IUCLID 6

Release notes

Archives

02/02/2024



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1 INTRODUCTION

These release notes are relevant to older versions of IUCLID. The latest release notes are available <u>here</u>.

Please also refer to the <u>Frequently Asked Questions</u> on the IUCLID 6 website 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 version 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).



2 VERSION 6.6.11.0 (7 MARCH 2022, INTERNAL RELEASE)

2.1 Data entry / representation

FIX The help text icon and content is now displayed for all field types (Ref. 652706)

FIX When deleting a record, the navigation tree does not collapse anymore (Ref. 653048)

FIX In case of hidden fields, extra empty lines had to be removed (Ref. 655165)

FIX Flags were not correctly displayed in sliding windows (Ref. 655191)

FIX PCN - Hazard pictogram icons should not be clickable in dossier (Ref. 655795)

FIX PCN - Hazard pictogram icons are not displayed for all sub-Table of Contents (Ref. 655802)

FIX "Unsaved Changes" warning popup message caching issue (Ref. 658982)

FIX The default name given to a created document should be unique (Ref. 659284)

IMP Inherited templates: improvement when removing a template from a dataset and when references to the template exist (Ref. 659230)

2.2 Dossier comparison

IMP The dossier comparison has been extended in case the dossiers to compare are not created based on the same dataset UUID. If the unique identifiers of the documents to compare are different, the comparison is done following the order of the documents of the same type in the dossiers. (Ref. 648502)

2.3 Fee calculator

FIX New hazard categories taken into account for the REACH fee calculations (Ref. 264152)

2.4 Filtering

IMP Update of the filtering configuration for EU Pesticides dossiers (Ref. 657768)IMP Update of the filter rule STUDY_REF_PPP (Ref. 657770)IMP Update of the filter rule STUDY_REF_AUTH_PPP (Ref. 657771)

2.5 Reporting

FIX Report fails if table headers span more than one column within a table (Ref. 653044)

IMP Improvement of the performance for generating the CSR report (Ref. 654205)

IMP Support for retrieving language specific fields data (Ref. 658957)

FIX Language-specific fields are now retrieved from datasets (Ref. 659309)

FIX The SCIP IUCLID reports display incorrectly the concentration range (Ref. 659425)

IUCLID6

2.6 Search

NEW Search by document UUID is now supported from the dashboard (Ref. 653054)

2.7 Updater

FIX Erroneous log entries generated during an update are removed (Ref. 265224)

FIX Desktop version, the menu to launch the web interface was not displayed after an update in certain cases (Ref. 265939)

FIX Handling of HTTP listener port for authentication in Linux by Updater tool v6.2.0 should be improved (Ref. 651533)

IMP Some cases of corrupted data reported to the Helpdesk are fixed with the updater (Ref. 658440)

2.8 Validation

NEW Server-side validation of rich-text field content (HTML text). When saving HTML texts to the IUCLID server, IUCLID will check the content against a positive list of accepted HTML tags and attributes. The implementation is based on JSOUP and the starting point for the whitelist can be found <u>here</u>. Investigations are ongoing to implement this validation during import in the future. (Ref. 265005)

NEW The uniqueness of identifiers used for repeatable elements in a document is now enforced during import (Ref. 655260)

FIX MD5 checksum check should not be case sensitive (Ref. 659605)

2.9 Miscellaneous

IMP Printing and reporting events are now recorded in the audit.log file (Ref. 647412)

FIX Import of documents without names are not failing anymore (Ref. 652205)

FIX An erroneous mandatory field message was displayed (Ref. 652705)

NEW API to retrieve all confidentiality claims in a dossier (Ref. 655025)

IMP Obsolete warning "default import pool wasn't found for user" removed (Ref. 650338)

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3 VERSION 6.6.8.0 (7 FEBRUARY 2022 – PUBLIC RELEASE)

This service release introduces new features, improvements and fixes that are presented by category in the following sections. To have an overview of the changes since the last public release of IUCLID, in October 2021, please refer to the release notes for all intermediate releases since v6.2.0, in the sections below.

3.1 Data entry and display

NEW IUCLID forms can now display adjacent fields on the same line. The GHS and Toxicological information summary are the first records to implement this change (Ref. 646867)

FIX Navigation tree does not load when the working context is changed without saving changes to the dataset first (Ref. 647203)

FIX Text templates were not listed in the correct order for some fields (Ref. 648804)

FIX Formatting of simple text fields is now kept and displayed in read-only mode too (Ref. 651775)

FIX Sub-Table of content are now displayed correctly for metabolites in EU PPP MRL applications and for other representative products in EU PPP active substance applications (Ref. 652728)

FIX When managing a REACH registration as a member of a joint submission, in case of optout, documents should be created or selected from the opt-out record under section 14 (Ref. 653588)

IMP Several improvements to the layout of the IUCLID document view:

- Document title hover state, display of UUID and top-level flags, full width of the screen is used for the help text, new item button and header fonts updates (Ref. 653803)
- Change in the way the number of documents and the document creation icon are displayed in the navigation tree (Ref. 653814)

IMP Update of the content of the BPR Summary of Product Characteristics working context (Ref. 654967, 656692)

FIX For SCIP notification, fix for the display of parent phrases in the Article category list (Ref. 655819)

FIX EU PPP MRL application, fix to display the correct sub-table of content for substances other than the active substance (Ref. 657271)

3.2 Report generator

NEW Advanced options for the report generator for datasets. It is now possible to select which data from the dataset should be included in the generated report (Ref. 265408)

IMP Latest report templates uploaded (Ref. 655323)

3.2.1 Report-specific updates

NEW A new SPC report (for single products) is available for the Working Context: BPR Summary of product characteristics (SPC)

FIX The following reports, with a CSV output, have been fixed because some rows were breaking (e.g., there should be one line per attachment for the List of attachments):

- List of attachments
- List of literature references
- List of confidentiality claims

IMP/FIX The List of literature references report has undergone the following improvements and fixes:

- If the Source and Study sponsor are the same, only one of them is displayed, otherwise both are displayed
- The GLP is now correctly displayed
- Where the same literature references are used between different IUCLID documents, the literature references are displayed once, with all associated IUCLID documents grouped together with this literature reference.
- CSV output only: Entity type added
- CSV output only: Entity document name added

3.3 User management

NEW With Instance-Based Security activated, it is now possible to share a substance or a mixture with all related entities (e.g., linked reference substances or legal entities) in one click (Ref. 261584)

IMP With Instance-Based Security activated, a user is now able to share in any existing security group (Ref. 651566)

3.4 Validation assistant

IMP Validation assistant alignment with the Official Candidate List that has been updated on January, the 17th

FIX TCC_0303_01 issue was fixed (ref. #650166). The message display was fixed.

FIX QLT_PPP_050 (ref. # 649812). The rule was fixed to fail if not exactly one component with linked substance entity is provided in the Mixture composition.

FIX VA report: incorrect sorting of the issues related to the Template entity was fixed (ref. # 644967).

IMP QLT_PPP_010, QLT_PPP_048, QLT_PPP_049 updates to the rule logic

NEW set of EU PPP Business rules checking Mixture composition



NEW BR846 PCN notifications: Mixture composition should not refer to itself – The notification Mixture dataset cannot have itself included as Mixture-in-mixture in composition (compares Mixture composition record UUID's).

3.4.1 Known issues and future improvements:

Issue in BR_PPP_086, checking that at least one Mixture composition is provided: the rule is not failing for the EU_PPP Basic substance application working context. Workaround: the completeness of the dataset mixture composition can be checked by using e.g., EU_PPP Active substance application (product) working context; if BR_PPP_085 doesn't fail, then it indicates that for the EU_PPP Basic substance application this requirement is addressed.

3.5 Miscellaneous

NEW Public API: support for the management of multilingual text fields (Ref. 265639)

IMP The user journey displayed when entering specific parts of the application has been removed as the vast majority of users are now familiar with the web user interface (Ref. 648589)

FIX Export of search list as csv file: carriage returns are now properly handled (Ref. 652094)

IMP Export of search list as csv file: for dossiers, the inventory is now included (Ref. 652117)

IMP i6z files imported to a IUCLID instance should not contain IUCLID documents in different versions (Ref. 652730)

NEW Aggregation of IUCLID dossiers is now supported via a specific tool that connects to a IUCLID instance (Ref. 635434)

FIX When cloning a substance, the correct date is now added to the created substance name (Ref. 653808)

FIX Update to solve false positive issued by virus scanners (Ref. 654003)

FIX Migration logic updated to solve cases of corrupted data detected in some databases (Ref. 654105)

FIX Error raised during migration due to incompatible versions (Ref. 650437)

NEW ENGINES: archive check for mixed-versioned archives (Ref. 652730)

NEW ENGINES: I6Z archive check for attachment existence and size (Ref. 650901)

4 VERSION 6.6.6.0 (13 DECEMBER 2021, INTERNAL RELEASE)

4.1 Comparison

FIX Comparison report fails for some SCIP and EU PPP dossiers (Ref. 653079

4.2 Filtering

FIX In some cases, the filtered dossier was created without a creation or modification dates causing the file to fail import to a IUCLID instance (Ref. 653976)

4.3 Migration

FIX Migration from a IUCLID 5 compatible database is not working (Ref. 651933)

4.4 Report generator

FIX Document meta data could not be retrieved (Ref. 648417)

FIX Space around rich text fields is reduced and the merged cells in tables are now represented correctly (Ref. 649610)

4.5 User interface

IMP More information is displayed in links to documents (Ref. 645256)

IMP Working context selection moved on top of the navigation tree (Ref. 650523)

FIX Classification and Labelling document is not refreshed correctly when switching between documents for the Poison Centre Notification working context (Ref. 650999)

FIX Hierarchical phrase groups are not displayed for single selection picklist (Ref. 651036)

FIX Hierarchical phrase groups multiselect picklist, checkboxes overlap with arrows (Ref. 651044)

IMP Back arrow option is removed from the top IUCLID bar when a navigation breadcrumb is displayed (Ref. 651224)

FIX Classification and Labelling document used in the Poison Centre Notification working context: calculate labelling option missing for sub-table of contents (Ref. 651279)

FIX Caching issue which causes fields from different documents of the same types to be displayed incorrectly unless the browser page is refreshed (Ref. 651691)

FIX Table of contents displayed incorrectly for metabolites and other representative products (Ref. 652728)



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4.6 Validation assistant

FIX Specific section name is now displayed for substance or mixture components in the validation assistant report (Ref. 643122)

FIX in TCC_ESR_09 (Ref. 652306), the rule was fixed not to fail for the "read-across from supporting substance (structural analogue or surrogate)" Type of information

IMP in QLT_PPP_010, the rule was updated to not fail for the Literature reference earlier than 2021

NEW QLT_PPP_049 rule to check in case a confidential document is provided a (sanitised) document for publication should be provided as well under section 10 Ecotoxicological studies or Effects on non-target organisms (relevant to Microorganism and Active substance application submission types)

NEW BR_PPP_085, -086 to check if a Mixture composition is provided

NEW BR_PPP_089 to check that exactly one Active substance component is provided in the Active substance application, Microorganism and MRL dossiers

4.7 Miscellaneous

IMP Update of Oracle and PostgreSQL drivers (Ref. 265932)



5 VERSION 6.6.4.0 (15 NOVEMBER 2021, INTERNAL RELEASE)

5.1 Data entry and user interface elements

FIX Selected document or entity is not displayed anymore in a list to make reference to another document or entity to prevent linking an element to itself (Ref. 264922) **NEW** Duplicate a repeatable item (Ref. 265161)

FIX Incorrect loading of multilingual values in reference substance (Ref. 265838) **NEW** Export dossier as dataset (Ref. 646582)

IMP Improved working context selection (Ref. 646850)

IMP Improved layout of the web interface for the header information (Ref. 649709)

IMP Improved layout of the navigation tree (Ref. 649711)

FIX Data caching mechanism: incorrect references are displayed when switching between records (Ref. 650021)

FIX Problem with loading Table of Contents of specific dossiers (Ref. 650403)

5.2 Filtering

FIX Update of filtering configuration for EU Pesticides dossiers (Ref. 651330)

5.3 Validation assistant

IMP Sorting improved: the documents part of inherited templates are now displayed in context (with the other substance or mixture documents) (Ref. 644967)

5.4 Report Generator

FIX Rich-text fields containing HTML tables are missing tbody elements when converted to DocBook (Ref. 644622)

5.5 User management

IMP Improvement of the layout of the groups in user preferences (Ref. 627852)

5.6 Miscellaneous

NEW Display of technical information about the field (e.g. field path) in the web interface (Ref. 261881)

IMP Cloning requires only write access and not 'full access' anymore (Ref. 265940)

IMP Deleting a working context does not require 'full access anymore (Ref. 265961)

FIX Export is not possible with many attachments in PostgreSQL (Ref. 643596) **FIX** IUCLID API does not return the UUID of a filtered dossier (Ref. 645475)



FIX Maximum size of attachment is now read from the configuration file (Ref. 647380) **NEW** Configuration of the web interface: possibility to display a Legal Notice to users (Ref. 650367)



6 VERSION 6.6.2.0 (25 OCTOBER 2021 FOR CLOUD USERS, 27 OCTOBER 2021 FOR ALL USERS)

This service release introduces new features, improvements and fixes that are presented by category in the following sections. In order to have an overview of the changes since the last public release of IUCLID, in April 2021, please refer to the release notes for all intermediate releases since v5.15.0 in the sections below.

This version has been made available to all IUCLID users on the <u>IUCLID website</u>, on the 27th of October 2021. <u>ECHA Cloud Services</u> are updated to this version during the same week, starting from the 25th of October.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

As in every major update of IUCLID, this version also comes with an update of the format to take into account:

- the latest versions of the OECD Harmonised Templates
- the latest evolutions of the CLP regulations (latest ATPs)
- the database on substance of very high concern in articles (SCIP) and the submission to European Poison Centres
- the needs of several regulatory organisations including the European Food Safety Authority (EFSA) and the organisations managing chemicals in Australia

The format information is available on the IUCLID 6 website:

https://iuclid6.echa.europa.eu/format

This page contains all information concerning the most recent version of the IUCLID 6 format as well as the documentation of the previous format versions.

6.1 Data filtering

IMP Update of the filtering configuration for REACH dossiers (Ref. 648075)IMP Update of the filtering configuration for Pesticides dossiers (Ref. 649675)

6.2 Report generator

IMP The set of default reports have been updated to the latest IUCLID format as well as improved and expanded. The core set of 'list-reports' such as the list of literature references, now respect the Working Context from which they are generated and are structured according to the Working Context being used at the time of report generation (whether generated from a dataset or dossier). Moreover, if a report is generated from a Mixture, the respective information from the Mixture's components is extracted. An issue (Ref. 648417) affecting the metadata of IUCLID documents is due to be fixed in a future release and affects the annotation and attachment reports respectively. Below is the list of updated reports:



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Old report name	Old output(s)	New report name(s)	New Outputs	Description of change
Table of attachments for substance datasets and dossiers	RTF			A single list of attachments is now available for Substance and Mixture entities in three
EU Biocidal Products Regulation (BPR) table of attachments for mixture datasets and dossiers	RTF/CSV		RTF/PDF/ CSV	formats (Note: a temporary separation between dataset/dossier generation due to a known error, Ref 648417, affecting report generation from datasets whereby metadata attachments are not extracted)
EU Biocidal Products Regulation (BPR) table of annotations	RTF/PDF	List of Annotations	RTF/PDF/ CSV	A single list of annotations, including an annex of further information from the annotation, is now available for Substance and Mixture entities in three formats (Note: annotations on a dataset will not be generated due to a known error, Ref 648417, affecting report generation from datasets whereby annotations are not extracted)
REACH Classification and Labelling report	PDF	GHS Classification and Labelling report	RTF/PDF	Classification and Labelling information is now available for Substance and Mixture entities, and includes C&L information from a Mixture's components
Inbound references report for substances	HTML	List of Inbound References	RTF/PDF/ CSV	A single list of inbound references is now available for Substance and Mixture entities in three formats
n/a	n/a	List of Confidentiality Claims	RTF/PDF/ CSV	A single and complete list of confidentiality claims is now available for Substance and Mixture entities in three formats (Note : that the report 'EU Biocidal Products Regulation (BPR) Confidentiality Report (BPR Article 66' is still available and contains a limited set of confidentiality claims according to BPR)
Literature References report for substance and mixture/product datasets and dossiers	RTF	List of Literature references	RTF/PDF/ CSV	A single list of Literature references is now available for Substance and Mixture entities in three formats

IMP PCN dossier viewer (Ref. 647525)

The PCN web dossier viewer has fully replaced the PCN Notification report and includes the following improvements:

Group submissions

- Display all the information on Group Submissions:
 - Show if dossier is a Group submission
 - o Display several mixture compositions in Mixture composition tab
 - Extract common components from different mixture compositions and only display variations in compositions
 - All the references to mixture compositions can be clicked and take the user to the mixture composition tab and specific entry for that composition
 - o Merge pH info from several mixture compositions
 - Merge Environmental Hazards in C&L card of the Common Product Information tab. Other Classification information should be the same across products.

