationInWaterAndSedimentSimulationTests ,  
reference field :TransformationProductsDetails.0.ParentCompoundS (Ref. 810427)

**FIX** Custom migration: Backward rule: ToxicityToBees field not migrated (Ref. 810740)

## 10.8 Report generator

**NEW** Filter the list of reports (Ref. 810701)

**NEW** Reporting API: function to generate display string for parameterised phrases (Ref. 675747)

**NEW** Reporting engine adaptations to support report generation in docx format (846716 806979)

### 10.8.1 Chemical Safety Report

**FIX / IMP** The Chemical Safety Report now contains an enhanced DNEL Chapter 5.11

**FIX** The Chemical Safety Report now contains again the 'Additional information' field from the following Endpoint Summaries:

- Carcinogenicity
- Toxicity to Reproduction
- Toxicological Information

### 10.8.2 SPC Report

**IMP** Provide translation of parameterised phrases

**FIX** Include Danish (DA) translations

**IMP** Change unit with uppercase 'L(itres)' to lowercase 'l(itres)'

**IMP** Change decimal '.' to ',' (Ref. 916014)

**IMP** Reduce white space in the report

**IMP** Include 'non-active substance' translation in property files for NO, IS, DA

**FIX** Field of use missing from authorised uses if no use description given. Field of use should be displayed as long as the Field of use value is given

**IMP** The full location of the manufacturer for active substances is now provided

**FIX** Some translated picklist values are not displayed using the Reporting Engine (Ref. 806820)

- All picklist values that are translated in the IUCLID User Interface should now also be shown in the SPC Report

## 10.9 User management

**NEW** Create new permission to allow users to import/export files from/to IUCLID Drive (Ref. 926363)

## 10.10 Validation assistant

**IMP** Open validation assistant report in a new tab (Ref. 921298)

### 10.10.1 REACH

**NEW** set of QLT checks for the Uses sections ensuring the correct combination of selections under the '*Environmental release category (ERC)*' and '*Subsequent service life relevant for this use*' fields.

**NEW** set of QLT rules for the Uses sections which give a warning in case of forbidden combination of selections under the '*Product category*' field.

**NEW** set of Business rules for REACH Downstream user notification of authorised uses.

**IMP** to two rules implemented following an update of the REACH Annexes (ref. # 923196):

- TCC\_070601\_A05 and TCC\_070601\_A07 checking relevant studies under sections 7.6.1 and 7.6.2 positive/ambiguous results in 7.6.1 - improved message functionality to display a message per incomplete section.

**FIX** to three rules updated following an update of the REACH Annexes (ref. # 278795, 278796, 278916):

- TCC\_ESR\_02 checking that each endpoint study record must be indicated either as a study summary, data waiving, testing proposal or a weight of evidence justification/conclusion. The rule was updated to accept a weight of evidence justification/conclusion type of document.
- TCC\_ESR\_03 ensuring that an endpoint study record cannot be indicated at the same time as a study summary, data waiving, testing proposal, and/or a weight of evidence justification/conclusion. The rule was updated to check for a weight of evidence justification/conclusion under the 'Type of information'.
- TCC\_ESR\_A52 checking that in vivo cytogenicity key study/weight of evidence or testing proposal must exist in section 7.6.2 if used as basis for waiving in 7.6.1. The rule was

updated to accept in vivo mammalian somatic cell study: combined micronucleus and DNA damage and/or repair.

### 10.10.2 BPR (SPC)

**NEW** set of rules for *BPR Summary of product characteristics (SPC)* working context.

**IMP** the following checks were improved (ref. #280121, #810496, # 926096):

- BR\_SPC\_005 checking that Every Authorised Use is complete (Single, Family SPC)
- BR\_SPC\_026 checking that set of Components in Meta SPC and Mixture Compositions must be the same as in Family SPC composition (Family SPC)
- QLT\_SPC\_014 checking the completeness of each Trade names block under the Mixture Composition (Single, Family SPC)

**FIX** the following issues were fixed:

- BR\_SPC\_020 (ref. #680536) the rule was incorrectly passing for incomplete 'Active substances, Substances of concern, Other substances' blocks under the Product summary composition.
- BR\_SPC\_038 (ref. #931293) the rule was incorrectly passing in case no Product Summary Composition was provided in Family SPC

#### Known issues and future improvements:

- Issues with the rules checking completeness of the Manufacturers of the active substance and Location of manufacturing site documents under the Active substance datasets linked under Mixture and Product summary compositions (BR\_SPC\_016, -017, -024, -025). The rules incorrectly passing in case more than one active substance dataset is provided and incomplete.

### 10.10.3 DWD

**NEW** set of rules checking substance identity for *DWD Notification of intention* working context.

### 10.10.4 EU\_PPP

**NEW** quality rule QLT\_PPP\_026B checking completeness of the GAP document.

**NEW** 2 rules (QLT\_PPP\_031 – 032) checking the presence of sanitised attachments.

**NEW** 2 rules (QLT\_PPP\_077, QLT\_PPP\_066) checking completeness of summaries:

- FLEXIBLE\_SUMMARY.ResiduesInLivestock
- ENDPOINT\_SUMMARY.MagnitudeResiduesPlants

**NEW** rule (QLT\_PPP\_073) preventing confidentiality claim from the mixture composition for substances with the function 'active substance', 'safener', 'synergist' or 'active substance (other not to be assessed)'

**NEW** rule (QLT\_PPP\_080) preventing confidentiality claim from the 'Reference substance' entity linked to substances with the function 'Active Substance'

**NEW** 3 QLT rules (QLT\_PPP\_137 – 139) checking 'Results and discussion' tables. The rules were replicated from existing REACH rules and are applicable to the following documents:

- ENDPOINT\_STUDY\_RECORD.SkinSensitisation
- ENDPOINT\_STUDY\_RECORD.EyelIrritation
- ENDPOINT\_STUDY\_RECORD.SkinIrritationCorrosion

**NEW** 3 QLT rules (QLT\_PPP\_155 – 157) checking 'Recovery', 'Repeatability' and 'LOQ/LOD' under the block 'Results and discussion' of ENDPOINT\_STUDY\_RECORD.AnalyticalMethods.

**NEW** QLT\_PPP\_144 checking completeness of 'Effect concentrations' for the document ENDPOINT\_STUDY\_RECORD.ToxicityToTerrestrialArthropodsOtherThanBees

**IMP** update to rule QLT\_PPP\_090 with additional mixture composition to be checked.

**IMP** update to rule QLT\_PPP\_125 to ensure that exactly one FLEXIBLE\_SUMMARY.MRLProposal is provided; the rule is also activated for Microorganism working context.

**IMP** BR\_PPP\_108, BR\_PPP\_109, BR\_PPP\_110, BR\_PPP\_111 checking the 'Pre-Application Identifier' in the dossier header. Rules were changed from quality warnings to business rules.

**IMP** QLT\_PPP\_118 rule checking 'Results and discussion' of ENDPOINT\_STUDY\_RECORD.BiodegradationInSoil was reactivated.

### 10.10.5 PCN

**NEW** BR690 MiM: For identifying the MiM, it is mandatory to provide either: a) UFI b) Available component(s): - If MiM is hazardous 'Supplier' record and available components (at least one Substance). - If MiM is non-hazardous, then providing the 'Supplier' record is enough

**NEW** QLT1000 There should be only one trade name per 'Trade name' field. If the product has multiple trade names they should be provided separately each in their own row in 'Trade names' table. (This rule is triggered if the provided trade name contains ; or : character.)

