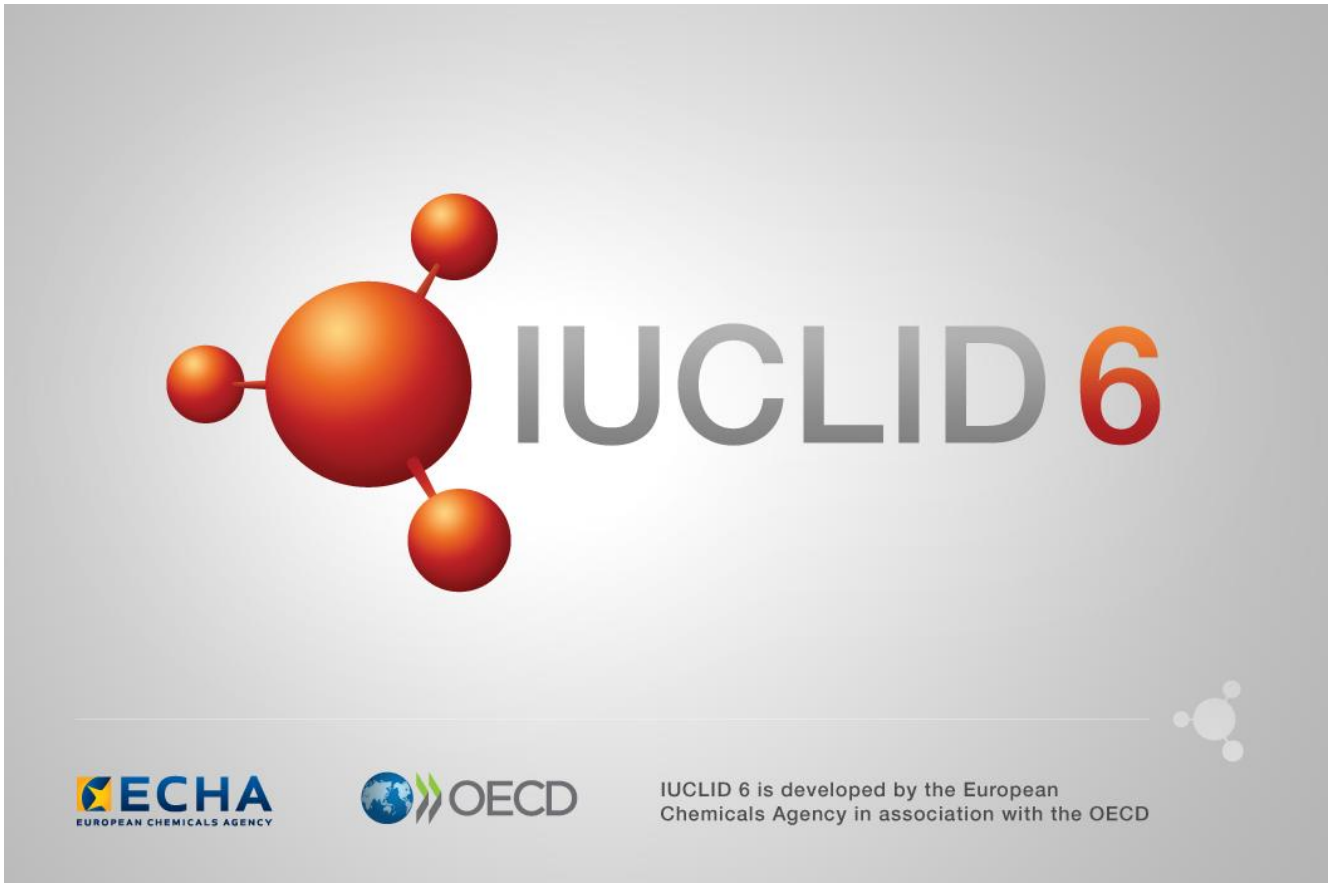
IUCLID 6

Release notes

Version 7.12.4

02/02/2024



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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 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

2.1 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)

2.2 Export

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

2.3 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

2.4 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)

2.5 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)

2.6 Miscellaneous

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

3 VERSION 7.12.2 (CLOUD RELEASE 11 DECEMBER 2023)

3.1 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)

3.2 Filtering

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

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

3.3 Import

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

3.4 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

4 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)

5 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)

6 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)

6.1 Comparison

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

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

6.2 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)

6.2.1 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)

6.3 Dossier creation

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

6.4 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)

6.5 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

6.6 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)

6.7 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)

6.8 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)

6.8.1 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

6.8.2 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

6.9 User management

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

6.10 Validation assistant

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

6.10.1 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.