Technical changes

- Improved PDF output when printing HTML reports via browser tools
- CSS fixes for better display of HTML

Expanded data points included in report

- New tab for "Specific Product Information" contains a card for each product information document, including Market Placement and Ceased Market fields
- Information contained in GHS documents, for both main mixture and components, need to be displayed even if mixture/component is not classified
- Show "Other identifiers: other:", taking into account the multilingual fields when "other:" is selected. That includes the "Remarks" field.
- Add IUCLID version to the HTML report

FIX

- Handle when working context is not defined in a dataset
- PCN HTML report does not show labelling and additional information (Ref. 643446).

IMP Chemical Safety Report (Ref. 647525)

- Include new additional test material information, if existing in an Endpoint Study Record (Ref. 646857)
- CSR report generator print uses in section 2 of the CSR even when "related assessment" field is empty (Ref. 635556)

IMP Reports updated under the Pesticides' Plant Protection Products Regulation (see https://zenodo.org/record/3714967#.YWbLPLhBzD4)



FIX Substance of Very High Concern (SVHC) report (REACH Annex XV)

• Report can now be generated with the latest IUCLID format (Ref. 647108)

Technical Fixes

- FIX Using the default custom landscape stylesheet causes a report to fail (Ref. 634211)
- **FIX** User with 'Evaluator' role in EFSA Agency instance cannot open a IUCLID document from a hyperlink in a generated report (Ref. 645019)
- FIX URL hyperlinks in RTF reports are incorrect and include a local file directory prefixed to the URL string (Ref. 644995)
- FIX Uploaded custom reports do not appear in the list of reports (EFSA Agency instance) (Ref. 644619)
- **FIX** EFSA reports timeout (rich-text fields containing html tables are missing tbody elements when converted to DocBook)

Known issues and future improvements

- Document metadata is not being retrieved by report from an in-memory dossier (the issue does not affect dossier-generated output) (Ref 648417)
 - Affecting the annotations report when generating from a dataset
 - o Affecting the attachments report when generating from a dataset
- When generating a PDF report, an unbroken string overruns the table and page margins (Ref. 645011)
 - o Affects only PDF reports and unbroken strings such as UUIDs
- Text template line breaks are not persisted in the reports generated from IUCLID (RTF/PDF format) (Ref. 263144)
- Literature reference report indication of confidentiality (based on source OHT), is incorrectly saying 'yes' when there is no confidentiality claim

6.3 Validation assistant

6.3.1 Validation assistant report updates

NEW Reminder icon in VA report.NEW parent dataset indicator in the VA report.



6.3.2 Validation rules regarding REACH and EU PPP

NEW Business rule checking that the 'State/form' of a composition is specified in Downstream user report dossiers.

NEW Business rule checking if a nanoform is covered by a registration in Downstream user report dossiers.

NEW Business rule checking if sets of nanoforms are not reported in Downstream user report dossiers.

NEW set of Business rules for characterisation of nanoforms for Downstream user report dossiers.

NEW Business rule checking if non-selectable phrase was not selected in the Registration dossier header under the Spontaneous update > Justification.

NEW set of completeness check rules for sections 3.5.1-3.5.6 checking if invalid environmental release category (ERC) value is provided under the 'contributing activity / technique for the environment' block. The rules fail if an obsolete ERC value is reported.

NEW QLT rules for section 7.6.2 checking if positive results were specified in at least one of the genetic toxicity in vitro gene mutation and/or chromosomal aberration studies, then the relevant endpoints should be provided in section 7.6.2. Depending whether the positive in vitro test detects gene mutation or chromosomal aberration, the in vivo information should be appropriate to investigate gene mutation or chromosomal aberration.

NEW set of QLT rules for sections 3.5.1-3.5.6 checking if combinations of environmental release category (ERC) values are consistent under the Contributing activity / technique for the environment block(s).

NEW set of QLT rules for sections 3.5.1-3.5.6 checking if the Contributing activity / technique for workers or consumers block created within the reported use is consistent with the option selected in the Article used.

IMP QLT189 is set to Reminder, rule instructions were updated.

IMP QLT134, QLT136 checking if consistent hazard statements are provided for the Repr. and Carc. hazard categories.

NEW set of rules checking Literature reference in EU_PPP dossiers.

NEW QLT rule checking that *Other representative products* mixture must have the same Active substance as in the main mixture.

NEW Business rules for EU_PPP dossiers checking that European joint submission number is provided in UUID format for the renewal applications.

NEW Business rules for EU_PPP dossiers checking the selection under the Lead applicant field and its justification for the renewal applications.

NEW QLT rule checking that each Confidentiality flag must be justified in EU_PPP dossiers.

NEW set of rules checking if a Confidential report was provided then a Sanitised version of the report must be included as well in EU_PPP dossiers.

IMP set of EU_PPP rules checking Literature reference.

IMP in EU_PPP validation scenario matrix.



FIX QLT176 issue was fixed (ref. #639611). The rule doesn't fail for the experimental studies used as Source for the read across.

6.3.3 Validation rules regarding PCN (Poison centre notifications)

Group submissions were added as new submission type.

NEW BR580 If 'Component' is indicated to be 'SF (Standard formula)/fuel' then name of the standard formula/fuel must be provided (Standard)

NEW BR693 All 'PCN multi-component product identifiers' must be linked from 'Product' records. (Standard and Group)

NEW BR695 Same country cannot be both 'Market placement country' and 'Ceased market' in same 'Product' record (Standard and Group)

NEW BR696 At least one 'Classification and labelling (GHS)' record must be provided (Group) **NEW** BR697 In 'Mixture information' (MainMixture): Either 'Not classified' must be selected or at least one selection in 'Hazard categories and statements' must be made. (Group)

NEW BR698 At least two 'Mixture composition' records should be provided (Group) **NEW** BR699 Each 'Mixture' record should be referenced at least once in some Product

record(s) (Group) **NEW** BR850 Each 'Mixture' record should be referenced in exactly one 'pH' record (Group) **NEW** BR851 Each 'Mixture' record should be referenced in exactly one 'Toxicological information' record (Group)

NEW BR852 All provided 'Component' blocks must be complete: If concentration was provided for the component then either 'Substance' or 'Mixture (MiM)' dataset must be included (Group)

NEW BR853 Check that the concentration for each mixture is not too low 70% (Group) **NEW** BR857 MiM: cannot have more than one 'Composition' record. (Group)

NEW BR858 Units provided for concentrations must be consistent (Group)

NEW BR859 For Group submissions the difference between the compositions cannot be more than 5%. (Group)

NEW BR860 The compositions can have difference only in components that have been indicated to be 'perfumes' (Group)

NEW BR862 Either 'Typical concentration' (exact concentration) or 'Concentration range' must be provided, not both (Group)

NEW BR864 Report only components which are present in the mixture. Concentration value must be above 0% for each Substance component and Mixture component (Group)

NEW BR872 At least one 'Toxicological information' record must be provided (Group) BR873 All 'Toxicological information' record(s) must be linked to 'Mixture composition' record. (Group)

NEW BR874 At least one pH record must be provided (Group)

NEW BR875 All 'pH' record(s) must be linked to 'Mixture composition' record. (Group) **NEW** BR876 All 'Packaging' record(s) must be linked to a 'Product' record. (Standard and Group)

NEW BR877 All 'Colour and physical state' record(s) must be linked to a 'Product' record. (Standard and Group)

NEW QLT691 'Trade name' seems to be quite short or long (expected to be at least 3 and less than132 characters) (Standard and Group)

NEW QLT694 'Main intended use' is recommended to be provided in 'Product' records also for Voluntary submissions. (Standard and Group)

NEW QLT854 Check that the concentration in each mixture is not too low 70-90% (Group) **NEW** QLT869 If MiM does not have UFI then the Supplier should be from EU country (Standard)

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IMP BR558 'Each country mentioned in dossier header as 'Country (market placement)' must have at least one corresponding 'Product information' record.' Was changed due to addition of the 'Ceased markets' field to be: 'Each country mentioned as 'Country (market placement)' must be mentioned as 'Active market (country)' or 'Ceased market (country)' in at least one 'Product information' record.'

IMP BR610 'Each country indicated in the 'Product information' record must be also indicated as a market placement country in the dossier header.' Was changed due to addition of the 'Ceased markets' field to be: 'Each country indicated in the 'Product information' record as 'Active market (country)' or 'Ceased market (country)' must be also indicated as a market placement country in the dossier header.'

FIX BR538 'Toxicological information' must be over 200 characters. Rule was incorrectly passing if table was included without the required 200 characters.

Known issues and future improvements regarding validation rules for PCN

VA report: the links from validation failures to the corresponding dossier/dataset sections do not work correctly in some occasions. The behavior will be improved in a subsequent IUCLID release.

6.3.4 Validation rules regarding SCIP (Waste directive)

No changes in IUCLID validation rules.

6.3.5 Known issues and future improvements

• VA report: incorrect sorting of the issues related to the Template entity. In case of the failure in the documents which are part of the Template, all such failures are listed in the end of the VA report grouped by the section. The issue will be fixed in the next IUCLID release.



7 VERSION 6.6.0.0 – ECHA INTERNAL RELEASE (18 OCTOBER 2021)

7.1 Data entry

NEW Provide a field-level indication that a field is confidential (Ref. 642752)

IMP Create a substance from a reference substance from the document view page (Ref. 643189)

7.2 Dossiers

IMP Clarify the warning displayed when a newer version of a dossier is available (Ref. 644936)

7.3 User manual

IMP Update of the IUCLID functionalities manual (Ref. 646897)

7.4 Miscellaneous

NEW Migrator adaptations to PostgreSQL – not officially supported (Ref. 266009)



8 VERSION 6.6.0.0-ALPHA.1 – ONLY FOR TESTING (6 SEPTEMBER 2021)

This release is a test version of IUCLID were the first adaptations to the new format have been made, i.e. the IUCLID forms have been adapted to the new format. Migration to and from the new format have started to be implemented but issues are likely to be observed when importing or exporting data. Not all IUCLID features have been adapted to the new format, for example the validation assistant, the report manager or the filtering.

8.1 Data entry

IMP Create new substance and select a reference substance (Ref. 265262)

FIX Inherited template counter is not displaying the number of linked templates (Ref. 266072)

NEW Working context sub-ToC: new activation clause 'OtherRepresentativeProduct' for EU PPP dossier preparation (Ref. 644630)

8.2 Search

IMP Option to select the number of results shown in one page (Ref. 638344)

8.3 User management

IMP Login and logout events to be logged in the audit file (Ref. 634662)

IMP Audit log to track user management events (Ref. 634684)

IMP System users give the false impression that they can be updated (Ref. 634753)

FIX Cloud Legal Entity is attached to entities instead of the Working Legal Entity (Ref. 637374)



9 VERSION 6.5.22.1 – ECHA CLOUD ONLY (26 AUGUST 2021)

This service release introduces new features, improvements and fixes that are presented by category in the following sections.

This version has been made available only to the users of the <u>ECHA Cloud Services</u>. The next version of IUCLID distributed to all users will be available at the end of October 2021 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

9.1 Data entry

NEW Populate repeatable block content by uploading csv file (Ref. 636311)

NEW Image attached to image fields are rendered in the interface (Ref. 636495)

FIX "Linked Categories" section in not available for existing mixture category members (Ref. 641352)

FIX Repeatable block ordering not retained for Hazard Statements in GHS document (Ref. 639683)

FIX A user (with a role that has update permissions in substances) cannot create a new working context (Ref. 641283)

FIX The standard view instead of custom definition is displayed in the sliding window of the BPR SPC dossier (Ref. 641371)

FIX [Rich Text Field] Cursor is moving to the beginning of the text (Ref. 643007)

9.2 Dossier creation / import / export

IMP Reduced category content for members of a category is now also applied to the content of inherited template (Ref. 637169)

FIX Attached Document is not included in the Export of a Literature reference (Ref. 639495)

FIX Import: Open button is not displayed beside the dataset/dossier in Chrome version 79 (Ref. 642470)

FIX The user is not able to validate/create dossier with working context EU PPP Basic substance application / EU PPP Active substance application (Ref. 643108)

9.3 Filtering

IMP Update of the filtering configuration for Pesticides dossiers (Ref. 641219)

9.4 Report manager

IMP Update of report templates for EFSA reports and PCN HTML report (Ref. 640918)



9.5 Search

NEW Export search results as csv file (Ref. 630549)

NEW Select all elements in the search results page (Ref. 636474)

NEW Substance, Mixture (including their dossiers) and Reference substance - Advanced search by 'other identifier' (Ref. 636480)

9.6 User management

IMP User management is disabled when synchronization is established with 3rd party system (Ref. 421967)

9.7 Validation assistant

FIX Sorting of failures fixed for section 6 (Ref. 262873)

IMP Sorting of the validation assistant messages organized by datasets (Ref. 266105)

FIX Sorting of failures for the same document fixed (Ref. 266116)

IMP Update of the Candidate list of substances (Ref. 640111)

FIX QLT146 and QLT146 warning: incorrect rule functionality was fixed (Ref. 635263)

Known issues and future improvements:

• QLT176 gives warning incorrectly for the studies which are used as the Source study in case of read-across. The inconsistency will be fixed in the future IUCLID releases.

9.8 Miscellaneous

IMP Fee calculation on SDS claims for nanomaterials (Ref. 626182)

FIX Print of fields marked 'confidential' does not work in a dataset (Ref. 638475)

FIX Export of IUCLID files >2GB fails in Derby database and >4GB in Oracle database (Ref. 642883)



10 VERSION 6.5.20.0 – NOT RELEASED TO ALL USERS (25 JUNE 2021)

This service release introduces new features, improvements and fixes that are presented by category in the following sections.