**FIX** QLT501 'Maximum pH value range width is 1 unit (when pH =<3 or >=10)' *Rule was previously incorrectly considering only the lower value of the range. Now it is modified to consider cases where pH ranges lower value is from -3 to 3 or pH ranges higher value is from 10 to 15*

### 10.10.6 SCIP

**NEW** BR738 'Colour': If you wish to provide information regarding 'Colour' please note that value *other*: is not allowed.

## 10.11 Miscellaneous

**FIX** [Aggregation] - Dossier header for "REACH" aggregated dossier is displayed as R\_COMPLETE (Ref. 808634)

- NEW** Clean-up mechanism for background tasks; remove all jobs that were completed at least 10 days ago (Ref. 761261)
- IMP** Performance, graph optimization (Ref. 846325, 914310, 919693, 921313, 927835), rename document (Ref. 775742)
- IMP** Upgrade to newer versions of Angular (Ref. 916672, 916675, 917885, 922697, 925245)
- FIX** Correct error in the Polish and Greek translations of eu\_clpV7.properties (Ref. 923539)
- IMP** Update of translation resources (Ref. 929273)
- IMP** Third party copyrights list automated generation (Ref. 923495)
- FIX** Liquibase locks while starting IUCLID (Ref. 874355)
- FIX** SPC XML import, Legal entity for active substance manufacturer not referenced (Ref. 930324)
- IMP** SPC XML import: qualifiers should not be added to content ranges during migration (Ref. 930802)

## 11 VERSION 7.0.7 (PUBLIC RELEASE 19 JULY 2023, CLOUD USERS 21 JULY 2023)

### 11.1 Data entry

**FIX** Issue introduced in v7.0.5. Unable to save range fields without units which are not in a repeatable block. (Ref. 919260)

### 11.2 Data migration

**FIX** Unable to run validation assistant or create dossier when previous versions of the database were migrated with the database migrator only and not with the updater tool (Ref. 917920 and 920977)

### 11.3 Report generator

#### EU REACH

#### Chemical Safety Report

- **Known issue:** DNEL Chapter 5.11 is omitted from the Chemical Safety Report in order to prevent report generation failure (*Note: that a temporary CSR template will be made available on the IUCLID website for users wishing to include the DNEL chapter*) (Ref. 915330)

### 11.4 Validation assistant

**FIX** Performance degradation when running the validation assistant from datasets (Ref. 917985)

## 12 VERSION 7.0.5 (CLOUD RELEASE 03 JULY 2023)

### 12.1 Data entry

**FIX** The picklist EUPCS phrase group is corrected so that *PP-BIO Biocidal products* and *PP-PRD Plant protection products* are both under the higher-level *PP Biocides and plant protection products* (Ref. 916356)

**FIX** The Table of Contents for BPR Microorganisms should include the relevant documents for 'Toxicity to terrestrial arthropods' (Ref. 916179)

**FIX** EFSA Chemicals database working context for substance is missing a sub-Table of Content configuration (Ref. 915158)

**IMP** The field 'data waiving' can be selected when 'weight of evidence justification/conclusion' has been selected. A dynamic content rule has been added to prevent this pairing. (Ref. 915214)

### 12.2 Data migration

**FIX** Issue with PCN dataset after migration to v7: unable to update *FLEXIBLE\_RECORD.ProductInfo* document and operations such as the Validation assistant and Dossier creation cannot be triggered (Ref. 915515)

### 12.3 Report generator

#### EU Plant Protection Products

**FIX** For reports generating Appendix E information, when the field 'Type' contains phrase *illustration (picture/graph)* and an attachment is provided for the following field:

*ENDPOINT\_STUDY\_RECORD.ToxicityToBirds.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedSanitisedDocsForPublication*

The report fails (Ref. 917763)

#### EU REACH

##### Chemical Safety Report

- v7.0.5 **Known issue:** When a Chemical Safety Report is generated with Toxicological Endpoint Summary information, the report fails due to an error in the DNEL chapter 5.11

**FIX** When the following field contains information, the Chemical Safety Report will now generate *ENDPOINT\_SUMMARY.PhototransformationInAir.KeyValueForChemicalSafetyAssessment.DegradationRateConstantWithOHRadicals* (Ref. 918443)

**IMP** Toxicity to soil arthropods has been introduced as chapter 7.2.2 of the Chemical Safety Report (both the Robust Study Summary information and Endpoint Summary information)

**FIX** The Additional Information field in the following Endpoint Summaries has been re-introduced into the Chemical Safety Report:

- ShortTermToxicityToFish
- ShortTermToxicityToAquaticInvertebrates
- LongTermToxicityToAquaticInvertebrates

## EU BPR

**FIX** For the SPC single product and family reports, when the field *UseSpecificInstructionsForUse* is completed in *FLEXIBLE\_RECORD.ProtectionMeasures*, the report will now generate.

## 12.4 Validation assistant

**IMP** Update of the list of candidate substances for SCIP dossiers (Ref. 809721)

**FIX** the following known issues are resolved:

1. The rule TCC\_ESR\_02 fails incorrectly (Ref. 914547)

The rule incorrectly fails for the documents with Type of information being set to 'weight of evidence justification/conclusion'.

2. The rule QLT232 gives a warning incorrectly (Ref. 914537)

The QLT232 is expected to check the link from the document indicated as 'weight of evidence justification/conclusion' under the Type of information field to the document indicated as 'weight of evidence' under the Adequacy of study.

The rule incorrectly gives a warning when a document indicated as 'weight of evidence' linked to 'weight of evidence justification/conclusion' and not vice versa.

**FIX** the message display issue is resolved for TCC\_0305\_07 rule (Ref. 913960)



## 13 VERSION 7.0.4 (PUBLIC RELEASE 12 JUNE 2023)

### 13.1 Data migration

**FIX** The content of the fields 'Description of key information' (KeyInformation) has been identified to be lost during the migration to IUCLID 6 v7 for the following endpoint summaries (Ref. 914277):

- Acute Toxicity
- Repeated dose toxicity
- Carcinogenicity
- Neurotoxicity
- Immunotoxicity

Endpoint summaries are the documents used to store the outcome of the assessment of the information available in relevant studies. This part of the format has been subject to changes in IUCLID 6 v7 as part of a harmonization effort.

We recommend the following actions in case you already migrated to IUCLID 6 v7 before this fix:

- In case you have not been using the fields or the IUCLID documents mentioned above, there is no action required.
- In case you have upgraded your database to IUCLID 6 v7, please make sure you have access to the backup taken before the update. We are working on a patch tool that will restore the data in the relevant fields.

### 13.2 Data visualization

**FIX** Issue with the visualization of linked references. In some cases, the UUID is displayed instead of the reference representation (Ref. 875148)

### 13.3 Validation assistant

**FIX** for the following known issues

Known issues in IUCLID v7.0.1 and v7.0.2 Validation assistant completeness check rules impacting REACH registrations:

1. The rules TCC\_070601\_A05, TCC\_070601\_A07, TCC\_070601\_A08, TCC\_070601\_A09 fail incorrectly (Ref. 913132)

These rules check that relevant follow-up studies are provided in section 7.6.2 Genetic toxicity in vivo if a positive or ambiguous result was reported in section 7.6.1 Genetic toxicity in vitro. These rules fail incorrectly if the requirement in section 7.6.2 is fulfilled

by providing an In vivo mammalian cell study: DNA damage and/or repair (key study, weight of evidence, data waiving or testing proposal).

Workaround: If you have fulfilled the data requirement in section 7.6.2 Genetic toxicity in vivo by providing a key study, weight of evidence, data waiving or testing proposal with the endpoint selection In vivo mammalian cell study: DNA damage and/or repair, then you can disregard the rules TCC\_070601\_A05, TCC\_070601\_A07, TCC\_070601\_A08, TCC\_070601\_A09. In any other situation these rules are reported correctly and must be corrected before the dossier submission.