6.10.2 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.

6.10.3 DWD

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

6.10.4 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.EyeIrritation
- 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.

6.10.5 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*

6.10.6 SCIP

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

6.11 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 Liquidbase 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)

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

7.1 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)

7.2 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)

7.3 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)

7.4 Validation assistant

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

8 VERSION 7.0.5 (CLOUD RELEASE 03 JULY 2023)

8.1 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)

8.2 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)

8.3 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.

8.4 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)

9 VERSION 7.0.4 (PUBLIC RELEASE 12 JUNE 2023)

9.1 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.

9.2 Data visualization

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

9.3 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.

10 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)

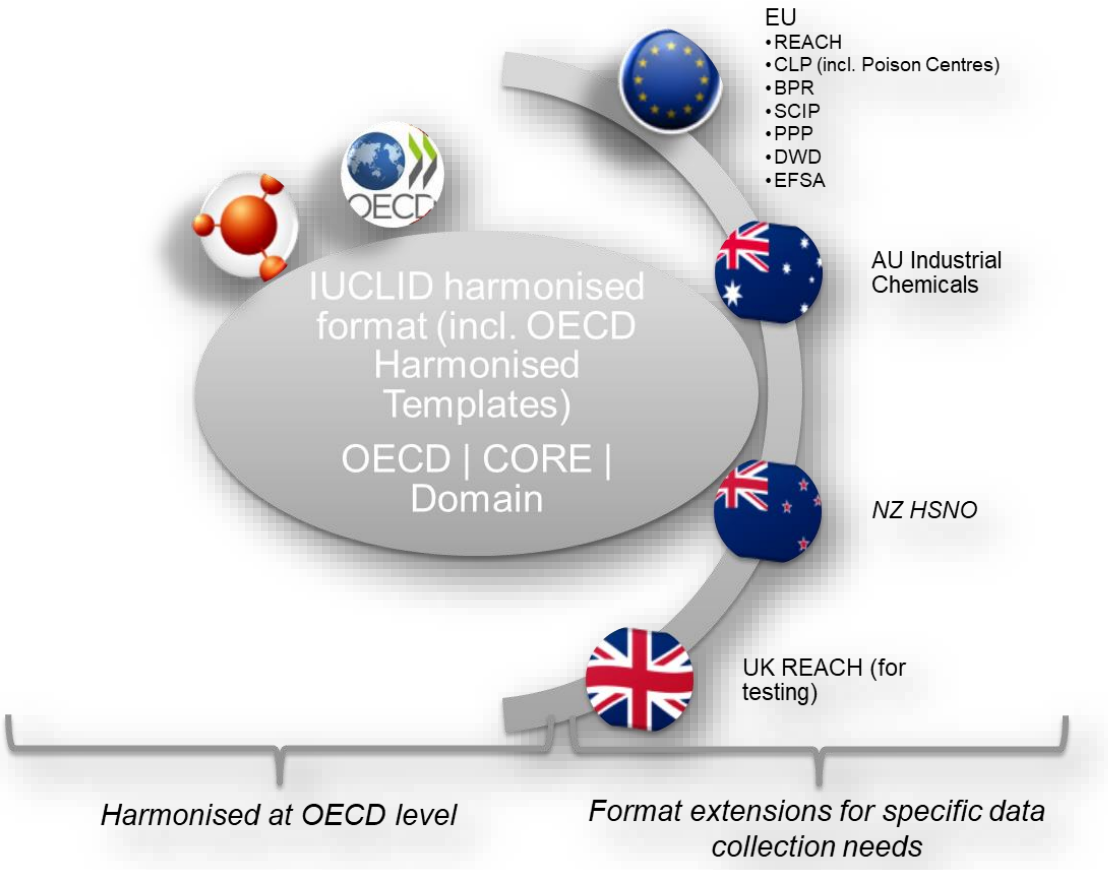
FIX The (obsolete) EU PPP Endpoint summary for toxicity to terrestrial arthropods did not allow referencing the newly created OECD Harmonised Templates for terrestrial arthropods. This created impossibility to import IUCLID files in some specific case (Ref. 874188)