This version has been made available only to specific user groups. The next version of IUCLID distributed to all users will be available at the end of October 2021 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

10.1 Data entry

IMP Increase of the width of the rich text field. In addition, fixes to the formatting in view mode – table borders and bullet points (Ref. 265476)

IMP Mixtures linked to a category are now displayed in the navigation tree (Ref. 265876)

IMP One-line field used for shorter text fields (Ref. 266117)

IMP Navigation tree view advanced customisations: show/hide referenced documents for specific Table of Contents (Ref. 362057)

IMP Order of references in the navigation tree to follow the order of references in the document (Ref. 630849)

FIX Hide empty fields feature hides some fields with data (Ref. 636296)

IMP Improve display of tabular repeatable blocks: do not display label of check-boxes (Ref. 636496)

FIX The "Save" button remains disabled in rich text fields if you do not move the mouse cursor (Ref. 640865)

10.2 Import

IMP Incorrect versions and legislations in the manifest file are not caught by an error (Ref. 266110)

IMP Engines: additional archive checks at the level of the manifest file (Ref. 634434)

NEW Open annotations after import (Ref. 265277)

FIX Engines: I6ZManifestParser should tell the truth about whether an archive is 'partial' (Ref. 638647)

FIX Import fails without error when the manifest.xml contains empty elements (Ref. 640859)

10.3 Performance

IMP Optimise queries linked to working contexts (Ref. 638299)



IMP Optimise the navigation tree client code while navigating from one tree node to another (Ref. 638303)

IMP Web UI should cache certain data when switching between tree node-views (Ref. 638302)

10.4 Reporting

IMP Freemarker updated to version 2.3.31 (Ref. 264842)

FIX Create RTF: alignment of some fields is not correct (Ref. 636372)

FIX Hyperlinks in reports are not functioning (Ref. 636883)

10.5 User management

FIX Last login date updated via the web interface (Ref. 531485)
FIX Password policy applied to user management (Ref. 634683)
FIX IUCLID customised ports to be taken into account during login (Ref. 636603)
IMP Clarified message for changed password (Ref. 264801)

10.6 Validation assistant

FIX Quality warnings duplicated (Ref. 635263) **IMP** Report sorting improvements (multiple datasets case) (Ref. 266105)

10.7 Miscellaneous

IMP Updated version of the user manual (Ref. 264161)

IMP Help menu link for videotutorials now points to the IUCLID YouTube channel (Ref. 635472)

FIX Scroll bar does not appear in Safari (Ref. 635873)

FIX RewriteFilter Exception on glassfish startup (Ref. 638440)

11 VERSION 6.5.17.2 – ECHA CLOUD ONLY (31 MAY 2021)

This service release introduces new features, improvements and fixes that are presented by category in the following sections.

This version has been made available only to the users of the <u>ECHA Cloud Services</u>. The next version of IUCLID distributed to all users will be available at the end of October 2021 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

11.1 Dossier creation, import, export

NEW Add Limited category content field option in Dossier creation and Export (Ref. 263218)

IMP Article - customised options when exporting dataset / creating dossier to not display non applicable options (Ref. 264960)

FIX Importing SCIP dossier of v6.4 into IUCLID v6.5 results in invalid dossier - selectable phrase became non-selectable (Ref. 635164)

FIX Dossier creation: Documents / entities that have selected AU: AICIS flag in the "regulatory programmes" are not included in the dossier (Ref. 635503)

FIX Import Fails when a category member is a mixture (Ref. 637267)

11.2 i6z files

IMP Keep distinct links in manifest.xml (Ref. 264021)

11.3 Print

NEW Create full PDF for dataset (Ref. 265477)

NEW Create full PDF for dossier (Ref. 265884)

FIX PDF advanced options (flag select) does not work when creating a PDF component (Ref. 574855, 634204)

NEW Support 'Create RTF' operation as an alternative for 'Create PDF' (Ref. 615787)

IMP Full PDF for dossier: Show all references (Ref. 635499)

IMP Add Limited category content field option in Create PDF (Ref. 636695)

11.4 Report manager

IMP Update of the layout of reports to be selecting when using the report generator (Ref. 334939)

IMP New version of the PCN HTML report (Ref. 633141)

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IMP Report generation for datasets: build an in-memory dossier for editable datasets before executing report generation (Ref. 633676)

11.5 User interface

IMP Attachments: display the ones included in the document itself and attachments linked to the document in the paperclip (Ref. 261384)

IMP Support editing the name of a section document in sliding window (Ref. 264900)

IMP Activate the filter search when a user wants to make a document cross reference (Ref. 265681)

IMP Inform the user on the inbound references when preventing document deletion (Ref. 265692)

FIX [Multi-Picklist] - Drop down list is displayed in the wrong position (Ref. 458660)

NEW Support "other names" and "other identifiers" in the Advanced Search for Articles (Ref. 615741)

FIX Loading time of inbound references (Ref. 633290)

IMP Add help text on Submission type label (PCN dossier header) (Ref. 634033)

IMP Add help text on Standard formulas page (PCN) (Ref. 634035)

FIX Obsolete values are shown in hierarchical phrase groups (Ref. 637158)

FIX An exception message appears when the user tries to access the Classic interface (Ref. 637445)

11.6 User management

IMP Improve message when the assigned username exists (Ref. 627828)

IMP Predefined roles must not be deleted or modified (Ref. 634891)

IMP Change label 'User preferences' to 'Default group access' in web-UI (Ref. 634969)

11.7 Validation assistant

IMP Provide a different icon for reminders and warnings (Ref. 265955)

IMP Indication of a Mixture and Substance dataset name (components) in validation report (Ref. 266118)

IMP Show draft dossier header each time user validates their dataset (Ref. 625419)



12 VERSION 6.5.15.0 (26 APRIL FOR CLOUD USERS AND 28 APRIL 2021 FOR ALL USERS)

This service release introduces new features, improvements and fixes that are presented by category in the following sections. In order to have an overview of the changes since the last public release of IUCLID, in December 2020, please refer to the release notes for the following IUCLID versions: 6.5.15.0 (this section), 6.5.12, 6.5.10, 6.5.9, 6.5.8, and 6.5.7.

This version has been made available to all IUCLID users on the <u>IUCLID website</u>, on the 28th of April 2020. <u>ECHA Cloud Services</u> are updated to this version during the same week.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

12.1 Data entry

IMP When listing documents to link to, the list now displays the generic document identifier in addition to the document name. After a document is selected, its representation has been updated to show the document icon, the generic document identifier, the document name and a summary of the key information included in the document itself (Ref. 264261)

FIX Simple text areas are now resized automatically (Ref. 265234)

FIX Documents copied from dossiers containing a reference are now handled correctly. The reference is kept only if the entity or the document is available to the dataset. Otherwise the reference is removed from the copied document (Ref. 266044)

IMP 'Other' fields in open picklists can now be entered in different languages when multilingual data entry is supported, for example for Poison Centres Notifications (Ref. 266092)

FIX For datasets, when clicking on an already displayed document, its content is not hidden anymore (Ref. 266104)

FIX The calculate button of the Classification and Labelling document for Poison Centre Notifications is now displayed consistently (Ref. 266138)

FIX The save button is now displayed at the bottom of the page (Ref. 280336)

IMP The guided dossier approach is now decommissioned as fully replaced by the standard dataset management (Ref. 246924)

IMP The metabolites document is added to MRL dossiers under EU PPP (Ref. 631421)

12.2 Dissemination preview (filtering)

NEW There is now an option to create a filtered dossier stored in the database (Ref. 263506)

IMP Fields of a dossier header can now be filtered via configuration (Ref. 265381)

IMP The filtering rule STUDY_REF_PPP is updated to include missing documents (Ref. 633638)

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12.3 Help system

IMP Update of the IUCLID functionalities manual (Ref. 633344)

12.4 Import / export / dossier creation

NEW The Remarks information inserted by the user when exporting a file is now visible when you import it using the advanced options. In addition, the last modification date of the entities contained in the file is displayed (Ref. 263620)

IMP For Cloud users only, the option 'Submit online' is displayed after the creation of a SCIP dossier (Ref. 264647)

IMP Several improvements done in order to fail the import of incorrectly formatted i6z file (Ref. 265499, 265357, 266047, 266185, 631166)

IMP The legal entity is now included by default for EU Plant Protection Products dossiers (Ref. 266151)

NEW Remarks can be added when exporting a IUCLID file (Ref. 629324)

FIX The correct Active substance Table of Content is now displayed for microorganisms, for EU BPR dossiers (Ref. 634331)



12.5 Report generator

IMP The full hierarchy of a phrase for a hierarchical phrase group can be retrieved by the report engine (Ref. 266054)

NEW The list of reports for Mixture entities has increased with this release:

EU Plant Protection Products

To support processing active substance dossiers under the EU Plant Protection Products regulation, a set of initial reports have been included as default built-in reports in IUCLID. These will continue to be updated and added to. For this release, the new reports are included in the table below:

Name of report	Output	Working contexts' report can be generated from
Documents M (Active Substance) - Section 2 (PhysChem)	RTF/PDF	EU PPP Active substance information EU PPP Microorganisms - active substance information EU PPP MRL application - active substance information EU PPP Active substance application (product) EU PPP Microorganisms - active substance application (product) EU PPP MRL application
Documents M (Product) - Section 2 (PhysChem)	RTF/PDF	EU PPP Active substance application (product) EU PPP Microorganisms - active substance application (product) EU PPP MRL application
Documents M (Active Substance) - Section 5 (Tox)	RTF/PDF	EU PPP Active substance information EU PPP Microorganisms - active substance information EU PPP MRL application - active substance information EU PPP Active substance application (product) EU PPP Microorganisms - active substance application (product) EU PPP MRL application
Documents M (Product) - Section 7 (Tox)	RTF/PDF	EU PPP Active substance application (product) EU PPP Microorganisms - active substance application (product) EU PPP MRL application
Documents D (GAP)	RTF/PDF	EU PPP Active substance application (product) EU PPP Microorganisms - active substance application (product) EU PPP MRL application
Documents D (GAP)	CSV	EU PPP Active substance application (product) EU PPP Microorganisms - active substance application (product) EU PPP MRL application
NoS Extraction Request	RTF/PDF	EU PPP Active substance application (product) EU PPP Microorganisms - active substance application (product) EU PPP MRL application
NoS Extraction Request	CSV	EU PPP Active substance application (product) EU PPP Microorganisms - active substance application (product) EU PPP MRL application

EU Classification and Labelling - Article 45

Another additional report has been added to support Poison Centre Notification (PCN) users. The new report is name 'PCN Dossier Viewer' and will be available under the PCN working contexts. The output of the report is a HTML report that opens in the computer's default web browser.

FIX Several issues have been fixed with the Chemical Safety Report:

- The EC/CAS identifiers are added to the cover of the report
- The EC number is added to the table of constituents (section 1.2)
- The reference substance as part of the information on transformation products in biodegradation in soil (table: Simulation tests for biodegradation in soil), is now displayed and if entered, does not cause the report to fail

Known issues:

SCIP Notification report (both non-sensitive and sensitive). The field value for 'Production in European Union' in the main article is repeated in all linked complex objects. This is fixed and is available on the IUCLID website <u>Report generator - IUCLID (europa.eu)</u> and will be available in the next IUCLID releases for Cloud and for the general public.

12.6 Report manager

Users can now use the IUCLID Report manager to manage and upload custom reports for generation from Substances, Mixtures and Articles. The custom reports will appear after the list of default in-built reports.

NEW Create a custom report (Ref. 266096)

NEW View/edit a custom report (Ref. 266097)

NEW Inventory of custom reports (Ref. 265435)

NEW Select custom report for generating report (Ref. 266101)

FIX When uploading empty Freemarker templates (FTLs) into the Report Manager, a warning is displayed, as no empty FTLs are permitted (Ref. 628507)

FIX Some HTML reports could not be uploaded into the Report Manager, but these can now be uploaded successfully (Ref. 266184)

12.7 User management

IMP The user icon is always displayed, giving the user the possibility to access user preferences including the possibility to select a different working legal entity (Ref. 266075)

NEW Role management (Ref. 266157)

NEW Group management when Instance-Based Security is enabled (Ref. 266158)

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12.8 Validation assistant

12.8.1 Validation rules related to REACH, CLP (except PCN) and PPP

FIX issues impacting TCC_0603_A01, TCC_ESR_A26 were fixed (Ref. 615944).

FIX QLT159 and QLT115 warning: incorrect rule functionality was fixed (Ref. 266023, 266079).

FIX issue with dataset validation when changes made in GHS document were not saved was fixed (Ref. 628222).

FIX issues with the message display and rule functionality in the EU_PPP rules checking substance identity information such as presence of IUPAC, EC or CAS number (e.g. QLT_PPP_028, -029, -022, -023) were fixed (Ref. 266186, 266187, 266180, 628356).

FIX issue with the message display in QLT_PPP_017 was fixed (Ref. 278135).

FIX issue with QLT_PPP_012 checking set of mandatory documents for EU PPP Microorganisms - active substance application (product) working context was fixed (Ref. 278174).

NEW and **IMP** set of Business rules for Application for authorisation (done as group applications) checking category member substances.

NEW Business rule for *CLP Notification*: Legal entity confidentiality claim must be justified in the dossier header under the 'Notifier's name: justification category' field.

NEW Business rule in GHS document, ensuring that the hazard classes Mutagenicity, Carcinogenicity and Reproductive toxicity are distinguished between Category 1A, Category 1B or Category 2 (per REACH and CLP regulations).

NEW Business rule for CLP Alternative name request, 'Only representative' role in the supply chain is not allowed.

NEW set of quality rules checking inconsistency between Endpoint and data waiving justification.

NEW warning in case SMILES notation entry is invalid.

NEW warning in case of inconsistent read-across from supporting substance (structural analogue or surrogate); when read-across with different species is identified (7.8.2: *Developmental toxicity / teratogenicity*).

NEW QLT176 warning if the test material identifiers do not match any substance identifier in 1.1 Identification, 1.2 Composition.

NEW quality warning when less than 5 strains have been used (7.6.1: Genetic toxicity in vitro (in vitro gene mutation in bacteria)).

Known issues and future improvements:

- QLT145 and QLT146 give duplicate errors when failing. When rules pass, no duplicate errors are shown. The message display issues will be corrected in future IUCLID releases (Ref. 635263).
- New QLT176 gives warning incorrectly for the studies which are used as the Source study in case of read-across. The inconsistency will be fixed in a future IUCLID

release.

12.8.2 Validation rules related to Poison center notifications (PCN)

NEW BR650-BR679 Rules regarding 'Language' requirements based on 'Market placement country' added

NEW BR639 only one tick box (SF/ICG/GCI) can be ticked per one component

NEW BR640 Interchangeable component group (ICG) should be reported as MiM, not as Substance

NEW BR683 Interchangeable component group (ICG) MiMs should have compositional information reported

NEW BR681 Standard formula (SF) component MiMs should have compositional information reported

NEW BR682 'Fuels' can be reported only in MainMixture, not as MiMs

DELETED BR604 GCI type 'Perfume' can only be used once.

DELETED BR617 GCI type 'Colourant' can only be used once.

DELETED BR547 'Physical state' must be same in all 'Colour and physical state' records.