## 2. The rule TCC\_ESR\_21 fails incorrectly (Ref. 913276)

This rule is expected to check that if a document with the adequacy of study 'weight of evidence' has been created on 1 June 2023 or later, there is at least one record with the type of information marked as 'weight of evidence justification/conclusion'. Currently this rule fails also on weight of evidence documents created before the above date.

Workaround: You may disregard the rule TCC\_ESR\_21 (irrelevant of the document creation date) until a fix has been implemented in the Validation assistant and a new version of IUCLID is available for download.

### **The following known issues still exist in v7.0.4**

#### 1. The rule TCC\_ESR\_02 fails incorrectly.

The rule incorrectly fails for the documents with Type of information being set to 'weight of evidence justification/conclusion'.

Workaround: You may disregard the rule TCC\_ESR\_02 for the document indicated as 'weight of evidence justification/conclusion' under the Type of information field.

#### 2. The rule QLT232 gives a warning incorrectly.

The QLT232 is expected to check the link from the document indicated as 'weight of evidence justification/conclusion' under the Type of information field to the document indicated as 'weight of evidence' under the Adequacy of study.

The rule incorrectly gives a warning when a document indicated as 'weight of evidence' linked to 'weight of evidence justification/conclusion' and not vice versa.

Workaround: You may disregard the rule QLT232 Warning if you have ensured the correct direction of the link: the 'weight of evidence justification/conclusion' must be linked under the 'Cross-reference' table to the relevant 'weight of evidence' document and not the opposite way.

## 14 VERSION 7.0.2 (PUBLIC RELEASE 29 MAY 2023)

**FIX** Working context for specific dossier types not fully migrated to IUCLID 6 v7. This impacts IUCLID 6 v6 dossiers of the following types, migrated to IUCLID 6 v7:

- AICIS dossiers
- EU PPP Active substance application (product)
- EU PPP Microorganisms - active substance application (product)
- HSNO category-based dossiers

The fix applies to all cases (data not yet migrated to IUCLID 6 v7 or data already migrated to IUCLID 6 v7) during upgrade to this version. The issue does not impact newly created dossiers in IUCLID 6 v7 and is mainly relevant to Authorities accessing these dossiers (Ref. 874098)

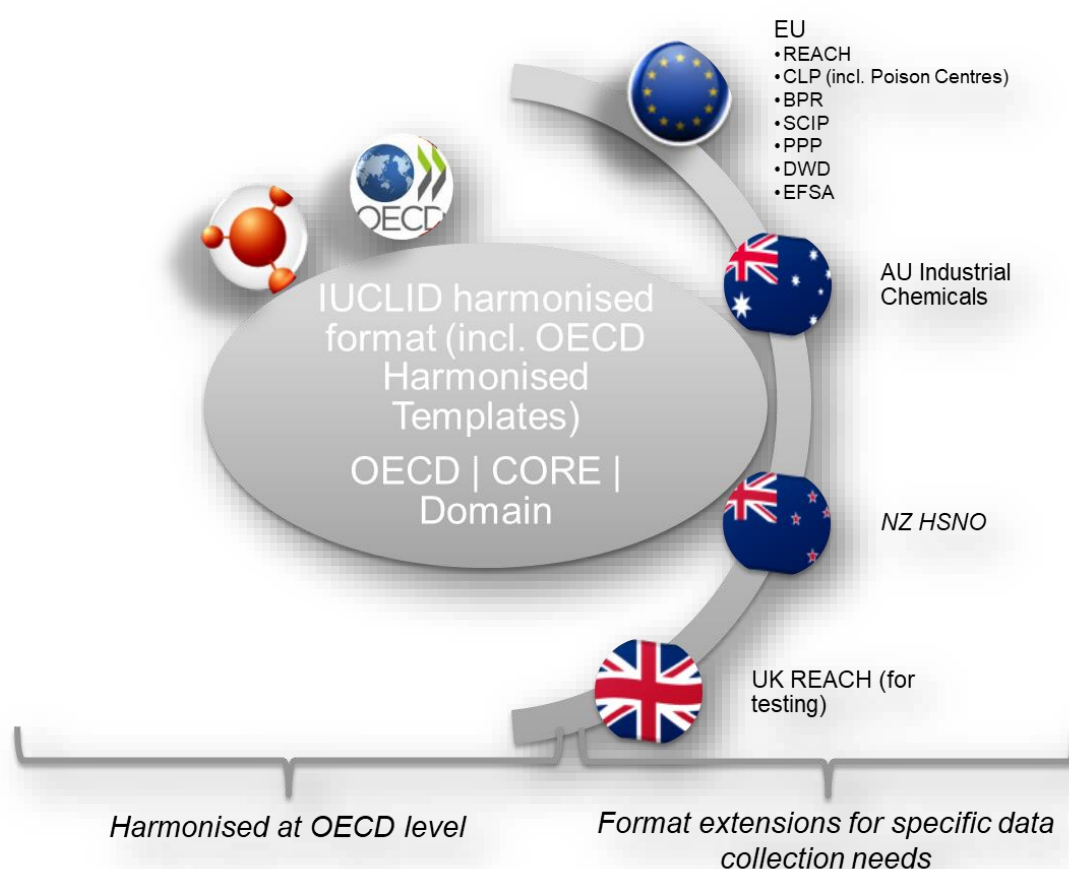
**FIX** The (obsolete) EU PPP Endpoint summary for toxicity to terrestrial arthropods did not allow referencing the newly created OECD Harmonised Templates for terrestrial arthropods. This created impossibility to import IUCLID files in some specific case (Ref. 874188)

## 15 VERSION 7.0.1 (PUBLIC RELEASE 22 MAY 2023)

### 15.1 Format changes

#### 15.1.1 Introduction

The IUCLID format is organized by definition providers and there is a distinction between Harmonised Templates that are shared with all IUCLID users and so-called specific definition providers that contain the IUCLID documents that are relevant for specific user groups or regulatory framework.



The main changes are highlighted below but full details are published on the IUCLID website: <https://iuclid6.echa.europa.eu/format>

#### 15.1.2 Changes to harmonized Templates

##### 15.1.2.1 OECD Harmonised Templates (OHTs)

Changes pushed forward by the OECD Secretariat in 2022 and approved recently to take into account the evolution of Test Guidelines

- OHT 41 Short-term toxicity to fish (TG 249)
- OHT 48-2 Endocrine disrupter testing in aquatic vertebrates – in vivo (TG 250)
- OHT 64 Skin irritation / corrosion (TG 439)
- OHT 66-1 Skin sensitisation (TG 442C)
- OHT 66-3 Phototoxicity in vitro (TG 498)
- OHT 85-5 Residues in crops (field trials) and in rotational crops (limited field studies) (TG 509)
- OHT 201 Intermediate effects - mechanistic information (TG 442C)
- OHT 50-2 Toxicity to terrestrial arthropods has been split into three templates
  - OHT 50-3 Toxicity to bees
  - OHT 50-4 Toxicity to terrestrial arthropods other than bees
  - OHT 50-5 Toxicity to soil arthropods

#### Other OECD Harmonised Templates changes:

- OHT 58 Basic toxicokinetics: alignment with [EFSA guidance](#)
- Pesticides series (OHTs 85-2, 85-3, 85-4, 85-8, 85-9, 85-10): small fixes and adaptation to MetaPath / MSS composers, particularly for the recording of metabolites and transformation products
- OHT 87 Analytical methods: follow-up on the 2021 consultation and incorporation of guideline SANTE/2020/12830 rev. 1
- Series of updates to OHT 201 Intermediate effects - mechanistic information