11 VERSION 7.0.1 (PUBLIC RELEASE 22 MAY 2023)

11.1 Format changes

11.1.1 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

11.1.2 Changes to harmonized Templates

11.1.2.1 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.

11.1.2.2 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

11.1.2.3 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'

11.1.3 Specific documents format changes

11.1.3.1 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

11.1.3.2 EU CLP

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

11.1.3.3 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'

11.1.3.4 EU ECHA

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

11.1.3.5 EU EFSA

NEW definition provider created to manage relevant EFSA databases information.

11.1.3.6 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

11.1.3.7 EU REACH

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

11.1.3.8 NZ HSNO

- Update of Help texts and Tables of Contents

11.1.4 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.

11.2 Annotations

NEW Transfer annotations (Ref. 265678)

11.3 Comparison

NEW Comparison of datasets (Ref. 657128)

11.4 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)

11.5 ECHA Cloud Services

NEW Support export to Cloud Drive (Ref. 675400)

11.6 Export

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

11.7 Import

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

11.8 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 FailedLoginAttemps (Ref. 697533)

11.9 Report generator

11.9.1 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)

11.9.2 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.

11.9.3 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)

11.9.4 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

11.9.5 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.

11.10 Validation assistant

11.10.1 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).

11.10.2 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.

11.10.3 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.

11.10.4 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 tickbox 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)

11.10.5 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.

11.11 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)

12 VERSION 6.27.7 (PUBLIC RELEASE 28 FEBRUARY 2023)

12.1 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)

13 VERSION 6.27.6 (INTERNAL AND CLOUD RELEASE 28 FEBRUARY 2023)

13.1 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)

14 VERSION 6.27.4 AND 6.27.5 (PUBLIC RELEASE 6 FEBRUARY 2023)

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

14.1 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)

14.2 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

14.3 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)

14.4 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)

14.5 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) (*)

15 VERSION 6.6.27.2 (10 NOVEMBER 2022)

See also the news alert for this release: IUCLID news - ECHA (europa.eu)

15.1 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)

16 VERSION 6.6.27.1 (31 OCTOBER 2022)

See also the news alert for this release: IUCLID news - ECHA (europa.eu)

16.1 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)

16.2 Printing

Known issue:

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

16.3 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

16.4 Validation assistant

16.4.1 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.

16.4.2 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) e.g., new OHTs.

16.4.3 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.

16.4.4 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

16.5 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)

17 VERSION 6.6.24.0 (12 SEPTEMBER 2022, INTERNAL RELEASE)

17.1 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)

17.2 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)

17.3 Plant protection products

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

17.4 Printing / reporting

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

17.5 User management

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

17.6 Web interface

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

17.7 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)

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

18.1 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)

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

19.1 Web interface

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

20 VERSION 6.6.19.0 (4 JULY 2022, PUBLIC RELEASE)

20.1 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)

20.2 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)

20.3 Export

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

20.4 Filtering

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

20.5 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)

20.6 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)

20.7 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)

20.8 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)

20.9 Search

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

20.10 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)

20.11 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)

20.12 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)

21 VERSION 6.6.14.3 (26 APRIL 2022, PUBLIC RELEASE)

21.1 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)

21.2 Dossier creation

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

21.3 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)

21.4 Import

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

21.5 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)

21.6 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).

21.7 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)

21.8 Server version management

NEW Support for Single Sign On – SSO

NEW Support for PostgreSQL databases

21.9 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)

21.10 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)