IMP QLT621 to BR621 "If 'pH not available' was indicated, then justification must be provided": rule changed from **warning** to **failure**

IMP BR630 to BR684 'MiM can have only one 'Composition' record. If more than one rule fails.': only rule number changed

Known issues and future improvements:

- There are no rules to check that components which are indicated to be 'Standard formula (SF) components are according to the concentration limits set by the legislation. Also, there is no rules to check that the 'Standard formula name' is indicated. Issues will be fixed when after IUCLID format allows to indicate the 'Standard formula name' also in the 'Component' level.
- BR681 Does not fail if no 'Composition' record is created (Ref. 634808)
- BR602 Should check that the total concentration of GCI 'colourant' components do not exceed 25%. Now it only checks that individual GCI 'colourant' component do not exceed 25%. (Ref. 634954)

12.8.3 Validation rules related to SCIP notifications

No changes to SCIP Validation rules in IUCLID



NEW Update of the way to access the Classic interface. More information is available at <u>https://iuclid6.echa.europa.eu/web/iuclid/learn-to-use-the-new-interface</u> (Ref. 634673)

13 VERSION 6.5.12.0 – UNRELEASED (12 MARCH 2021)

This specific version of IUCLID is not released publicly. The next version of IUCLID distributed to all users will be available at the end of April 2021 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

13.1 Data entry

FIX The entry 'Aerosol 1-H222: Extremely flammable aerosol, H229: Pressurised container: May burst if heated' selected for Poison Centres Notifications is not saved correctly (Ref. 265577)

NEW Generate UUID option added to EU Pesticides dossier headers (Ref. 266163)

IMP Representation of linked entities are now using the full length of the screen (Ref. 266174)

NEW Display confidentiality claim justification in CLP notification dossier header (Ref. 278097)

FIX Toxicity to terrestrial arthropods - ESR: request to reactivate obsolete phrase numbers 61067, 61068, 61069 (Ref. 615944)

FIX Changes made in GHS document are not saved when made from the validation assistant report (Ref. 628222)

FIX Create dossier is not possible for mixture with working context BPR Biocidal product authorisation or BPR Biocidal product authorization (representative product) (Ref. 629757)

13.2 Filtering (dissemination preview)

IMP Update of the filtering configuration for EU PPP dossiers (Ref. 615982) **NEW** New filter rule: STUDY_REF_AUTH_PPP (Ref. 628469)

13.3 Report generator

NEW Create a custom report (Ref. 266096)

NEW View and edit a custom report (Ref. 266097)

FIX Cannot upload an HTML report (Ref. 266184)

IMP Upload latest reports into IUCLID (Ref. 629065)

13.4User management

NEW Display inventory of groups when Instance Based Security is enabled (Ref. 266155)

NEW Delete role (Ref. 627837)

NEW View a role (Ref. 629440)



14 VERSION 6.5.10.0 – UNRELEASED (1 MARCH 2021)

This specific version of IUCLID is not released publicly. The next version of IUCLID distributed to all users will be available at the end of April 2021 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

14.1 Data entry

NEW Dynamic content rules added to relevant dossier headers for pesticides to identify mandatory fields (Ref. 280257)

NEW For Poison Centres Notifications, notes can be added in the classification and labelling section (Ref. 616893)

14.2 Filtering

NEW Extension of the filtering configuration to additional Pesticides dossier types (Ref. 613379)

14.3 User management

NEW Use token-based authentication for the web interface (Ref. 266040)

NEW List of roles (Ref. 266154)

NEW Assign role to user (Ref. 627829)

14.4 Validation assistant

FIX Bug fixes and small improvements to Pesticides rules

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15 VERSION 6.5.9.0 – UNRELEASED (15 FEBRUARY 2021)

This specific version of IUCLID is not released publicly. The next version of IUCLID distributed to all users will be available at the end of April 2021 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

15.1 User management

NEW Create a user (Ref. 266156)

NEW View / edit a user (Ref. 266159)

15.2 Validation assistant

NEW Integration of the validation rules specified in the IUCLID Template Manager (Ref. 265214)

FIX Bug fixes and small improvements to the Pesticides and Poison Centres rules

FIX The wrong title appears when editing a record from the validation report (Ref. 286708)



16 VERSION 6.5.8.0 – UNRELEASED (1 FEBRUARY 2021)

This specific version of IUCLID is not released publicly. The next version of IUCLID distributed to all users will be available at the end of April 2021 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

16.1 Data edition

IMP Improved flow for entering 'other:' and 'remarks' fields for multi-select picklists (Ref. 264314, 265163)

FIX Help text not available for some fields (Ref. 266122)

IMP EU PPP Basic substance is not available anymore for substance datasets after the simplification of this dossier type (Ref. 278107)

16.2 Filtering

NEW New filtering rule for literature references in pesticides dossiers (Ref. 266165)

IMP Extension of the Test Material rule for pesticides dossiers (Ref. 280358)

IMP Update of filtering configuration for Pesticides dossiers (Ref. 338441)

16.3 Report generator

IMP The report generator, and the Freemarker templates, can now access the information provided by the selected Working Context (Table of Contents for the main entity and for linked entities) (Ref. 264843)

IMP Reporting engine can now recursively iterate through all the fields of a IUCLID document (Ref. 264844)

NEW Listing the inventory of custom reports (Ref. 265435)

NEW Custom reports can now be selected for generating a report (Ref. 266101)

16.4 User management

NEW Listing of the inventory of users (Ref. 266153)



17 VERSION 6.5.7.0 – ECHA CLOUD ONLY (1 FEBRUARY 2021)

This service release introduces new features, improvements and fixes that are presented by category in the following sections.

This version has been made available only to the users of the <u>ECHA Cloud Services</u>. The next version of IUCLID distributed to all users will be available at the end of April 2021 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

17.1 Data edition

NEW Move up or down a repeatable record in a list of repeatable sets or in a table (Ref. 260571)

FIX Document default naming has inconsistent numbering (Ref. 264731)

FIX It is now possible to edit inherited template data in context with the relevant warning displayed (Ref. 265041)

FIX Annotations are missing from the new document view (datasets) and the new simple entity view (Ref. 265371)

IMP Opening an item of Substance, Mixture and Template should land directly to the navigation tree-based view (Ref. 265727)

FIX "Sponsor document" is not displayed correctly in Navigation Tree View (Ref. 266112)

17.2 Dossiers

IMP The mixture icon should be displayed when navigating from a dossier to a mixture dataset (source) (Ref. 262604)

NEW Light dossier export and import support for EU Plant Protection Products dossier updates. Unchanged attachments are not included in the dossier update if this option is selected, in order to reduce the size of the export file (Ref. 265474, 265475)

IMP Simplification of the Basic substance dossier for EU Plant Protection Products (Ref. 266088)

17.3 Navigation

NEW As a user, I want to be able to open in a new tab my lists of entities and documents (Ref. 263031)



17.4 Report generator

FIX PCN Preview Report with no content (Ref. 265740)

FIX Occasional PDF report creation failure (StackOverflowError) (Ref. 266095)

17.5 Validation assistant

IMP Apply advanced options to validation assistant (from datasets) (Ref. 262985)

FIX QLT159 warning: incorrect rule functionality was fixed (Ref. IUCVI-16975)

NEW validation scenarios for EU PPP Basic substance application submission type

NEW set of rules ensuring that minimum data on *substance identity* is present in the EU_PPP dossiers/datasets, such as in *Mixture composition(s)* and *Active substance composition(s)*

NEW rules ensuring that *European reference number* is provided for four EU_PPP submission types supported by Validation assistant (EU PPP Active substance application (product), EU PPP Microorganisms - active substance application (product), EU PPP MRL application, EU PPP Basic substance application)

Known issues and future improvements

- Issues with the message display and rule functionality for a number of EU_PPP rules. Rules checking substance identity information such as presence of IUPAC, EC or CAS number (e.g. QLT_PPP_028, -029) are not correctly triggered. Rules functionality and message display issues will be corrected in future releases.
- Issues with TCC_0603_A01, TCC_ESR_A26 related to the extended endpoint selection. The issues will be fixed in the IUCLID 6.5 April release. Contact ECHA for support.

17.6 Miscellaneous

FIX Import job should fail in case of missing manifest.xml (Ref. 265682)

IMP Import and file validation: do not allow unselectable phrases (Ref. 266090)



18 VERSION 6.5.4.1 (16 DECEMBER 2020)

The web user interface has been improved so that the gap with the classic interface is limited to specific use cases such as user and role configuration or the management of reports. In order to progress with the decommissioning of the classic interface, which is scheduled for the coming months, the default interface in this release is now the web interface and all Improvements, Fixes or new Features, are related to the web interface, unless stated otherwise.

In case the access to the classic interface is still needed, more information can be found on the IUCLID website: <u>https://iuclid6.echa.europa.eu/web/iuclid/learn-to-use-the-new-interface</u>

Note on the versioning: IUCLID 6 version 5.4.1 is the latest official IUCLID 6 release since version 5.1.2 published in October 2020. The versioning of the official releases available on the IUCLID 6 website is not consecutive as other intermediate versions of the application can be made available to specific users or groups of users, for example to:

- answer some specific bugs experienced by users,
- provide new features relevant to a specific users group, for example to the <u>ECHA</u> <u>Cloud Services</u> users.

Fixes and improvements included in this version

IMP Dynamic Content Rule update for Poison Centres information: "Product not packaged" and "Link to packaging information" are not mutually exclusive anymore

Ref. IUCVI-17047

FIX Server installation with Oracle database: Issue during update: ValidationFailedException Ref. IUCVI-17020

FIX Instance fails to start due to SecurityProvider unavailability

Ref. IUCVI-16964



19 VERSION 6.5.4.0 (3 DECEMBER 2020)

This specific version was not publicly released on the IUCLID website.

Note on the versioning: the versioning of the official releases available on the IUCLID 6 website is not consecutive as other intermediate versions of the application can be made available to specific users or groups of users, for example to:

- answer some specific bugs experienced by users,
- provide new features relevant to a specific users group, for example to the <u>ECHA</u> <u>Cloud Services</u> users.

19.1 Create PDF

FIX PDF is not created when a "Site" is linked to a "Site" document of a dataset Ref. IUCVI-16737

19.2 Dataset / dossier content

FIX The user is not able to see the "Linked Categories" in a substance/dossier

Ref. IUCVI-16982

FIX The user is not able to view FLEXIBLE_SUMMARY.ProductSummaryComposition via classic interface

Ref. IUCVI-16977

FIX Scroll to top button is not available at substance view

Ref. IUCVI-16952

FIX New documents created have the section name instead of the document name

Ref. IUCVI-16703

IMP Support operations of dataset view in the navigation-tree based view

Ref. IUCVI-16503

FIX Users cannot copy in bulk unless they have full access rights (affects web interface only) Ref. IUCVI-16481

19.2.1 BPR dossiers

IMP Update SPC XML to IUCLID Import module to support in-situ substances

Ref. IUCVI-16909

FIX The IUCLID web interface crashes when loading certain BPR dossiers

Ref. IUCVI-16874

19.2.2 New Zealand data

FIX Import fails if the dataset has [HSNO] documents Ref. IUCVI-16901

19.2.3 REACH dossiers

FIX Classic interface: opt-out concept is not enforced if the user does not use the advanced dossier creation settings

Ref. IUCVI-16965

FIX ENDPOINT_SUMMARY.Carcinogenicity cannot be included in R_JS_MBER dossiers using the web interface

Ref. IUCVI-16942

FIX Create dossier button is enabled while errors exist in dossier header document Ref. IUCVI-16914

19.2.4 Dossier comparison

FIX Dossier comparison report cannot be displayed (for specific dossiers)

Ref. IUCVI-16949

IMP Compare dossiers should include only dossiers of the same entity

Ref. IUCVI-16814

19.3 Filtering (dissemination preview)

FIX Unexpected behaviour filtering PPP test data with Annotations Ref. IUCVI-16721

19.4 Search

FIX Search by UUID in Classic interface throws SQLSyntaxErrorException: ORA-01795 Ref. IUCVI-16891

19.5 Templates (inherited)

IMP Apply new navigation tree to inherited templates Ref. IUCVI-16559



19.6 Reporting

FIX PCN Preview report failure when a Mixture component added without any entity references Ref. IUCVI-16876

19.7 Validation assistant

IMP the completeness check rule (TCC_0102_23) checking the state/form selection of a boundary composition was deactivated.

NEW the business and technical completeness check rules ensuring that no documents in sections 2.1 and/or 4-7 present in the member dossier without being opted-out.

NEW report improvement (open in a new tab)

Ref. IUCVI-15720

NEW Advanced options for Validation Assistant (for datasets)

Ref. IUCVI-16299

IMP report: display scenario description fully

Ref. IUCVI-16473

FIX issue with QLT115 when incorrect warning is triggered in case no GHS record being present in section 2.1 was fixed

Ref. IUCVI-16919

Known issues and future improvements:

- The ordering of the failures or warnings reported in the web interface of IUCLID is different from the ordering of the issues in the classic user interface. This will be corrected in future releases.
- Issues with the message display for several EU_PPP rules, such as section number is incorrectly displayed for the issues related to Active substance incomplete minimum requirements for the submission. The section number in the message itself and not in the message header should be considered. The number in the header refers to the mixture section number and not to the linked active substance, therefore incorrect (i). The link to an incomplete document and section is missing and only incomplete entity name is displayed in the VA report for the rule checking Literature reference entries (EU_PPP_010) (ii). The message display issues will be corrected in future releases.
- Issue in QLT159 warning which is triggered when the endpoint study record in section 7.4.1 indicated as a key study or weight of evidence addressing the endpoint skin sensitisation in vivo (non-LLNA). It is expected that under the 'Results and discussion 'heading, under 'In vivo (non-LLNA)' results for each of the following are reported: negative control group, test chemical group and



positive control group. The rule is incorrectly triggered even when the results under 'In vivo (non-LLNA)' are reported as expected. The rule behaviour will be improved with the future IUCLID 6 releases.

19.8 Miscellaneous

FIX Chesar plugin not fully working when connecting to IUCLID desktop applicationRef. IUCVI-16845FIX Lists sorting should be case insensitiveRef. IUCVI-12651



20 VERSION 6.5.1.2 (28 OCTOBER 2020)

The web user interface has been improved so that the gap with the classic interface is limited to specific use cases such as user and role configuration or the management of reports. In order to progress with the decommissioning of the classic interface, which is scheduled for the coming months, the default interface in this release is now the web interface and all Improvements, Fixes or new Features, are related to the web interface, unless stated otherwise.

In case the access to the classic interface is still needed, more information can be found on the IUCLID website: https://iuclid6.echa.europa.eu/web/iuclid/learn-to-use-the-new-interface

As in every major update of IUCLID, this version also comes with an update of the format to take into account:

- the latest evolutions of the CLP regulations (latest ATPs) and the latest revision of the Globally Harmonised System (GHS)
- the database on substance of very high concern in articles (SCIP) and the submission to European Poison Centres
- the needs of several regulatory organisations including the European Food Safety Authority (EFSA) and the organisations managing chemicals in Australia and New Zealand.

Note on the versioning: IUCLID 6 version 5.1.1 is the latest official IUCLID 6 release since version 4.14.2 published in July 2020. The versioning of the official releases available on the IUCLID 6 website is not consecutive as other intermediate versions of the application can be made available to specific users or groups of users, for example to:

- answer some specific bugs experienced by users,
- provide new features relevant to a specific users group, for example to the <u>ECHA</u> <u>Cloud Services</u> users.

20.1 IUCLID definition providers

The format information is available on the IUCLID 6 website:

https://iuclid6.echa.europa.eu/format

This page contains all information concerning the most recent version of the IUCLID 6 format as well as the documentation of the previous format versions.

20.1.1 Migration

NEW Forward migration of the data implemented (from IUCLID 5.6 and previous IUCLID 6 versions to IUCLID 6.5)

NEW Backward migration of the data implemented (from IUCLID 6.5 to the previous major version of IUCLID: 6.4)

Known issues

 The structure of some ecotoxicological endpoint summaries has been extended to allow the specification of dose descriptors. No default values are selected after migration.