#### Changes made to several OECD Harmonised Templates:

- Harmonisation of units for microorganisms in relevant OHTs
- Change 'Study period' field in OHTs from text field to date fields for 'start', 'end' + remark
- Add nanomaterial-relevant units in all OHTs
- Field 'Illustration' moved to the 'Attachments' fields in all OHTs
- Identification of metabolites extended, added in relevant endpoints
- As part of the REACH annexes revision
  - Clarification of the justification for Weight of Evidence
  - Clarification of the dose-setting information
  - New entries in 'Endpoint' or 'Justification for data waiving' picklists

105 Endpoint summaries have been updated and also made part of the OECD Harmonised Templates.

### 15.1.2.2 ***IUCLID entities (Domain)***

Changes to harmonised IUCLID entities:

- Remove the mandatoriness of Legal Entity for main entities (substance, mixture, category)
- Field size increase for Title under Literature Reference
- New name types CN (Combined Nomenclature) and CUS (Custom inventory in EU) for 'Substance'
- Update of the Regulatory programme list in the IUCLID flags
- Update of the list of countries
- Article: update of the article categories and the EU Product Category System (PCS) lists

### 15.1.2.3 ***Changes to other IUCLID documents***

- Mixture composition and summary, in-situ substances
- Summary composition, label change for linked products
- Field size increase for service life name
- Field size increase for Brief description under Mixture composition
- New section 'QC data' in 'Analytical profile of batches'
- Endpoint summary 'Effectiveness against target organisms'
- Biological properties', classification of organisms
- Use documents: new fields for 'authorisation number', 'substitution activities', 'regulatory status'

## 15.1.3 **Specific documents format changes**

### 15.1.3.1 ***EU BPR***

- Update of the document 'Intended uses and exposure'
- Update 'Language' phrase group in the SPC dossier header
- Update of phrase groups 'Product type' (phrases related to biocides)
- **NEW** document for 'use-specific directions for use'
- **NEW** document for 'other SPC information'
- Add a unit to the 'Application rate' phrase group
- Update of 'Function' phrase groups in composition documents
- Adaptation of phrase groups containing country names to SPC requirements

### 15.1.3.2 **EU CLP**

- Poison Centres Notifications
  - Update of the EU PCS list
  - Update of the Product information document

### 15.1.3.3 **EU DWD**

New definition provider created to organize the documents relevant to the Drinking Water Directive:

- **NEW** 'Data on migration of the substance'
- **NEW** 'Intended application of substance'
- **NEW** Dossier header for DWD Application Article 11
- **NEW** Dossier header for DWD Notification of intention
- **NEW** Element(s) or substance(s) for consideration in the migration water
- **NEW** Electrochemical test (passivation)
- **NEW** 'Microbiological activity of the substance'
- **NEW** 'Reports'

### 15.1.3.4 **EU ECHA**

**NEW** definition provider created to manage the publication of information by ECHA.

### 15.1.3.5 **EU EFSA**

**NEW** definition provider created to manage relevant EFSA databases information.

### 15.1.3.6 **EU PPP**

- **NEW** Genomic characterisation of the microorganism
- **NEW** Expression in a Freshwater Environment
- **NEW** Expression in a Terrestrial Environment
- **NEW** Expression in soil
- **NEW** Expression in water
- **NEW** Environment qualitative exposure assessment
- **NEW** Information on metabolites of ecotoxicological concern
- **NEW** Information on metabolites of toxicological concern
- **NEW** Assessment on potential infectivity and pathogenicity of the microorganism to humans
- **NEW** Assessment of potential toxicity

- **NEW** Consideration of isomeric composition in risk assessment
- **NEW** Additional Transparency Regulation Information
- Update of:
  - Definition of the residue for food of plant and animal origin
  - Estimation of concentrations
  - Magnitude of residues in pollen and bee products
  - Toxicological Reference Values
  - Residues in livestock, feeding studies (summary)
  - Metabolites - remove attachments
  - Dossier headers
  - Manufacturer EU PPP

#### **15.1.3.7 EU REACH**

- Opt-out document update (justifications structure improved)
- Inquiry: type 5 for read across
- Update of Annex III criteria

#### **15.1.3.8 NZ HSNO**

- Update of Help texts and Tables of Contents

### **15.1.4 Technical changes**

**NEW** Format change: new mandatory elements (Ref. 652925). Every document included in a IUCLID file must include 'documentType', 'creationDate' and 'lastModificationDate'. Dates need to be recorded according to ISO-8601.

### **15.2 Annotations**

**NEW** Transfer annotations (Ref. 265678)

### **15.3 Comparison**

**NEW** Comparison of datasets (Ref. 657128)

### **15.4 Data entry and view**

**IMP** 'none' placeholder should be removed from the flags too (Ref. 683852)



**FIX** Delete option should not be available for cross-references displayed in the navigation tree (Ref. 678859)

**IMP** When creating a new document in a table of content, the name of the documents to be created should be taken from the document name specified in the table of content (Ref. 666336)

**IMP** Remove duplicate information in linked document representations (Ref. 667447)

**IMP** Link to document sections: right and left arrows should be displayed only when needed (Ref. 680197)

**FIX** Bulk delete view displays endpoint summary documents at incorrect location (after the child section nodes) (Ref. 670638)

**NEW** Enable the possibility to change the language of the user interface; translations are provided only for the working context 'EU BPR Summary of Product Characteristics' (Ref. 695287)

**NEW** As a user I would like to see the units in a hierarchical picklist (Ref. 696709)

**IMP** Floating text feature removed from fields of type 'Text' (Ref. 702454)

**IMP** Link to repeatable items in a document: 'other:' text is not displayed (Ref. 678700)

## 15.5 ECHA Cloud Services

**NEW** Support export to Cloud Drive (Ref. 675400)

## 15.6 Export

**NEW** Provide options for dossier export (Ref. 682791, 685236)

## 15.7 Import

**FIX** Import of an SPC xml file to IUCLID - truncation to be removed for the field 'Field of use description' (Ref. 675950)

## 15.8 Installation / Upgrade

**FIX** When using Derby Network Server, the database is not created by default (Ref. 696960)

**FIX** Symlinks used in Linux installations cause the updater to fail (Ref. 697117)

**FIX** Updater overwrites sso-default-third-party.jks breaking SSO (Ref. 702138)

**FIX** Clean-up of table IUCLID\_GROUPS fails during upgrade to v6.27.7 (Ref. 736202)

**FIX** Duplicate server property for FailedLoginAttempts (Ref. 697533)

## 15.9 Report generator

### 15.9.1 Bug fixes

**FIX** Formatting in rich text fields is not persisted in the RTF/PDF Report outputs (Ref. 675443)

**FIX** Text overruns the page and tables in generated PDF reports (Ref. 675447)

**FIX** Translation of non-Latin-based characters are not rendered in Reports (Ref. 689791)

### 15.9.2 Extended functionality

**NEW** Make report generation a background job (Ref. 677876)

When generating a report, this will be part of a background job (see Ref. 736190), meaning that after generation has started, a user can check the status of the generation in the background tasks and download the result (i.e., the generated report or, if an error, the error text file)

**NEW** Generate reports from a referenced entity or entities (aka Generate sub-entity report) (Ref. 685751)

Sub-entity report generation can be used by any IUCLID user developing reports. In summary, sub-entity generation permits, if a report template (FTL) is customised accordingly, to generate a report directly from a sub-entity of a parent root entity, e.g., an active substance of a composition in a Mixture parent entity). Currently, all reports are shown in the list for sub-entity generation, and for those reports not compatible with sub-entity generation, the default behaviour of the report is to generate directly from the sub-entities parent root entity.