20.2 Data management

FIX Dynamic Content Rules are not working when opening a custom document in sliding window

Ref. IUCVI-16688 NEW Clearly inform the user when he is working on an inherited template Ref. IUCVI-16711

20.2.1 Copy

NEW Bulk copy from documents from dossiers to a dataset Ref. IUCVI-15471 IMP Copy of documents is now allowed for the same dataset Ref. IUCVI-15935

20.2.2 (new) Dataset view

NEW Working context selector added to the dataset navigation page Ref. IUCVI-16296 NEW Support inheritance of a template from a mixture or substance through navigation tree Ref. IUCVI-16297 NEW Create PDF (component PDF, document PDF) in datasets Ref. IUCVI-16315 NEW Reorder document in the navigation tree Ref. IUCVI-16071 FIX When deleting a document, the redirection to the root node is not always performed Ref. IUCVI-16303

20.2.3 Delete

NEW Bulk delete of entities Ref. IUCVI-16467



20.2.4 Display of values

FIX '0' value in a half-bounded range is not visible
Ref. IUCVI-16469
FIX The user is able to exceed the maximum limit of characters in text templates
Ref. IUCVI-14365
FIX Flag fields at the top of some documents are currently not visible
Ref. IUCVI-16549
FIX Estimated quantities ESR - The last number might get deleted during the entry
Ref. IUCVI-15560

20.2.5 Inbound references

NEW View a document's (including entities) inbound references Ref. IUCVI-12554

20.2.6 Phrase groups

IMP Improve display of large phrases in the single picklist component

Ref. IUCVI-16316

NEW Support displaying Hierarchical phrase groups in single picklist components

Ref. IUCVI-16294

20.3 Export

NEW Bulk export of entities Ref. IUCVI-14501

20.4 Filtering (dissemination preview)

NEW EU_PPP filtering scenarios following the IUCLID format extension to make possible Pesticides submissions in Europe: Please note that the Pesticides submissions filter rules currently implemented in IUCLID (and verifiable by means of the Dissemination Preview) are provisional and may be subject to changes or correction prior to 27 March 2021.

20.5 Import

NEW Advanced import of i6z files Ref. IUCVI-16476



20.6 Print

NEW Advanced options for printing dossiers, including document selection

Ref. IUCVI-16385

20.7 Reporting

All reports are adapted to the IUCLID 6.5 format. Below is a summary of new improvements or functionalities both for the reporting engine and the report templates used to generate reports from IUCLID. Moreover, there are specific details about the CSR and PCN reports, as well as about a new set of reports.

General improvements

- NEW Allow generation of the Summary of product characteristics (SPC) report for SPC submission type Ref. IUCVI-15984
- NEW Allow generation of a report from a single entity without section documents. This
 improvement only applies to Category and Article entities and can only be generated
 from the web user interface.
 Ref. IUCVI-15996

CSR report

- **NEW** Make CSR Freemarker templates modularized and re-usable. Modules will be provided separately on the IUCLID website: <u>https://iuclid6.echa.europa.eu/reports</u>
- **NEW** Display links to endpoint study records from endpoint summaries
- Ref. IUCVI-14034
- FIX Nanomaterial section is now displayed without error

PCN report

- NEW GPI changed to GCI
- NEW GCI indication included if GCI flagged for substance component of MiM
- NEW SFC included for Substance/Mixture components
- Ref. IUCVI-16267
- NEW ICG included for Mixture components
- Ref. IUCVI-16280
- **NEW** Full classification of MiM substance components included
- **NEW** New icons for GCI/ICG/SFC
- **NEW** Adjusted layout of the mixture composition (section 1.4) to take into consideration the new amount of information contained in the Composition



- NEW Added multi-lingual output for the dossier header field 'other update reason'
- Ref. IUCVI-16674
- FIX Report is printed if no components in a composition record
- Ref. IUCVI-16761

New reports

NEW SCIP Notification Preview report [PDF]
 Full Article-based report which presents information for the main article and referenced complex articles

Ref. IUCVI-14816

 NEW SCIP Notification Preview without sensitive information report [PDF] Article-based report with potentially sensitive business information excluded, and presents information for the main article and referenced complex articles. The sensitive fields are outlined below:

• Dataset reporting:

does not include Article UUID in the first page of the document

• Dossier reporting:

does not include Dossier UUID in the first page of the document does not include Article UUID in the first page of the document does not include Dossier UUID in the Dossier header section

• Applicable to both Dataset and Dossier reporting:

does not include in the categorisation section of the sub-components the EU Production information the identifiers section of the sub-component article contains only the Article name

- NEW Assessment entity summary report for nanoforms [HTML]
 Substance-based report for displaying the linked Endpoint Summaries and Compositions to an assessment entity
- NEW Inbound references report for section documents (REACH/CLP) [HTML] Shows inbound references of section documents
- **NEW** Composition of a substance for inquiries (REACH)
- **NEW** Substance of Very High Concern (SVHC) report (REACH Annex XV) [RTF/PDF] report. The report extracts the key substance identifiers and composition as well as scientific information from IUCLID sections 4-7, and structures the report based on the



Annex XV template found on ECHA's template page: <u>https://echa.europa.eu/support/guidance-on-reach-and-clp-</u> implementation/formats/formats-for-the-authorities

Known issues

- Inbound references report for section documents (REACH/CLP) may be slow to generate, up to ten minutes for very large datasets and dossiers
- SCIP reports do not have the full Article category text available, only the Category value selected. Ref. SCIP-125

20.8 Search

NEW Advanced search in the list of entities Ref. IUCVI-15438 FIX Submission type 'REACH complete' cannot be retrieved by search Ref. IUCVI-13344

20.9 Validation assistant

NEW and **IMP** completeness check rules for nanoforms and sets of nanoforms for registration dossiers; the new rules ensure that name of nanoform or name of set of nanoforms is provided; the updated rules ensure that each legal entity composition has a reference to a boundary composition covering the nanoform or set of nanoforms. Validation of characterisation of nanoforms and sets of nanoforms are available also for boundary compositions

NEW the 'Value' field datatype under *In vitro / in chemico* table in IUCLID section **7.4.1 Skin sensitisation** was changed to *Numeric* (decimal, <u>including unit</u>) from the *Range* datatype <u>without a unit</u>. Due to this update a unit must be selected in IUCLID 6.5, otherwise the rule **TCC_070401_03** is triggered.

IMP the rule **TCC_0305_08** where a service life is required based on the technical function is deactivated. It will also not be present as a quality rule. Therefore as of the IUCLID 6.5 release, all TCC failures for section 3.5 should be treated as real failures.

NEW and **IMP** updates to the automated checks, business rules, for the Application for authorisation. The rules were extended to check category member substances.

Known issues and future improvements:

• The ordering of the failures or warnings reported in the web interface of IUCLID is different from the ordering of the issues in the classic user interface. This will be corrected in future releases.



20.9.1 PCN related changes

NEW BR632 "'Market placement country' cannot be 'United Kingdom of Great Britain and Northern Ireland [GB]' or 'United Kingdom: Northern Ireland [XN]'"

IMP BR543 Since option 'other:' was removed from 'Justification' dropdown list from 'Reasons for update' BR543 rule was modified to: 'If submission is an update' is indicated, then 'Justification' must be selected from dropdown list or 'Other update reason' must be provided.

NEW BR633 MiM's components need to provide also 'Classification and labelling' record.

NEW BR636 'Classification and labelling' record must be provided either in MiM or for all MiM's components if the MiM is marked to be ICG

NEW BR621 If 'pH not relevant' was indicated then justification must be provided.

NEW QLT634 'IUPAC name needs to be meaningful' and QLT635 'Substance name needs to be meaningful' (rule checks that the provided name is not for instance 'not available' or 'proprietary substance'.)

NEW BR629 replaces BR590

IMP BR542 rule was changed so that 'Product not packaged' and Link to packaging information can be provided both in the same Packaging record.

IMP Many rules regarding Substance identification, MiM identification and concentrations were modified to exclude components that were marked to be 'Standard formula (SF)' components or 'Interchangeable Component Group (ICG)' components

Known issues and future improvements:

- The links from Validation assistant report which are supposed to lead to the failing section currently open in many cases section where it is not possible to correct the failure.
- There are yet no rules to check that the Standard formula (SF) components were provided correctly.
- There are no rules checking that Interchangeable component group (ICG) components have provided composition.

20.9.2 Waste directive (SCIP)

For Waste directive (SCIP) there were no new rules added.

20.9.3 AICIS (Australia)

IMP update in AICIS configurations.

20.9.4 EU Plant Protection Product (EU PPP)

NEW and **IMP** new EU_PPP validation scenarios following the IUCLID format extension to make possible Pesticides submissions in Europe and implementation of new EU_PPP dossier types. Three EU_PPP submission types are available for validation. New EU_PPP rules ensuring minimum requirements are fulfilled for the validated submission types. Updates to the existing EU_PPP rules, extension to all available for validation dossier types.

UCLID6

Known issues and future improvements:

Issues with the message display for several EU_PPP rules, such as section number is
incorrectly displayed for the issues related to Active substance incomplete minimum
requirements for the submission. The section number in the message itself and not in the
message header should be considered. The number in the header refers to the mixture
section number and not to the linked active substance, therefore incorrect (i). The link to
an incomplete document and section is missing and only incomplete entity name is
displayed in the VA report for the rule checking Literature reference entries (EU_PPP_010)
(ii). The message display issues will be corrected in future releases.

20.10Miscellaneous

FIX IUCLID logo cannot be configured by a user in Server or Desktop (Windows) environments

Ref. IUCVI-16565

FIX Attachments are not accessible in dossiers (when navigating for a second time to a record)

Ref. IUCVI-15943

FIX Update installation fails when derby database located under 'javadb' folder

Ref. IUCVI-16248

FIX Inconsistent access to share operation in web-UI vs classic-UI

Ref. IUCVI-16680

NEW Support for Oracle 19c

Ref. IUCVI-15964

20.10.1 Public API

NEW Provide a REST resource for listing working contexts
Ref. IUCVI-16734
NEW Provide a REST resource for listing the registered section trees (TOC)
Ref. IUCVI-16728

20.10.2 i6z format

NEW Adaptations to the IUCLID 6.5 format

Ref. IUCVI-16011

IMP Update the manifest xml file so all submission types for a Mixture are added for all Mixture-based reports

Ref. IUCVI-16370

IMP Adapt i6z file content to reflect Working Context and Table of Content



Ref. IUCVI-16597

20.10.3 Menu

IMP The IUCLID menu, accessible from the Dashboard, has been updated taking into account all latest developments in this release and making the web interface the main one to use (i.e. the link to the IUCLID client is now hidden; more information can be found on the following page: <u>https://iuclid6.echa.europa.eu/web/iuclid/learn-to-use-the-new-interface</u>).

Ref. IUCVI-16363

IMP The startup menu of IUCLID Desktop has been updated to display only the link to the web interface of IUCLID

Ref. IUCVI-16575



21 VERSION 6.4.19.2 – ECHA CLOUD ONLY (13 JULY 2020)

This service release introduces new features, improvements and fixes that are presented by category in the following sections.

This version has been made available only to the users of the <u>ECHA Cloud Services</u>. The next version of IUCLID distributed to all users will be available at the end of October 2020 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

21.1 Annotations

IMP Display modification history for annotations

Ref. IUCVI-14525

IMP Manage attachments for annotations

Ref. IUCVI-12729

NEW All annotations in a dossier can be exported as one zip archive

Ref. IUCVI-12081

21.2 Article

NEW Article referencing Ref. IUCVI-15744

21.3 Data edition

NEW Simplified GHS document and labelling calculation is now available in the dataset view for Poison Centre Notifications

Ref. IUCVI-15890

NEW Simplified forms are displayed for Poison Centre Notifications in the dataset view

Ref. IUCVI-15297

NEW A new navigation tree is available for datasets. Document creation and deletion operations are supported.

Ref. IUCVI-15304

FIX It is now possible to select several STOT classifications in the simplified GHS form Ref. IUCVI-16055

21.4 Dossiers

IMP Support for opt-out in REACH registration dossiers for members of a joint submission



Ref. IUCVI-14992

21.5 Import

NEW Zip archive containing i6z files can be imported Ref. IUCVI-16155

21.6 Report generator and create PDF

IMP Report generation now available for articles
Ref. IUCVI-15914
IMP Creation of PDF files for components of a dossier
Ref. IUCVI-15163
FIX Create PDF for a single document is available again
Ref. IUCVI-15786

21.7 Search

NEW Advanced search options for article-based dossiers Ref. IUCVI-15868 NEW Advanced search options for mixture-based dossiers Ref. IUCVI-15867 IMP UUIDs can be used in the quick search for templates, for copying documents and for list of entities Ref. IUCVI-15852 NEW Advanced search options for substance-based dossiers Ref. IUCVI-15449

21.8 Validation assistant

IMP Validation assistant report can be filtered by rule level or typeRef. IUCVI-14681IMP Validation assistant report can be exported as an Excel fileRef. IUCVI-14680



IMP The TCC_0305_08 rule, related to that the technical function of the substance requires article service life to be reported, was changed from failure to warning (QLT186). As for all quality rules reported by the Validation assistant, when QLT186 is triggered, it is recommendable to review the corresponding information reported in IUCLID.

21.9 Miscellaneous

NEW PNEC calculator added to fill automatically the ecotoxicological information summary

Ref. IUCVI-15766

IMP Dossier selection for dossiers comparison can now be done using the dossier UUID

Ref. IUCVI-14775

NEW Hierarchical phrase groups: complex picklists can now be organized in different levels, facilitating the selection of the correct entry by the user (e.g. article category, EU PCS codes)

Ref. IUCVI-15586 and IUCVI-16122



22 VERSION 6.4.14.2 – PATCH RELEASE (7 AUGUST 2020)

This patch release includes six bug fixes that are described below.

22.1 Installation

FIX The update can proceed even if IUCLID uses an external Derby database installed in the IUCLID server structure. Please note that we recommend avoiding placing the javadb in glassfish's internal structure, i.e. glassfish4\glassfish\domains\domain1\databases.

Ref. IUCVI-16248

22.2 Printing

FIX The user is able to print individual IUCLID documents from the classic user interface

Ref. IUCVI-16259

FIX The user is now able to print using the web interface's document selection, which failed when certain combinations of documents were selected

Ref. IUCVI-15113

22.3 User Management

FIX The correct information is presented in the web interface for users with all roles assigned or 'Access all' users

Ref. IUCVI-16460

FIX The user is now requested to enter the current password when wanting to change their password in the web interface

Ref. IUCVI-16282

FIX The user is now able to use special characters when setting their password such as !, ", \pounds , in the web interface

Ref. IUCVI-15926



23 VERSION 6.4.14.1 (29 APRIL 2020)

This service release introduces new features, improvements and fixes that are presented by category in the following sections. In order to have an overview of the changes since the last public release of IUCLID, in October 2019, please refer to the release notes for the following IUCLID versions: 6.4.14.1 (this section), 6.4.9 and 6.4.8.

This version has been made available to all IUCLID users on the <u>IUCLID website</u>, on the 29th of April 2020. <u>ECHA Cloud Services</u> are updated to this version the week following the publication of the April 2020 IUCLID release.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

23.1 Articles

FIX Hide empty fields in articles dossiers

Ref. IUCVI-15463

IMP Generate UUID (unique identifier) for a new article

Ref. IUCVI-15107

FIX 'Other:' field cannot be changed after selection

Ref. IUCVI-15542

FIX Searching by article dossier UUID redirects to error page

Ref. IUCVI-15487

FIX Article's view page is unresponsive when many reference substances are linked to article Ref. IUCVI-15472

FIX Article navigation tree is not refreshed when user edits the article from the VA report Ref. IUCVI-15314

23.2 Comparison

FIX Compare list not loaded the second time user chooses to compare dossiers

Ref. IUCVI-15453

FIX Comparison report does not display all field-level changes anymore

Ref. IUCVI-15351

IMP Comparison report of two dossiers must be supported for multilingual fields Ref. IUCVI-15175



23.3 Copy

NEW Bulk copy for dataset records of mixtures, substances and templates

Ref. IUCVI-13209

FIX Copied records now have a -COPY suffix

Ref. IUCVI-14334

23.4 Category

NEW Create a substance dossier including category information Ref. IUCVI-15673 NEW Create a category dossier Ref. IUCVI-15672 NEW Create PDF, export and import categories Ref. IUCVI-14440 NEW Create and edit a category Ref. IUCVI-13911 NEW Delete a category Ref. IUCVI-13910 NEW List categories Ref. IUCVI-12513

23.5 Datasets and dossiers

IMP Access to the draft dossier header information simplified

Ref. IUCVI-15040

NEW Navigation tree for substance and mixture dossiers, including the possibility to navigate, in context, to all related information.

Ref. IUCVI-15563

IMP Alignment of the views and user interface components between the datasets and dossiers

Ref. IUCVI-14965

NEW Possibility to view simplified IUCLID documents displaying only relevant fields for selected submission type (for Poison Centres)

Ref. IUCVI-15633, IUCVI-15539

NEW Simplified Classification and Labelling document, including a Labelling calculator, now available in dataset view for Poison Centres

Ref. IUCVI-15890

FIX "Mandatory field" messages should not be displayed in populated table fields of dossiers

Ref. IUCVI-15820

FIX The tonnage band is not mandatory anymore for CLP notifications

Ref. IUCVI-15753

FIX Incorrect representation of references in the Guided dossier approach

Ref. IUCVI-15545

FIX Document name deleted after an attachment upload

Ref. IUCVI-15540

FIX Other option is not displayed in the RegulatoryProgrammeFlags of export i6z sliding window

Ref. IUCVI-15506

FIX Alignment of headers in table view

Ref. IUCVI-15404

FIX Text wrapping in table view

Ref. IUCVI-15403

FIX Create PDF for individual document in PCN dossier: multilingual fields not included

Ref. IUCVI-15379

FIX Linking a document to itself triggers issue

Ref. IUCVI-15191

FIX Field help is not displayed in dossier headers

Ref. IUCVI-15148

FIX PCN: Dynamic content rules on Product details - Colour and physical state

Ref. IUCVI-15110

FIX Internal document reference: UUID displayed instead of the reference name Ref. IUCVI-14828

FIX Order of the text templates' options in section 1.2 (substance composition) is random Ref. IUCVI-13546

23.6 DNEL calculator

NEW Calculate DNEL in the Summary of toxicological information Ref. IUCVI-14502

23.7 Inventories

NEW Manage sites inventory Ref. IUCVI-12550



IUCLID6

NEW Manage contacts inventory Ref. IUCVI-12548 NEW Manage literature references inventory Ref. IUCVI-12546 NEW Manage test materials inventory Ref. IUCVI-12541

23.8 Report generator

IMP Update of report templates (PCN preview report and Chemical Safety Report) Ref. IUCVI-15799

23.9 Validation assistant

IMP Update of the configuration for AustraliaRef. IUCVI-15758, IUCVI-15757IMP Update for EU Plant Protection Regulations

23.9.1 REACH

NEW and **IMP** automated checks on key hazard endpoints, IUCLID sections 5.2.1, 5.2.2, 5.2.3, 7.6.1. 7.6.1, 7.8.1 and 7.8.2 following the revision of the completeness check.

NEW completeness check rules for nanoforms and sets of nanoforms for registration dossiers; the new rules ensure that each legal entity composition has a reference to a boundary composition covering the nanoform or set of nanoforms.

NEW completeness check rules for nanoform specific requirements in IUCLID sections 5.2.2 and 6.1.3 related to data waiving.

NEW completeness check rules for IUCLID section 3.5 – detection of missing Article service life based on information provided in other uses.

NEW completeness check rules checking completeness of the summaries provided in sections 6 and 7 in joint submission member dossiers.

23.9.2 SCIP

NEW SCIP quality rules added to warn that if obligatory information is provided then the provided information should be complete. (QLT703, QLT704, QLT706, QLT707, QLT708, QLT709, QLT710, QLT711, QLT712, QLT713).

NEW SCIP rules added to prevent that same information would be provided multiple times in error (BR720, BR721, BR722).

IMP SCIP rule requiring to indicate 'Candidate list version' (BR713) and rule requiring to include 'Number of Units' (BR712) were deactivated.

23.9.3 Poison Centre Notifications (PCN)

NEW PCN rule checking concentration range: If concentration range is reported then qualifiers must be included (BR625). **IMP** of the rule BR607 checking that only positive values allowed as concentration. **IMP** rule following the requirement to provide same legal entity in dossier header and Mixture (BR520) was deactivated.

NEW PCN rule checking that mixtures Classification information is provided (BR546 and BR613).

IMP PCN rule BR592 changed from failure to warning QLT592.

IMP PCN rules modified to reflect the 1st amendment of legal text (Annex VIII): identification of 'Mixture in mixture' related rules deactivated (BR579, QLT512) **IMP** BR527, BR606.

NEW PCN rule to check that the supplier of Mixture in mixture is not the same as Duty holder added (BR624).

IMP PCN fragrance related rules modified (BR583, BR603, BR590) and deactivated (BR616).

NEW rules and validation scenarios for EU_PPP submissions, EFSA (European Food Safety Agency).

23.9.4 Known issues and future improvements

- Due to the possibility to add several endpoint records in section 1.3 Regulatory identifiers, some business rules checking content in that section do not work properly if several endpoint records are created.
- The ordering of the failures or warnings reported in the web interface of IUCLID is different from the ordering of the issues in the classic user interface. This will be corrected in future releases.
- Validation of characterisation of nanoforms and sets of nanoforms to be available also for boundary compositions.
- Referencing to previously submitted notification not yet possible (SCIP)
- Validation report links: the links from validation report failures to the corresponding dataset sections do not work correctly in all occasions. The behaviour will be improved in a subsequent IUCLID release.
- PCN 'Group submission' notifications are not implemented yet, therefore it is not possible to validate Group submissions at the moment

23.10Search

NEW Advanced search for Articles list (not dossiers)

Ref. IUCVI-15623

NEW Advanced search for Mixtures list (not dossiers)

Ref. IUCVI-15622

NEW Advanced search for Substances list (not dossiers)



23.11User settings

NEW Possibility to change the working Legal Entity Ref. IUCVI-15566 NEW Change user's password Ref. IUCVI-15565 NEW View user information, including roles and security groups (when Instance Based Security is activated) Ref. IUCVI-15564

23.12Miscellaneous

IMP Differentiation between the icons for 'close' and 'delete' actions
Ref. IUCVI-15209
IMP UUID (unique identifier) of IUCLID documents are now displayed
Ref. IUCVI-15116
NEW Users are now informed in case the connection to the IUCLID server or database is not available
Ref. IUCVI-14780
IMP Update of the IUCLID functionalities manual
Ref. IUCVI-15834
IMP Update of GlassFish distribution to newer version (Payara)



24 VERSION 6.4.9 – ECHA CLOUD ONLY (17 FEBRUARY 2020)

This service release introduces new features, improvements and fixes that are presented by category in the following sections.

This version has been made available only to the users of the <u>ECHA Cloud Services</u>. The next version of IUCLID distributed to all users will be available on the 29th of April 2020 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

24.1 Annotations

FIX The second Remarks field can now be populated Ref. IUCVI-15409

24.2 Articles

NEW Submit you SCIP notification online when working in the Cloud Services

Ref. IUCVI-14819

NEW View article-based dossiers

Ref. IUCVI-15186

NEW User journey for Articles

Ref. IUCVI-15255

FIX The Description field cannot be filled in by a user in the sliding window

Ref. IUCVI-15273

FIX Display of annotations and modification history

Ref. IUCVI-15320

FIX Attachment cannot be added to the document when 'Safe use instructions' is not empty Ref. IUCVI-15323

24.3 Poison Centres Notifications (guided dossier approach)

FIX Dossier submission remark can be entered Ref. IUCVI-15333

24.4 REACH registration (guided dossier approach)

FIX Guidance on safe use fails at first step Ref. IUCVI-15395



24.5 Validation assistant

FIX Dynamic content rule is not working for the dossier header accessed from the validation assistant

Ref. IUCVI-15200

FIX The user is not able to create a CLP notification without providing a tonnage band

Ref. IUCVI-15244

24.6 Web interface

FIX Attachments made at the document level can now be deleted in datasets even when attachment is already included within the document itself.

Ref. IUCVI-12977

NEW Export reference substance from the inventory

Ref. IUCVI-15263

IMP Advanced export options are now customised depending on the export possibilities available for each entity.

Ref. IUCVI-15332

NEW Inventory of Legal entities

Ref. IUCVI-15288

FIX CLP notification: the tonnage band is not mandatory anymore



25 VERSION 6.4.8 – ECHA CLOUD ONLY (27 JANUARY 2020)

This service release introduces new features, improvements and fixes that are presented by category in the following sections.

This version has been made available only to the users of the <u>ECHA Cloud Services</u>. The next version of IUCLID distributed to all users will be available on the 29th of April 2020 on the IUCLID website.

All issues reported below are relevant to the web interface of IUCLID unless specified otherwise.

25.1 Articles

NEW Support of a new entity 'Article' for preparing notifications under the EU Framework Directive. More information on <u>https://echa.europa.eu/scip-database</u>

Ref. IUCVI-14805

25.2 Chemical Safety Report (CSR)

IMP Data from section 7.8.3 'Toxicity to reproduction: other studies' are now extracted to the CSR.

Ref. IUCVI-14676

25.3 Clipboard / copy

NEW Clone entities, including substance and mixture datasets Ref. IUCVI-14485

25.4 Dossier

NEW A previously selected submission type can now be removed from the list of submission types. The related dossier header is deleted at the same time. Ref. IUCVI-12617

25.5 Data entry / edit

FIX Numeric values are not incorrectly rounded anymoreRef. IUCVI-15147FIX Repeatable blocks are now numbered in ascending orderRef. IUCVI-14829





25.6 Filtering / dissemination preview

IMP Filtering is now available for mixtures

Ref. IUCVI-15159

IMP Specific filtering configuration can be applied per submission types

Ref. IUCVI-15160

25.7 i6z files

FIX Optional fields from manifest.xml are not required anymore during import.

Ref. IUCVI-15098

25.8 Poison Centres Notifications

NEW Simplified form for entering and updating Classification and Labelling information. The new form includes a 'Calculate' option to automatically present to the user the labelling corresponding to the specified classification.

Ref. IUCVI-12224

NEW Inline editing previously available in other parts of IUCLID is now available for the forms included in the guided dossier approach.

Ref. IUCVI-14781

NEW A new user interface component is available to select the C&L pictograms.

Ref. IUCVI-14949

NEW Dynamic content improved.

Ref. IUCVI-14736

IMP Updated dynamic content rules in the dossier header for the Poison Centres Notifications

Ref. IUCVI-13968

IMP Support of multilingual fields for Poison Centre Notifications in the standard IUCLID view (for dossiers and datasets)

Ref. IUCVI-14747, IUCVI-15123

IMP Multilingual fields supported in Create PDF

Ref. IUCVI-15118

IMP Tasks for the guided dossier approach for Poison Centre Notifications have been simplified

Ref. IUCVI-14459, IUCVI-14457, IUCVI-14523

25.9 Print

NEW Create PDF for the entire dataset is now available when specific records are displayed Ref. IUCVI-14743



25.10Validation assistant

NEW Completeness check rules: TCC_070601_A01, TCC_070601_A02, TCC_070601_A03 for section 7.6.1 - Genetic toxicity in vitro. These rules are part of the upcoming completeness check revision for REACH registrations. The rules are not part of the completeness check carried out by ECHA until April 2020.

25.11 Web user interface

FIX Dynamic content for 'Use takes place under rigorously contained conditions' fixed to display the related field correctly

Ref. IUCVI-14885

FIX Dynamic content rules for the document 'Article service life advised against'

Ref. IUCVI-15026

FIX Document selection: disabled sections are now displayed as disabled.

Ref. IUCVI-15052

FIX Dynamic content rules in the dossier header for 'REACH member of a joint submission - standard'



IUCLID6

26 VERSION 6.4.2 (30 OCTOBER 2019)

The web user interface, which is meant to become in the future the only user interface for IUCLID, has been improved. This version includes, for example, direct navigation to referenced documents in dossiers, advanced dossier creation, export and printing options including document selection, and a slightly more compact view for documents.

As in every major update of IUCLID, this version also comes with an update of the format to take into account:

- the latest evolutions of the REACH (for example, new nanoforms requirements) and CLP regulations (latest ATPs);
- the future database on substance of very high concern in articles; and
- the needs of several regulatory organisations including the European Food Safety Authority (EFSA) and the organisations managing chemicals in Australia and New Zealand.

Note on the versioning: IUCLID 6 version 4.2.1 is the latest official IUCLID 6 release since version 3.16.1 published in April 2019. The versioning of the official releases available on the IUCLID 6 website is not consecutive as other intermediate versions of the application can be made available to specific users or groups of users, for example to:

- answer some specific bugs experienced by users,
- provide new features relevant to a specific users group,
- provide fixes to the ECHA Cloud Services users.

26.1 IUCLID definition providers

The format information is available on the IUCLID 6 website:

https://iuclid6.echa.europa.eu/format

This page contains all information concerning the most recent version of the IUCLID 6 format as well as the documentation of the previous format versions.

26.2 Web interface

26.2.1 Dossiers

IMP View for dossier content improved

Ref. IUCVI-14316

NEW Inline editing implemented for dossier headers

Ref. IUCVI-14893

NEW View category information in a dossier

Ref. IUCVI-14396

NEW Document selection for dossier creation

Ref. IUCVI-14592

NEW Simple URL to view a dossier. Specifically, a link of the form: <http://<IUCLID_SERVER>/iuclid6-web?dossier=<DOSSIER_UUID> navigates the user to the dossier subject page.

Ref. IUCVI-14675

26.2.2 Document edition

NEW Support of dynamic content rules. The web interface now implements the support of conditional display of fields depending on user input. Depending on the data entered in a form, some fields, picklist items or sections will be shown/hidden, enabled/disabled or made mandatory

Ref. IUCVI-14553

NEW Reference substances now support inline editing

Ref. IUCVI-14366

FIX Additional text is now displayed in picklists

Ref. IUCVI-14004

NEW Templates can now be deleted

Ref. IUCVI-13896

NEW User is warned when leaving a page with unsaved changes

Ref. IUCVI-12281

26.2.3 Export

NEW Export to the previous major version is now possible

Ref. IUCVI-14693

NEW Advanced export options

Ref. IUCVI-13629

NEW Document selection for export

Ref. IUCVI-14656

26.2.4 Performance improvements

IMP Improved performance for searches on dossiers

Ref. IUCVI-14409

IMP Improve performance of loading a dataset



IMP Improve performance of importing a file with many documents

Ref. IUCVI-13718

IMP Improve performance of loading users and groups (particularly in sharing and change ownership operations)

Ref. IUCVI-14529

26.2.5 Print (create PDF)

NEW Advanced print options

Ref. IUCVI-13630

NEW Document selection for print (datasets only)

Ref. IUCVI-14655

FIX Annotations are not printed with dossiers

Ref. IUCVI-14068

26.2.6 User interface improvements

IMP Reduced white space in document window

Ref. IUCVI-14498

IMP Table component to represent relevant repeatable set of fields for the dataset view

Ref. IUCVI-14497

IMP Representation of linked entities and documents is now based on key fields from these documents. For the dataset views only.