### 15.9.3 Format changes

**IMP** All reports have been updated to the latest 6.7 format

#### Assessment reports

Note that with the format changes to the Endpoint Summaries, a different approach to displaying these summaries have been implemented across assessment reports, e.g., Chemical Safety Report, Doc M reports, SVHC. The Endpoint summaries for the following endpoint sections are now reported in a tabular display:

- Environmental Fate and Behaviour
- Ecotoxicology
- Toxicology
- Physical-chemical properties (currently, Doc M reports only)

### 15.9.4 Updates to reports

**IMP** SPC Reports (single and family)

The SPC reports for a single product and product family have been updated. The major update refers to the translation of the reports. When a user selects a language in the dossier header, that language will be used for the output of the report in two respects:

1. The non-IUCLID values (such as the Headers and Table text)
2. The IUCLID values, such as the Function name

### 15.9.5 Known issues

- Not all IUCLID phrases are currently translated, e.g., Hazard statements
- The Active Substance manufacturer and location are sometimes not displayed

**IMP** The *List of Study Summaries* report has officially replaced the now deprecated *List of Literature References (extended study details)* report, [see 5.2](#).

## 15.10 Validation assistant

### 15.10.1 EU REACH

**NEW** set of rules following an update of the REACH Annexes, see details in the [‘Completeness check of REACH registration dossiers: what changes in 2023 and how you can prepare’](#) webinar and in the updated REACH registration manual [‘How to prepare registration and PPORD dossiers’](#) (Annex 2 and 3).

**NEW** rule ensuring that under section 4.10\_Surface\_tension an endpoint document indicated as *surface tension of an aqueous solution* is provided.

**NEW** rule ensuring that an opt-out of jointly submitted data is justified following new document structure. In addition, a new rule was introduced to remind the leads who submit a dossier with an opt-out to ensure that the dossier contains the required information.

**NEW** rule for sections 7.3.1\_Skin\_irritation\_corrosion and 7.3.2\_Eye\_irritation ensuring the consistency between the endpoint selection and provided justification for data waiving.

**IMP** the relevant set of rules checking 6.3.2\_Toxicity\_to\_soil\_arthropods section was updated following format updates.

**NEW** rule for Inquiry ensuring that if the update is justified as *‘agreement with data owner on access to Robust Study Summary(ies) older than 12 years cannot be reached’* then at least one study must be indicated under the Inquiry section.

**NEW** set of rules for REACH Downstream user notification of authorised uses.

**FIX** the issue with rules QLT216-221 was fixed (ref. # 684331).

### 15.10.2 EU PPP

**FIX** QLT\_PPP\_122. The order of failures reported were not displayed in the correct order. The issue was fixed.

**FIX** QLT\_PPP\_125. The rules were fixed to only check the Active Substance dataset. Fix also covers other rules checking Active Substance.

**IMP** update to business rules BR\_PPP\_038, BR\_PPP\_039, BR\_PPP\_051 and BR\_PPP\_052. The rules were updated to check when 'Joint Application' field of the dossier header is set to 'yes'.

**IMP** BR\_PPP\_090. The rule was updated to check that main mixture is not linked under the components in the mixture composition.

**NEW** set of quality rules checking results in OHTs

- ENDPOINT\_STUDY\_RECORD.ShortTermToxicityToAquaInv
- ENDPOINT\_STUDY\_RECORD.ToxicityToAquaticAlgae
- ENDPOINT\_STUDY\_RECORD.ToxicityToAquaticPlant
- ENDPOINT\_STUDY\_RECORD.ToxicityToTerrestrialPlants
- ENDPOINT\_STUDY\_RECORD.ToxicityToBirds
- ENDPOINT\_STUDY\_RECORD.AcuteToxicityInhalation
- ENDPOINT\_STUDY\_RECORD.RepeatedDoseToxicityDermal
- ENDPOINT\_STUDY\_RECORD.ToxicityReproduction
- ENDPOINT\_STUDY\_RECORD.DevelopmentalToxicityTeratogenicity
- ENDPOINT\_STUDY\_RECORD.LongTermToxicityToAquaInv

**NEW** business rule BR\_PPP\_159 checking the dossier header (Reason for resubmission).

**IMP** QLT\_PPP\_117. The rule was updated due to format changes. The paths of the checked reference substance were updated for two documents:

- ENDPOINT\_STUDY\_RECORD.BiodegradationInSoil
- ENDPOINT\_STUDY\_RECORD.BiodegradationInWaterAndSedimentSimulationTests

**IMP** QLT\_PPP\_045. The rule was updated to remove the document FLEXIBLE\_SUMMARY.Metabolites from the check.

**IMP** QLT\_PPP\_118 and QLT\_PPP\_144. The rules were deactivated due to new format changes in the affected documents.

**IMP** BR\_PPP\_001, BR\_PPP\_009, BR\_PPP\_010, BR\_PPP\_011, BR\_PPP\_014, BR\_PPP\_015, BR\_PPP\_016, BR\_PPP\_017, BR\_PPP\_018, BR\_PPP\_019, BR\_PPP\_020, BR\_PPP\_021, BR\_PPP\_025, BR\_PPP\_047, BR\_PPP\_050, BR\_PPP\_063, BR\_PPP\_071, BR\_PPP\_072, BR\_PPP\_079, BR\_PPP\_091, BR\_PPP\_099, BR\_PPP\_100, BR\_PPP\_106, BR\_PPP\_112, BR\_PPP\_113, BR\_PPP\_114, and BR\_PPP\_115. Rules were changed from quality warnings to business rules.

**IMP** PPP rules checking the presence of mandatory documents (e.g. endpoint study records and summaries) were updated to remove documents modified due to the new format change (e.g. Ecotoxicological and Toxicological endpoint study records).

**IMP** QLT\_PPP\_057, QLT\_PPP\_058, QLT\_PPP\_059, QLT\_PPP\_060. The rules were deactivated for Microorganisms working context.

### 15.10.3 EU BPR

**IMP** the BR\_SPC\_030 rule, checking that the type of formulation is provided, was activated for Single and Family SPC. BR\_SPC\_049 was deactivated.

### 15.10.4 EU CLP (PCN)

**NEW BR544** ICG: Concentration is to be provided only for the 'Interchangeable component group (ICG)' – not for the individual interchangeable components. (G)

**NEW BR828** ICG: 'Interchangeable component group' cannot be indicated both in MainMixture and in Mixture in mixture (MiM) level (G)

**NEW BR830** SF Fuels: 'If component is indicated to be 'fuels' then it must have the specific fuel name. More precisely if the 'Standard formula checkbox is ticked and in 'Other identifiers' table 'Name type' is selected to be 'fuels' then the adjacent 'Name' field must have selected the fuel name from the dropdown list.) (G)

**NEW BR890** SF Fuels: 'Fuels' can be reported only in MainMixture, not as MiMs (G)

**NEW BR950** (S) and **BR951** (G) Reported concentration value cannot be above 100% (rule checks each constituent's concentration value separately)

**NEW QLT821** If in the Mixture composition the Component's function is indicated to be '*other:*' then it must be explained in all the relevant languages (G)

**NEW QLT822** MiM's UFI can be the same as mixture's UFI only if the composition is reported to be 100% MiM (MainMixture has one 'Mixture' constituent which exact concentration is indicated to be 100%) (G)

**NEW QLT825** (S) and **QLT826** (G) If in the Substances 'Other substance identifiers' table 'Identifier' is indicated to be '*other:*' then it must be explained in all the relevant languages

**NEW QLT847** If the MiM does not have UFI and is instead identified with providing the available component(s) of the composition, then the legal entity in the 'Suppliers' record should be from EU country. Please note that the responsibility for mixtures imported into the EU remains on the importer. (G)

### 15.10.5 EU WFD (SCIP)

**NEW BR734** If 'Additional material characteristics' are included then 'Material category' should be included as well.

**NEW QLT735** If in 'Other article identifiers' 'Type' is selected to be *other:* then it must be explained in the adjacent field.