Ref. IUCVI-14496

IMP Better differentiation between datasets, dossiers and reusable entities

Ref. IUCVI-14005

IMP Clearer icons for documents

Ref. IUCVI-13961

IMP possibility to open referenced documents and entities in a sliding window for dossiers

Ref. IUCVI-13406

IMP The confidentiality and regulatory programmes flags are now displayed more clearly for datasets

Ref. IUCVI-13355

26.2.7 Miscellaneous

NEW View the modification history of the document displayed

Ref. IUCVI-12409

NEW Provide a link to the error report of a background job (e.g. for a failed import)

Ref. IUCVI-14389 NEW Display a progress indicator for a background job Ref. IUCVI-14388 FIX Bulk import fails sporadically with large set of files Ref. IUCVI-12419

26.3 Article and SCIP database

For more information, please refer to <u>https://echa.europa.eu/scip-database</u> **NEW** Support import of a SCIP dossier (article-based)
Ref. IUCVI-14567 **NEW** Article entity (not yet available at the user interface level)
Ref. IUCVI-14471

26.4 Chesar

IMP Support the two latest versions of Chesar. The latest version of IUCLID will now be compatible with the existing Chesar version (at the time of publication) and the next one. Ref. IUCVI-13984

26.5 Dossier comparison

IMP Dossier comparison has now been removed from the classic user interface as the new comparison report has been implemented in the web interface only

Ref. IUCVI-14832

26.6 Filtering module

IMP Filtering configuration for REACH dossiers updated to take into account the updated format of IUCLID Ref. IUCVI-14908

26.7 Guided dossier approach for Poison Centre Notifications (PCN)

NEW Create a GPI componentRef. IUCVI-13957FIX Additional labelling requirements addedRef. IUCVI-14382



NEW Start a PCN dossier from an existing mixture
Ref. IUCVI-14085
NEW (only in the Cloud version) Possibility to submit a PCN online
Ref. IUCVI-13486
IMP Revised form content for product information and composition components
Ref. IUCVI-14464, IUCVI-14463, IUCVI-14462, IUCVI-14461
FIX Legal entity is included by default for PCN dossiers
Ref. IUCVI-14359
FIX Several documents are created unintentionally by the user
Ref. IUCVI-13889

26.8 Help system

IMP Oracle help updated for the classic interface

- Ref. IUCVI-14988
- FIX The help text for headers is now aligned correctly in the web interface
- Ref. IUCVI-14984
- IMP Update of the user manual for the web interface
- Ref. IUCVI-14875
- IMP Help links updated in the REACH guided dossier preparation approach
- Ref. IUCVI-14874
- **NEW** Link to dossier preparation manuals added to the top bar of the web user interface
- Ref. IUCVI-14868
- NEW Link to the LinkedIn IUCLID group added to the top bar of the web user interface
- Ref. IUCVI-13598
- IMP Help text displayed for repeatable blocks in the web user interface
- Ref. IUCVI-14839
- IMP Update to User Journeys
- Ref. IUCVI-14518
- FIX Help text is now available for endpoint summaries
- Ref. IUCVI-13587

26.9 Installation / start-up

FIX Insertion of a missing part of the domain.xml configuration file that was preventing the IUCLID server to restart



FIX Launching the IUCLID client is not available anymore for Desktop installations

Ref. IUCVI-14434

IMP Improve error message displayed when the user tries to start two conflicting installations of IUCLID on the same computer

Ref. IUCVI-14418

IMP The IUCLID client can be launched from the menu directly without accessing a new page first

Ref. IUCVI-14060

26.10Report generator

The Report Generator wizard contains all the in-built reports which ECHA has made available to IUCLID users.

The reports available for generation from a substance dataset or dossier include:

- Chemical safety report (CSR)
- List of attachments for substance datasets and dossiers in RTF format
- Classification and labelling report for lead registrants
- Literature References report for substance and mixture/product datasets and dossiers
 in CSV format
- Literature References report for substance and mixture/product datasets and dossiers in RTF format (*re-added for substances*)

The reports available for generation from a mixture/product dataset or dossier include:

- Summary of product characteristics (SPC) report
- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in PDF/RTF formats
- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in CSV format
- Literature references report for substance and mixture/product datasets and dossiers in RTF format
- Literature References report for substance and mixture/product datasets and dossiers
 in CSV format
- List of attachments for biocidal mixture/product datasets and dossiers in RTF format (removed and replaced by the CSV version)
- List of attachments for biocidal mixture/product datasets and dossiers in CSV format
- List of annotations for biocidal mixture/product datasets and dossiers [PDF/RTF]
- PCN Preview report (Annex VIII of the CLP Regulation) [PDF]

All report templates above, as well as other report templates, can be found from the IUCLID 6 website and uploaded into a IUCLID 6.4 instance via the IUCLID Report Manager:

https://iuclid6.echa.europa.eu/reports



Note: To upload your own report templates, you will still need to use the IUCLID Report Manager in the classic user interface. When uploading a report, you will see the report available in both the classic and the new (web) user interfaces.

26.10.1.1 New report template functionality

IMP Server URL (hostname/port) must be available to reporting engine

Ref. IUCVI-13012

This new functionality allows report templates to include a hyperlink which opens the IUCLID web interface for either:

- The table of contents of a composite entity (i.e. a substance, mixture, template) or,
- A IUCLID document, such as the endpoint study record for acute toxicity (oral).

The hyperlinks will only appear for reports generated from the web interface. The following embedded reports include such hyperlinks:

- Chemical safety report (CSR)
- List of attachments for substance datasets and dossiers in RTF format
- Literature References report for substance and mixture/product datasets and dossiers
 in CSV format
- Literature References report for substance and mixture/product datasets and dossiers
 in RTF format
- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in CSV formats
- Literature references report for substance and mixture/product datasets and dossiers in RTF format
- Literature References report for substance and mixture/product datasets and dossiers
 in CSV format
- List of attachments for biocidal mixture/product datasets and dossiers in CSV format
- List of annotations for biocidal mixture/product datasets and dossiers [PDF/RTF]

A freemarker report template can be used to embed a URL for the entity or document inside a piece of text with the following calls:

Entity: iuclid.webUrl.entityView(<entity>.documentKey)

Document: iuclid.webUrl.documentView(<document>.documentKey)

In case of a composite entity (substance, mixture or template), iuclid.webUrl.entityView(...) and iuclid.webUrl.documentView(...) will render different URLs: the former pointing to the "Table of contents of the main entity", while the latter to the "IUCLID document".

Here is a theoretical example of a URL which will open a IUCLID document which is embedded inside the text 'This is a link to a document':

<#local docUrl=iuclid.webUrl.documentView(<document>.documentKey) />
<#if docUrl?has_content>
<ulink url="\${docUrl}">This is a link to a document</ulink>
<#else>
<DEFAULT_CONTENT>
</#if>

Here is a practical example from the annotations report which embeds a hyperlink to the mixture table of contents into the mixture name which is displayed at the start of the report:

<#assign docUrl=iuclid.webUrl.entityView(mixture.documentKey)/>
<#if docUrl?has_content>
<ulink url="\${docUrl}"><@com.text mixture.MixtureName/></ulink>
<#else>
<@com.text mixture.MixtureName/>
</#if>

26.10.1.2 Summary of updated reports

All reports embedded inside IUCLID have been updated to the latest 6.4 format. The significant changes are described below per report:

- Chemical safety report (CSR) (see the section on CSR below for the fixes and improvements)
 - Characterisation of nanoforms section was adapted to the latest format
 - Adaptation of the physcochemical properties table for substances with assessment entity
 - Hyperlinks included in the CSR generated from the web interface pointing to the relevant section of IUCLID
 - Annex 1 References content streamlined
- List of attachments for substance datasets and dossiers in RTF format
 - Report now includes new attachments in the:
 - Reference substance
 - Analytical information (1.4)
 - Substance composition (1.2)
- Literature References report for substance and mixture/product datasets and dossiers
 in CSV format
 - Expanded the report to include more information from the (eco)toxicological studies in which the literature reference is contained, including:
 - Species / test organism
 - Strain / cell type
 - Route of application / dose method
 - Exposure duration
 - Metabolic activation
 - Metabolic activation system
 - Study outcome (value/result)



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- A matrix of what new study information has been added is published on the IUCLID 6 website, under the Report Generator webpage.
- Literature References report for substance and mixture/product datasets and dossiers in RTF format (re-added for substances)
 - Report re-designed based on feedback from the BPR IT Tools Group for inclusion inside a Product Authorisation Report (PAR)
 - Re-organisation of information to help make the table clearer, whilst retaining the information on one table row
 - Added the Report date
 - Added the Type of publication
 - Removed the 'Applicable for assessment report' column
- List of attachments for biocidal mixture/product datasets and dossiers in CSV format
 - Added the name of Biocidal product or component per row
 - \circ $\;$ Added the function of the Biocidal product component per row
- PCN Preview report (Annex VIII of the CLP Regulation) [PDF]
 - Updated the dossier header information to capture voluntary submissions and the justification for the update.

26.10.1.3 Other fixes and improvements

```
<u>CSR</u>
```

IMP URL implementation - make consistent across stylesheets

Ref. IUCVI-14961

IMP Data Extraction-Toxicity for reproduction: other studies

Ref. IUCVI-14676

FIX CSR generation PBT assessment (section 8) - space added

Ref. IUCVI-11165

IMP do not print the label "report date" references (Annex 1)

Ref. IUCVI-14701

<u>PCN</u>

FIX PCN Preview report generation - document is generated broken

Ref. IUCVI-14801

FIX Preview PCN in pdf does not correctly format rich text (toxicological information)

Ref. IUCVI-14516

FIX Improve rendering of rich text pasted from HTML in PCN preview report Ref. IUCVI-14337

Report template - general

FIX & character in attachment filename causes PDF export to fail Ref. IUCVI-14990

FIX URL wrapping in CSV (Excel) - comma separation issue

Ref. IUCVI-14962

FIX Generate report fails for substance datasets and dossiers in RTF format

Ref. IUCVI-14944

FIX Literature reference report (rtf) fails due to special characters not being escaped

Ref. IUCVI-14938

26.11 Validation assistant

NEW completeness check rule checking that the 'State/form' of a composition is specified. The rule supports the completeness check implementation for nanoforms of substances.

NEW completeness check rules for characterisation of nanoforms and sets of nanoforms for registration dossiers; corresponding business rules for inquiry notifications.

NEW completeness check rules for nanoform specific requirements in sections 4-7.

NEW completeness check rules for sections 4.28.8 'Nanomaterial dustiness' and 5.7.1 'Dispersion stability of nanomaterials'.

NEW updated business rules to reflect the end of the phase-in scheme for REACH registrations.

NEW Validation scenarios created for the new submission types 'AICIS Certificate application - Health and environment focus', 'AICIS Certificate application - Health focus', 'AICIS Certificate application - Environment focus', 'AICIS Certificate application - Very low to low risk' and 'AICIS Certificate application - Comparable hazard assessment'. The scenarios have been configured with a preliminary set of business rules, completeness check rules and quality rules; to be extended in coming releases.



27 VERSION 3.16.1 (24 APRIL 2019)

Please also refer to the Frequently Asked Questions on the IUCLID 6 website.

The releases notes are highlighting changes compared to previous versions of IUCLID 6. In the next sections, improvements are identified with **IMP** and bug fixes with **FIX**.

The April service release features improvements to the web interface such as:

- Inline editing (merging the read and edit views)
- Clearer navigation within a dataset and enhanced data edition mode
- The full report generator
- Full management of reference substances
- Improved comparison and validation reports
- More advanced dossier creation and import

It includes in addition a new guided dossier preparation for Poison Centre Notifications (PCN), which allows industry to prepare notifications for hazardous mixtures (Article 45 and Annex VIII to the CLP Regulation). Guided Dossier Preparation provides a simplified, task-based, approach to dossier creation. More information can be found on the Poison Centres website.

This service release does not bring changes to the IUCLID format. Hence, it remains fully compatible with IUCLID 6.3 It accepts all files from IUCLID 5.6 and later, while it can also export files that are compatible with IUCLID 6.2.

This new version takes into account the update of the release policy of Java provided by Oracle and the related changes are embedded in the installers and updaters published for this new IUCLID version.

The IUCLID Cloud services have been automatically updated to the latest version.

Note on the versioning: IUCLID 6 version 3.16.1 is the latest official IUCLID 6 release since version 3.1.1 published in October 2018. The versioning of the official releases available on the IUCLID 6 website is not consecutive as other intermediate versions of the application can be made available to specific users or groups of users, for example to:

- answer some specific bugs experienced by users,
- provide new features relevant to a specific users group,
- provide fixes to the ECHA Cloud Services users.

27.1 IUCLID functionalities

In preparation for the transition from the classic user interface to the new web interface (introduced with IUCLID 6.3, in October 2018), the vast majority of the fixes and improvements delivered in newer versions of IUCLID are made to the web interface.

27.1.1 Clipboard

FIX In the web interface, attachments were not copied together with the document. Ref. IUCVI-13454

27.1.2 Comparison (web interface)

IMP View the differences in referenced documents

Ref. IUCVI-9458

IMP Improvements to the layout and the organization of the content of the HTML comparison report

Ref. IUCVI-13323, IUCVI-13583

IMP List of dossiers to be compared is now sorted (newer first)

Ref. IUCVI-13340

27.1.3 Data entry and navigation

NEW The data edition mode for IUCLID documents has been completely revisited in the web interface. Instead of switching from read to edit mode, the user has the possibility to edit directly the relevant IUCLID fields.

Ref. IUCVI-13627

NEW Reference substances can be fully managed from the web interface (search, list, creation, edition, deletion)

Ref. IUCVI-13856, IUCVI-13867, IUCVI-13868, IUCVI-13898

IMP Clickable area for checkboxes are including their labels

Ref. IUCVI-12288

NEW When a reference needs to be added to another document, the web interface proposes available documents to be linked and, in addition, gives the option for the user to create a new relevant document

Ref. IUCVI-13019

IMP Sliding windows can now be closed by clicking on another part of the interface

Ref. IUCVI-13545

NEW The relevant table of content is now displayed to the user while browsing the content of a dataset

Ref. IUCVI-13626

FIX Documents from an inherited template are now displayed in the correct order

Ref. IUCVI-13087

IMP The user interface component used to edit rich text fields (HTML) has been updated to offer more formatting options and a better rendering of the information pasted to the fields



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FIX Picklist can now be opened when clicking the arrow on the right side of the field

Ref. IUCVI-13409

IMP Improvement of the representation of repeatable sets of fields

Ref. IUCVI-13375

FIX 'Go to source' option is not displayed anymore when the corresponding dataset is not available for a dossier

Ref. IUCVI-14048

IMP There is now a possibility to navigate to the components of a mixture in a dossier and in a dataset

Ref. IUCVI-14051

27.1.4 Dossier

NEW Dossiers can now be created with advanced options in the web interface. Document selection is not yet available though.

Ref. IUCVI-12544

FIX Dossier creation default settings are fixed in the web user interface (i.e. legal entities are not included by default)

Ref. IUCVI-13891

27.1.5 Import

NEW Advanced import options are now available from the main page of the IUCLID web interface. It offers the possibility to select the overwrite mode and, if Instance-Based Security is activated, the destination security group. Document selection before import is not yet available in the web interface.

Ref. IUCVI-12273

NEW Summary of Product Characteristics XML files generated with <u>ECHA SPC editor</u> can now be imported as IUCLID dossiers.

Ref. IUCVI-13300

27.1.6 Lists of substances and mixtures (web interface)

IMP The list of substances and mixtures and their related dossiers are not grouped anymore by substances or mixtures. All dossiers and datasets are now displayed directly in the lists.

Ref. IUCVI-13864

IMP The legal entity is now displayed in the lists of substances and mixtures

27.1.7 Menus and options

IMP Options available for a specific dossier or dataset are now placed in a menu Ref. IUCVI-12611

27.1.8 Poison Centres Notification (PCN) wizard

NEW A new guided dossier approach is available in the web interface of IUCLID. It supports the creation of the Poison Centres Notifications (PCN) in the European Union. Currently, the PCN guided dossier approach does not support Group submissions.