**NEW QLT737** If in 'Additional material characteristics' is selected to be *other:* then it must be explained in the adjacent field.

## 15.11 Miscellaneous

**NEW** Support IUCLID 6 Web interface to be embedded in an iframe (Ref. 685568)

**FIX** Error message on exceeding login attempts limit is incorrect and misleading (Ref. 775840)

**IMP** Prevent import of 'orphan' annotations (Ref. 278101)

**NEW** Display list of background tasks and their status (Ref. 736190)

## 16 VERSION 6.27.8 (PUBLIC RELEASE 2 MAY 2024)

### 16.1 Single sign on (SSO)

**FIX** Setting eu.echa.iuclid6.idp.relay.verify to false breaks SSO (Ref. 702152)

**FIX** Updater overwrites sso-default-third-party.jks breaking SSO (Ref. 702138)

**FIX** User with SSO group permission granting "instanceAccess" removed and re-added stays suspended (Ref. 672720)

**FIX** Clean-up of table IUCLID\_GROUPS fails during upgrade to v6.27.7 (Ref. 736202)

## 17 VERSION 6.27.7 (PUBLIC RELEASE 28 FEBRUARY 2023)

### 17.1 Updater

**FIX** The updater tool indicated that a Server installation was a Desktop installation. The fix includes a way for a user to change between a Desktop installation and a Server one. (Ref. 700668)



## 18 VERSION 6.27.6 (INTERNAL AND CLOUD RELEASE 28 FEBRUARY 2023)

### 18.1 Security

**FIX** Several vulnerabilities have been addressed

- Cross Site Scripting (XSS) – Reflected (Ref. 699784)
- Authentication bypass vulnerability (CVE-2023-26089) (Ref. 699749)
- Server-side Template Injection (SSTI) Vulnerability (CVE-2023-26546) (Ref. 699781)

## 19 VERSION 6.27.4 AND 6.27.5 (PUBLIC RELEASE 6 FEBRUARY 2023)

Changes included in v6.27.5 are identified with (\*).

### 19.1 Data entry

**FIX** When creating a cross reference to another document, the sliding window displays documents from inherited templates not linked to the selected dataset (Ref. 690541)

**IMP** Caching layer introduced in order to prevent reloading the full section tree for operations that do not require it, for example for cross reference to existing documents. A button to refresh the list on demand has been added (Ref. 690227)

**FIX** Cross reference / The inherited documents missing the indicative icon (Ref. 684575)

### 19.2 Report generator

**FIX** Invalid XML format is triggered in reports in 6.29.0 but the content was valid in 6.19 (Ref. 690735)

**FIX** Update for the PCN report, e.g., display of the Precautionary statements (Ref. 691076)

**IMP** Update of several report templates (Ref. 694036)

- **NEW** List of Study Summaries (CSV output)
- **IMP** SPC Report (single and family) improved based on user feedback
- **Known issue of the SPC Report** The Suppliers and their Sites of the Main Mixture and Active Substance are not currently displayed correctly

### 19.3 Updater

**FIX** After an upgrade from v2.0.0, the user is always redirected to the login page (Ref. 692093)

**FIX** \javadb\bin folders missing after upgrade (Ref. 695986 and 697850) (\*)

**FIX** Updater cannot update domain.xml in the case of systems initially installer with v2 or earlier (Ref. 690545)

### 19.4 Validation assistant

**IMP** Update of the list of candidate substances for SCIP dossiers (Ref. 690830)

**IMP** Update of validation assistant messages for REACH (Ref. 695054)

### 19.5 Miscellaneous

**FIX** Firefox: large icons displayed in specific cases (Ref. 692955)

**FIX** User cannot change working LE or import i6z files: 'More than one result was returned from Query.getSingleResult()' (Ref. 692895) (\*)

## 20 VERSION 6.6.27.2 (10 NOVEMBER 2022)

See also the news alert for this release: [IUCLID news - ECHA \(europa.eu\)](https://eucha.europa.eu)

### 20.1 Updater

**FIX** The navigation tree cannot be loaded in dossiers and substances after an upgrade of an existing IUCLID database to version 6.27.1(Ref. 688075)

**FIX** IUCLID does not start after an upgrade under Windows and MacOS (Ref. 687273, 687823)

**FIX** Updater tool for Linux does not start (Ref. 688058)

## 21 VERSION 6.6.27.1 (31 OCTOBER 2022)

See also the news alert for this release: [IUCLID news - ECHA \(europa.eu\)](https://iuclid6.echa.europa.eu/news)

### 21.1 Data entry

**FIX** Keyboard navigation: the selection 'other' is not visible at the end of the picklist list when using keyboard (Ref. 678963)

**FIX** Document scrolled automatically to top when editing a table with many entries, in a Firefox browser (Ref. 679722)

### 21.2 Printing

Known issue:

- Document selection for PDF and RTF creation does not work for dossiers

### 21.3 Report generator

**FIX** CSR failing to generate when Key Values for Freshwater or Marine fish are included in the Endpoint Summary; Long-term Toxicity to Fish (Ref. 684030)

**NEW** Include Category information in the Chemical Safety Report (Chapter 1.3 of the report)

**IMP** The 'List of Attachments' report (RTF/PDF) now groups together attachments which have been used across different Endpoints

**IMP** The GHS Classification and Labelling report now includes AICIS-specific content when generated from an AICIS Working Context

**IMP** The 'Substance composition report' now includes Type of composition information:

- FLEXIBLE\_RECORD.SubstanceComposition.GeneralInformation.TypeOfComposition

**IMP** The following reports have been improved to support faster generation:

- List of Literature References
- List of Confidentiality Claims

**IMP** The following EFSA-based templates have been updated:

- NoS Extraction Request
- MRL Application Report

## 21.4 Validation assistant

### 21.4.1 REACH

**NEW** Business rule failing in case incompatible with Downstream user roles in the supply chain were set.

**NEW** Business rule checking if reason for updating was indicated.

**NEW** set of quality rules checking sections 3.5.1-3.5.6. New checks ensure that there are no duplicate Use names in the same section (i); and Activity names and descriptors should not be identical in the use document (ii).

**NEW** reminder in case Third Party Representative is set in 1.1\_Identification.

**NEW** set of quality rules ensuring that data being provided under the Results of examinations for short-term, oral (Annex VIII) and for sub-chronic (Annex IX).

**IMP** BR035 was updated with extended last submission number format in the dossier header.

**IMP** QLT222 improved message display.

### 21.4.2 EU\_PPP

**NEW** set of quality rules checking presence of EU\_PPP Flexible and Endpoint summaries.

**NEW** set of quality rules checking results in OHTs:

- ENDPOINT\_STUDY\_RECORD.BiodegradationInSoil
- ENDPOINT\_STUDY\_RECORD.ShortTermToxicityToFish
- ENDPOINT\_STUDY\_RECORD.AcuteToxicityOral
- ENDPOINT\_STUDY\_RECORD.RepeatedDoseToxicityOral
- ENDPOINT\_STUDY\_RECORD.GeneticToxicityVitro

**NEW** set of quality rules checking the dossier header (Pre-Application and Notification of Studies Identifiers).

**NEW** quality rule QLT\_037\_A checking DATA\_PROTECTION.Confidentiality and replacing quality rule QLT\_PPP\_037. The new rule checks that a justification is provided when a confidentiality flag is set.

**NEW** business rule BR\_PPP\_090 removing any duplicate datasets from the 'Other Representative Product' section.

**FIX** the issues ('other:' selection) with the rules were fixed in QLT\_PPP 067 and QLT\_PPP\_095.

**IMP** the QLT\_PPP\_010 rule was updated to check the format of the Notification of Studies Identifiers in the literature reference entity and to ensure that information is always provided in either the 'Study ID' or the 'Remarks' fields.

**IMP** the QLT\_PPP\_027 and QLT\_PPP\_048 rules were updated to remove the constraint that only one literature reference (QLT\_PPP\_027) or only one row in the 'Attachments' block with the selection 'full study report' (QLT\_PPP\_048) can be provided.

**IMP** the QLT\_PPP\_011 - 016 rules were updated to fulfil the new data requirements applicable to microorganisms ([https://food.ec.europa.eu/plants/pesticides/micro-organisms\\_en](https://food.ec.europa.eu/plants/pesticides/micro-organisms_en)) e.g., new OHTs.

### 21.4.3 BPR

**NEW** set of rules checking BPR Summary of product characteristics (SPC).

**NEW** set of rules checking BPR Technical Equivalence.

**IMP** BR\_SPC\_005 was updated with extended completeness check for the *Packagings* and *Application methods* fields

Known issues and future improvements:

- Issue with new BR\_SPC\_020 rule checking BPR Summary of product characteristics (SPC). The rule doesn't fail as expected for the existing 'Active substances, Substances of concern, Other substances' blocks in Family or Meta SPC document(s), with function = Active substance, but with no Substance entity linked.
- Message display issue in QLT216-221 rules, checking that Activity names and descriptors are not identical in the use document. The message incorrectly displayed only for one block with duplicate data, the message should be displayed for each duplicate.

### 21.4.4 PCN

See the latest update of the manual 'Validation rules for Poison Centres Notifications' at [https://poisoncentres.echa.europa.eu/documents/1789887/5577602/pcn\\_validation\\_rules\\_en.pdf](https://poisoncentres.echa.europa.eu/documents/1789887/5577602/pcn_validation_rules_en.pdf)

## 21.5 Miscellaneous

**IMP** New version of the IUCLID user manual added (Ref. 685656)

**IMP** The integrated application server (Payara) used in IUCLID has been updated to version 5. Server administrators are invited to consult the installation and update manual to check the latest instructions related to the server configuration (Ref. 659132)

## 22 VERSION 6.6.24.0 (12 SEPTEMBER 2022, INTERNAL RELEASE)

### 22.1 Comparison

**NEW** Comparison of individual documents (Ref. 657126)

**FIX** Content of 'other:' field in picklist is not highlighted when differences are found in content (Ref. 674391)

### 22.2 Data entry

**FIX** Remove references to inherited template document when the inherited template is not linked anymore to a dataset (Ref. 669189)

**FIX** Ranges can be imported with a csv file (Ref. 673660)

**NEW** Keyboard navigation, support for picklist selection (Ref. 674658), support for repeatable block (Ref. 675742), support for ranges (Ref. 675527), support for references and attachments (Ref. 676594), support for hierarchical phrase group (Ref. 676602)

**NEW** Parameters can now be added in relevant phrases in picklist. This is available under the SPC working context for Hazard and Precautionary statements (Ref. 263313)

**NEW** Cross references have been improved by displaying document within the section tree (Ref. 657319)

**IMP** Separator added between range values (Ref. 657237)

**NEW** Create dataset from a dossier. This includes a comparison with potentially existing datasets and entities (Ref. 664491)

### 22.3 Plant protection products

**IMP** Adaptation to the table of contents for microorganisms (Ref. 678206)

### 22.4 Printing / reporting

**FIX** Document selection freezes for a dossier component (Ref. 666310)

### 22.5 User management

**NEW** User settings. The user can define the default security groups for import and entities creation (Ref. 261451)

### 22.6 Web interface

**NEW** Refactored navigation tree. Access to linked datasets is now done in a separate tree to enhance performance and clarity (Ref. 657239)



## 22.7 Miscellaneous

- FIX** Single Sign On (SSO), overlapping Legal Entities breaking authentication (Ref. 667507)
- FIX** User with SSO group permission granting "instanceAccess" removed and re-added stays suspended (Ref. 672720)
- FIX** Error icon remains visible (Ref. 671318)
- IMP** Dossier creation does not impact anymore the modification date of elements in a dataset (Ref. 673318)
- FIX** jvm-options are not reset anymore by the updater (Ref. 677470)

## 23 VERSION 6.6.19.2 (17 NOVEMBER 2022, RELEASED TO SPECIFIC USERS)

### 23.1 Data entry

**FIX** Other text in picklist is not rendered in document 'HSW requirements' in field 'Safe Work Instrument requirements under the Health and Safety at Work Act' (Ref. 689227)

## 24 VERSION 6.6.19.1 (12 AUGUST 2022, RELEASED TO SPECIFIC USERS)

### 24.1 Web interface

**NEW** Refactored navigation tree. Access to linked datasets is now done in a separate tree to enhance performance and clarity (Ref. 657239)

## 25 VERSION 6.6.19.0 (4 JULY 2022, PUBLIC RELEASE)

### 25.1 Comparison

- FIX** Boolean are displayed and compared despite no changes made (Ref. 659909)
- FIX** Differences in the 'remarks' fields are not displayed (Ref. 261517)
- FIX** HTML tables are not rendered correctly sometimes (Ref. 263537)
- IMP** Differences identified in text fields are now highlighted to the users (Ref. 657125)

### 25.2 Data entry

- IMP** Reference sections in the table of content are now differentiated from the standard sections (Ref. 661952)
- FIX** Cannot reorder documents when they used to have the same name (Ref. 266067)
- IMP** CSV import: all data types are now supported, and phrases text can be used instead of the code (Ref. 657230)
- FIX** Unsaved data warning is not displayed for annotations (Ref. 667139)
- FIX** Unsaved data warning is displayed incorrectly in a sliding window (Ref. 672376)
- IMP** Navigation between document fields is now possible using the keyboard (Ref. 672629). Further improvements are planned in order to facilitate data entry in the IUCLID documents.
- FIX** Documents not relevant to the BPR regulation after the annexes update and removed in the April 2022 release are displayed again (Ref. 673550)
- FIX** PCN working context: only Perfume and Colourant are available for GCI (Ref. 665513)
- FIX** Inventory type and number are now displayed in the representation of reference substances (Ref. 664912)
- IMP** Update of the BPR Technical Equivalence table of content to reflect the changes to the BPR Annexes (Ref. 668393)

### 25.3 Export

- IMP** Exporting as light dossier is now available for EU PPP Product Authorisation (Ref. 280333)

### 25.4 Filtering

- IMP** Update of the filtering configuration for EU PPP dossiers (Ref. 671716)

## 25.5 Import

- FIX** Light dossiers created from EU PPP working contexts cannot be imported (Ref. 669219)
- FIX** Large dossiers can fail to be imported due to a time out (Ref. 673538)
- IMP** When the HTML content verifier is activated during import (note: it is deactivated by default), the error messages now indicate which tag / attribute was found unsafe (Ref. 661977)
- IMP** Multilingual format is checked during import for dossiers created before IUCLID 6 version 6 (Ref. 663792)
- IMP** SPC XML mapping during import has been improved at the following levels: manufacturing sites, link between classification and labelling and the composition document, scientific names for target organisms, formulation type for SPC families, generation of unique names for meta SPC and product documents, product family name (Ref. 657142)
- FIX** Some overwriting settings are not taken into account when selecting documents in advanced import (Ref. 666520)

## 25.6 Print

- FIX** Document selection is not fully functioning when creating PDF/RTF (Ref. 663373)
- FIX** Error when printing a dossier component for a mixture-based dossier (Ref. 667678)

## 25.7 Report generator

- IMP** Report generator errors can now be downloaded by the user (Ref. 657206)
- IMP** New version of several reports have been uploaded (Ref. 672061)

## 25.8 REST API

- IMP** Extraction of confidentiality claims:
  - new property added for the table of content node information (Ref. 665829)
  - new property added for the block identifier (Ref. 667329)
  - new property added to indicate the document to which a claim refers (Ref. 665653)
  - all flags information is now reported by the API, not only confidentiality claims but also justifications and regulatory programmes (Ref. 671743)
- FIX** Extraction of confidentiality claims: claims are reported twice (Ref. 666434)

## 25.9 Search

- IMP** Search by security group is now possible when Instance Based Security is enabled (Ref. 657222)

## 25.10 User interface

**NEW** Navigation to level headers is now available in the documents (Ref. 263011)

**FIX** Attachments, modification history and annotations are not fully visible in some custom definitions (Ref. 665511)

**IMP** Labels of the links added to the IUCLID top bar can now be configured (Ref. 657210)

**NEW** The content of the navigation tree can now be filtered (Ref. 657211)

## 25.11 Validation assistant

**IMP** Validation assistant alignment with the Official Candidate List that has been updated on June 2022 (Ref. 669008)

**NEW** set of rules checking *BPR Summary of product characteristics (SPC)*

**NEW** rule for *EU PPP Basic substance application* checking that exactly one Component with Function = Active substance must be present in the Mixture Composition

**FIX** BR\_PPP\_085 and BR\_PPP\_086 issue was fixed. The rules correctly fail under the Main mixture only

**FIX** QLT\_PPP\_095 message display issue was fixed (Ref. 665738)

Known issues and future improvements:

- issue with QLT\_PPP\_067 and QLT\_PPP\_095 the rules incorrectly fail despite that 'Principles of method if other than guideline' field is provided (Ref. 673033)

## 25.12 Miscellaneous

**IMP** Aggregation can now be done also with only one dossier (Ref. 664791)

**FIX** Data transfer tool fails if jdbc url contains a space (Ref. 664968)

**FIX** Dissemination preview sub menus not displayed correctly (Ref. 658359)

**IMP** Contact can be added to IUCLID users (Ref. 629193)

**FIX** Scroll to top not available for dossiers (Ref. 669158)

## 26 VERSION 6.6.14.3 (26 APRIL 2022, PUBLIC RELEASE)

### 26.1 Data entry

**NEW** Bulk delete documents in a dataset (Ref. 265221)

**FIX** Hazard category "Repr. 1A-H360Fd" not saved when in a PCN working context (Ref. 659416)

**FIX** Certain picklists created in templates open upwards not downwards, hiding phrases to select (Ref. 659536)

**IMP** Alignments of the labels in the custom section SPC Product Summary Composition (Ref. 659566)

**IMP** Alignment of headers and labels in the custom section SPC Product Summary Composition (Ref. 660258)

**IMP** Product summary composition and mixture(composition) records renamed in the SPC working context (Ref. 660450)

**IMP** Amendment to the ToC BPR Summary of product characteristics – SPC (Ref. 660455)

**IMP** Adaptation of phrase groups containing country names to SPC requirements (Ref. 660464)

**IMP** Allow changing the record name upon document creation in a sliding window (Ref. 660470)

**IMP** Change to the logic for the default name of a document created from another document (Ref. 660488)

**FIX** Issue with attachments when duplicating a table row (Ref. 652578)

**FIX** Caching issue in annotations, dossier headers and specific fields in endpoint study records (Ref. 663516, 665538, 660512)

### 26.2 Dossier creation

**IMP** Legal entity to be included in SPC dossiers by default (Ref. 659762)

### 26.3 File format validation

**IMP** Check consistency between manifest.xml and i6z content (Ref. 661254)

- Check that the document id is unique in the manifest.xml
- Check that all the i6d files that appear in the i6z file are referenced (via xlink:href) either from a <document> tag or from an <attachment> tag
- Check that all the binary files that appear in the i6z file under attachments folder are referenced (via xlink:href) from an <attachment> tag

**IMP** i6Z archive check for zip corruption (Ref. 656796)

## 26.4 Import

**IMP** Improved advanced import. Possibility to see the content of the imported file organized by Table of Contents (Ref. 657208)

## 26.5 Report generator

**NEW** Support report generation in different languages (support for translated pick-list items and for translated hardcoded texts in the ftl report template) (Ref. 657117)

- Includes the possibility to upload, **into Report Manager**, a language properties file from which contains the translated texts

**FIX** Special character not printed in PDF Print output (Ref. 660903)

**FIX** Attached TIFF file causes Print and Reports to fail (Ref. 660908)

**IMP** Update of report templates (Ref. 662926)

- **NEW** SPC Product Family report (prototype)

## 26.6 Validation assistant

**NEW** set of REACH quality rules checking section *7\_Toxicological\_information* summary.

**NEW** REACH quality rule checking *Type of classification* being indicated in GHS document.

**NEW** BR\_PPP\_086 checking that at least one Mixture composition is provided in EU\_PPP Basic substance application.

**NEW** set of EU\_PPP rules checking Other representative products Mixture.

**NEW** set of EU\_PPP rules checking Metabolites substance.

**FIX** QLT207, QLT208 (Ref. 647369). The issues with QLT rules for section 7.6.2 were fixed.

**FIX** VA report: some EU\_PPP rule failures were not displayed in the relevant tab (Ref. 657078). The issue was fixed.

**IMP** QLT\_PPP\_016 updated not to fail for the *10\_Effects\_on\_non-target\_organisms* section.

**IMP** BR274 (Ref. 654456). The rule is checking if there are documents in the dossier which were not opted out. The rule was updated to check endpoint study records which are not required under REACH.

**IMP** requirements checked for REACH Annex VII were applied to the *Registration, lead TII 1-1000, own TII>1000* submission type (validation scenario SC0155).

Known issues and future improvements:

- Issue with BR\_PPP\_085 and BR\_PPP\_086. The rules should check Main Mixture composition only, however, the rules fail for other than Main Mixture dataset e.g. Other representative products.
- QLT\_PPP\_095 message display issue: substance section number and name are not displayed (Ref. 665738).



## 26.7 Search

**NEW** Search based on reference substance identifiers for substance dataset (Ref. 657215)

**NEW** Search mixture by legal entity (Ref. 657218)

**IMP** Support search for exact match using double quotations marks, e.g., "<exact term to be searched>" (Ref. 657216)

## 26.8 Server version management

**NEW** Support for Single Sign On – SSO

**NEW** Support for PostgreSQL databases

## 26.9 User interface

**NEW** Indicators for the attachment, modification history and annotations buttons (Ref. 640720)

**IMP** Data entered in fields is now displayed in black instead of dark grey (Ref. 657212)

**FIX** Confidentiality flags caching issue (Ref. 658626)

**IMP** The options View Dossiers, Validate, Create dossier in raw dataset, have been moved next to the '3 dots' menu (Ref. 659917)

**IMP** Adjacent fields are now displayed in all relevant documents (Ref. 657883)

**IMP** Representation of links: the document type and identifier are displayed only on hover from now on (Ref. 659564)

**IMP** Changes to the attribute "Part of document summary" used for the representation of linked documents and entities (Ref. 661689)

**IMP** Implementation of relevant custom definition to support DU66 'REACH notification of authorised uses' (Ref. 661796)

**IMP** PPORD document, help text for the check box 'Substance not placed on the market' (Ref. 661908)

**IMP** Adaptation of BPR tables of contents (Ref. 662365)

## 26.10 Miscellaneous

**IMP** Improve REST API response for list of confidentiality claims: path information should identify repeatable entries unambiguously (Ref. 661432)

**FIX** Backward migration missing for Estimated quantities, when exporting information in the previous major version format (Ref. 662923)

**FIX** Generate comparison report is not possible due to "<ExtensionComponentNotFound: Extension component not found." (Ref. 663602)