More information can be found on the Poison Centres website:

https://poisoncentres.echa.europa.eu/

Ref. IUCVI-12945

27.1.9 Search

FIX In the web interface, mixture-based dossiers could not be searched by submission type. Ref. IUCVI-13452

27.2 IUCLID modules

27.2.1 Dissemination preview

IMP Several improvements to the dissemination preview report: ordering of the report according to the sections numbering, removed redundant information for filtering results of repeatable set of fields, dossier header fields are displayed at the beginning of the report.

Ref. IUCVI-13878

27.2.2 Fee calculator

NEW The fee calculator is now available in the web user interface Ref. IUCVI-13207

27.2.3 Help system

IMP Update of the IUCLID functionalities manual in the web interface Ref. IUCVI-14263

27.2.4 Report generator

NEW IUCVI-13178: The full Report Generator Wizard is now available from the IUCLID web user interface for the applicable datasets or dossiers. To generate a report, the user should go



into a dataset or dossier, click on the menu icon in the top right-hand corner, select 'Generate report' and then, from the list of available reports, select a report to generate.

Note: To upload your own report templates, you will still need to use the IUCLID Report Manager in the classic swing user interface. When uploading a report here, you will see the report available in the Report Generator Wizard in both the classic and web user interfaces.

The Report Generator wizard contains all the in-built reports which ECHA has made available to IUCLID users. The reports available for generation from a **substance dataset or dossier** include:

- Chemical safety report (CSR)
- Literature references report for substance and mixture/product datasets and dossiers
- List of attachments for substance datasets and dossiers
- Classification and labelling report for lead registrants
- Literature references csv report for substance and mixture/product datasets and dossiers NEW

The reports available for generation from a mixture/product dataset or dossier include:

- Summary of product characteristics (SPC) report
- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in PDF/RTF formats
- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in CSV formats
- Literature references report for substance and mixture/product datasets and dossiers
- Literature references csv report for substance and mixture/product datasets and dossiers NEW
- List of attachments for biocidal mixture/product datasets and dossiers (in RTF format)
- List of attachments for biocidal mixture/product datasets and dossiers (in CSV format)
- List of annotations for biocidal mixture/product datasets and dossiers
- Preview PCN (in PDF) NEW

All report templates above, as well as other report templates, can be found from the IUCLID 6 website and uploaded into your own IUCLID instance via the IUCLID Report Manager:

https://iuclid6.echa.europa.eu/reports

27.2.4.1 Summary of new reports

Literature references csv report for substance and mixture/product datasets and dossiers

This report is based on the existing literature reference report but includes more information per endpoint, and is in CSV format so that the relevant IUCLID data can be viewed in a tabular format. The new information included in this report (if included in the endpoint) is listed below:

- Indication of whether the study is a Robust Study Summary
- Data waiving
- Type of information
- Reliability
- Data Access



- Test Material Guideline
- GLP Compliance
- Test Material name and reference substance information
- Indication of whether endpoint is flagged as confidential

Preview PCN (in PDF)

Based on Article 45 and Annex VIII to the CLP Regulation companies placing hazardous mixtures on the market have an obligation to provide information on these mixtures to appointed bodies. As part of this obligation, there is now a PCN Preview Report which summarises that information. The report is an in-built report inside IUCLID, and in addition to being launched from the web interface, can also be launched through the Guided Dossier Preparation task screen 'Preview notification'.

IMP IUCVI-14251: The Preview PCN report also extracts <u>multi-lingual text</u> from the following fields:

- FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ReproductiveToxicity.Reproductiv eToxicity.SpecificEffect (extracted from both main mixture and c&l in component of main mixture)
- FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicitySingle.Toxicity.Toxicity.Or gans (extracted from both main mixture and c&l in component of main mixture)
- FLEXIBLE_RECORD.Ghs.Classification.HealthHazards.ToxicityRepeated.Toxicity.Toxicity .Organs (extracted from both main mixture and c&I in component of main mixture)
- FLEXIBLE_RECORD.Ghs.Labelling.HazardStatementsBlock.HazardStatements.Additiona
 IText
- FLEXIBLE_RECORD.Ghs.Labelling.PrecautionaryStatementsBlock.PrecautionaryStateme nts.AdditionalText
- FLEXIBLE_RECORD.SDSInfoMixtures.InformationOnMixtures.TradeNamesAndSafetyDat aSheetsOfTheMixture.SDSsection11

1.1.1.1. Other improvements in current reports

• IUCVI-14161

The customized stylesheet has been updated to allow the generation of PDF reports

 As part of the development of the PCN Preview report, the extraction of temporary 'raw' dossier headers is now available using the reporting engine, and the latest macros_common freemarker template (available from the IUCLID 6 report generator webpage). This affects how you extract the root document in all report templates. In the main body of a report template, to get the rootdocument of a substance or a mixture, you need to use the following <u>assign directives</u> respectively:



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- <#assign substance = _subject />
- <#assign mixture = _subject />

To get the dossier header information (whether a raw or read-only dossier header), you need to use **_dossierHeader**. For example, if you want to extract the Dossier name, you would use **_dossierHeader.Name** in the body of your main freemarker template.

1.1.1.2. Known issues and future improvements

• IUCVI-14368

The PCN Preview Report extracts the 'Submitting Legal Entity' information from the following field:

LEGAL_ENTITY.ContactInfo.ContactPersons.ContactPerson

However, in line with the Legal Entity information as entered in the Legal Entity of ECHA Accounts, the information should be extracted from:

LEGAL_ENTITY.ContactInfo.ContactAddress

In the next July release of IUCLID Cloud, the submitting legal entity information will be extracted from LEGAL_ENTITY.ContactInfo.ContactAddress

• IUCVI-14337

Currently, when copying and pasting text from a webpage into a rich text field, it is not rendered as displayed on the webpage, as the html tag **nbsp** is removed during paste. This tag is removed so that the text does not stretch and run over the page margin.

1.1.2. Validation assistant

IMP Business rule BR207 was improved to check that registration dossiers containing an optout record in section 14 have both a justification and at least one document selected for optout.

IMP An improvement was made to the inquiry business rules: an attachment must always be provided with the methods and results related to the identification of the substance (BR228).

NEW Includes a first version of validation rules for the submission type 'CLP Poison centres notification' (see below for known issues and future improvements).

1.1.2.1. Known issues and future improvements

• Validation report for CLP Poison centres notifications (PCN)

When validating Poison Centres notifications in the *Guided approach for dossier preparation*, the links from validation failures to the corresponding dossier/dataset sections do not work correctly on all occasions. The behavior will be improved in a subsequent IUCLID release this year. Moreover, the validation report does not check PCN Group submissions.

• BR608 – legal entity must be included in PCN dossiers

At present, the legal entity can only be included in the dossier using the *Advanced settings* feature. The feature is not available when validating the PCN mixture dataset and therefore the rule cannot be made to pass during dataset validation. The rule <u>should not be disregarded when validating the final dossier</u> as this will mean that the notification will fail the submission checks when uploaded to the PCN Portal. The behavior will be improved in a later IUCLID release this year.

PCN validation scope

Part 2 of the validation rules for Poison centres notifications will be published in subsequent IUCLID releases this year.

27.3 Technical changes

IMP Derby databases can now have a different schema name than 'iuclid6'

Ref. IUCVI-13613

NEW The new IUCLID version is now running with Open JDK 8. The provided installers and updaters are taking care of implementing the change for the vast majority of users. Administrators of IUCLID servers will have to perform the changes to the IUCLID installations they maintained, if necessary. More information is available on the IUCLID website and in the server installation and update instructions:

https://iuclid6.echa.europa.eu/view-article/-/journal_content/title/iuclid-is-switching-to-open-jdk

Ref. IUCVI-14009, IUCVI-14154, IUCVI-14148

FIX Several fixes were made to the web user interface in Safari browsers

Ref. IUCVI-13377

FIX Issues to work with the web interface when the maximum days of user's inactivity was set to larger than 99 days in the system settings, for Oracle-based installations

Ref. IUCVI-13702

FIX Users with non latin characters in their user name are now able to login



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28 VERSION 3.1.1 (24 OCTOBER 2018)

Please also refer to the Frequently Asked Questions on the IUCLID 6 website.

The releases notes are highlighting changes compared to previous versions of IUCLID 6. In the next sections, improvements are identified with **IMP** and bug fixes with **FIX**.

Here are the main new features (NEW) introduced by the update:

- A new web-based interface that allows IUCLID to be run without the need to install
 additional software. This version of the web interface contains the basic essentials of
 the IUCLID functionality, with the intention of extending the features until it can be the
 only interface available. In the meantime, the previous interface is still supplied, so that
 users always have access to the full functionality.
- Changes to the IUCLID format that include: the latest OECD Harmonised Templates, the incorporation of specific elements for microorganisms datasets, and the support of European Poison Centres notifications.

Note on the versioning: IUCLID 6 version 3.1.1 is the latest official IUCLID 6 release since version 2.0.0 published in November 2017. The versioning of the official releases available on the IUCLID 6 website is not consecutive as other intermediate versions of the application can be made available to specific users or groups of users, for example to:

- answer some specific bugs experienced by users,
- provide new features relevant to a specific users group,
- provide fixes to the ECHA Cloud Services users.

28.1 IUCLID definition providers

The format information is available on the IUCLID 6 website:

https://iuclid6.echa.europa.eu/format

This page contains all information concerning the most recent version of the IUCLID 6 format as well as the documentation of the previous format versions.

In order for the users to be aware of the differences between two versions of the format, a series of Release Notes are made available, per group of documents, so-called 'definition providers'.

28.2 IUCLID new user interface

NEW IUCLID 6.3 comes with an alternative web user interface. This new user interface was initially developed for the purpose of the IUCLID databases provided by the ECHA Cloud services. It has now been integrated as an inherent part of the IUCLID 6 application and will be further enhanced in order to reduce the gap in the functionalities provided compared to the

'classic' IUCLID user interface. This new web interface is meant to replace the 'classic' IUCLID interface which will not be maintained in the future.

The IUCLID Cloud users already benefited from the following IUCLID features in the new web interface:

- REACH dossier creation
- REACH registration dossier 'guided dossier preparation'

In addition to the features already supported by the IUCLID interface made available to the Cloud users, the following functionalities have been (re-)developed in the new IUCLID web interface:

- Annotations management Ref. IUCVI-12077, IUCVI-12078, IUCVI-12101
- Annotations: list all annotations of a dossier at the level for the dossier header Ref. IUCVI-12471
- Anonymous access to a IUCLID instance, without providing credentials Ref. IUCVI-12163
- Configurable top banner Ref. IUCVI-12159
- Copy documents (the list is not limited to 10 records anymore and records from the current dataset can be retrieved) Ref. IUCVI-12336, IUCVI-13284
- Edit the dossier header associated to a submission type, at the dataset level Ref. IUCVI-12507
- Export the dataset, dossier or a single document to PDF Ref. IUCVI-12223, IUCVI-12240
- Login with the IUCLID database authentication Ref. IUCVI-12485
- Management of several submission types for a dataset Ref. IUCVI-12390
- Mixtures management Ref. IUCVI-12239
- Provide a link from a dossier to its corresponding dataset if available in the same database Ref. IUCVI-12459
- Search by dossier UUID Ref. IUCVI-12377
- Share access and change ownership, when Instance-Based Security is activated Ref. IUCVI-12103, IUCVI-12394
- Templates (copy and inherited) options Ref. IUCVI-12535
- User permissions Ref. IUCVI-12381
- View a list of dossiers made from the same dataset Ref. IUCVI-12458
- View datasets and dossiers in a combined list (for substances and mixtures) Ref. IUCVI-12229

This version of the web interface contains the basic essentials of the IUCLID functionality, with the intention of extending the features until it can be the only interface available. In the



meantime, the previous interface is still supplied, so that users always have access to the full functionality. In order to provide access to the different user interfaces, modifications have been introduced to the IUCLID 6 Server main page and to the Starting screen of the Desktop version:

- Updated IUCLID 6 Server main page

	Welcome to IUCLID 6 (3.1.1)
	IUCLID 6 Server is running on the machine that hosts this web page. This version introduces a new interface that you can use via your web browser.
	◀ Use the new IUCLID user interface
	If you would like to use the classic IUCLID user interface, click the button below.
	✓ Use the classic IUCLID user interface
	To run a client to connect to IUCLID 6 Server, Java 8 (JRE) is required, which can be downloaded from the Oracle website.
	Version details
	 The version of this release is 3.1.1 Time of build was 09/10/2018 10:45
	Diagnostics
	Debug info on <u>API endpoint health check</u> Debug info on <u>SSL and headers</u> Client OSGI <u>ars available on this server</u> Legislations <u>installed on this server</u>
	Websites
	IUCLID 6 ECHA Support (ECHA Helpdesk)
-4	· · · ·



- Updated starting screen of the Desktop version



28.3 IUCLID functionalities

28.3.1 Assessment entities

IMP Assessment entities are now handled as standard IUCLID documents under section 1.10. Ref. IUCVI-12443

28.3.2 Clipboard

FIX Progress bar / icon is missing when the user tries to copy endpoint study records & summaries from a template.

Ref. IUCVI-11987

28.3.3 Database migration tool

IMP Update DB migrator tool for v4 format changes. Ref. IUCVI-12734

28.3.4 Document selection

FIX Document Selection step during Import and Export does not properly display Reference Substance Representations.

Ref. IUCVI-11971, IUCVI-11974



28.3.5 Dossier comparison

IMP Possibility to export the dossiers comparison outcome as an HTML file.

Ref. IUCVI-9299

IMP Enhancement of the comparison of dossiers migrated from IUCLID 5.6.

Ref. IUCVI-11120

IMP Export comparison result is not correct if you have changes in repeatable blocks.

Ref. IUCVI-12132

FIX Export comparison result is not possible if you have differences in assessment entities.

Ref. IUCVI-12134

FIX Wrong representation in comparison report appears when we have different dossier type.

Ref. IUCVI-12137

IMP Dossier Creation date/time must appear in comparison report.

Ref. IUCVI-12140

28.3.6 Dossier creation

IMP Specific Table of Content applied for micro-organisms datasets added to a Biocides dossier under the European Biocidal Products Regulation.

Ref. IUCVI-12389

28.3.7 Export

IMP Export to the previous major version has been updated so that IUCLID 6.2 compatible files can be exported from IUCLID 6.3.

Ref. IUCVI-13089

28.3.8 Instance-based security (IBS)

FIX Exception when deleting a group manager.

Ref. IUCVI-11876

28.3.9 Import

FIX Import mechanism removes inherited templates while substance sections have links to inherited documents.

Ref. IUCVI-11854

FIX Ordering of imported summaries & records has inconsistent behaviour.



28.3.10 Printing and reporting

IMP Support of Japanese characters in printing and reporting.

- Ref. IUCVI-11082
- FIX Print process fails for complex rich-text fields.
- Ref. IUCVI-12361
- FIX Inventory entries may not be loaded correctly when printing a reference substance
- Ref. IUCVI-12850
- **IMP** Removing the dossier name from the printed document header.
- Ref. IUCVI-13296

28.3.11 Updater

IMP Introduce new action during upgrade/restore that will remove the impbroker lock file Ref. IUCVI-11965

28.4 IUCLID modules

28.4.1 Dissemination preview

IMP adaptation of the filtering logic to the IUCLID 6.3 changes.

Ref. IUCVI-12906

28.4.2 DNEL calculator

The DNEL calculator now takes into account the information on the toxic effect type available in the endpoint summaries 7.5 Repeated dose toxicity and 7.8 Developmental toxicity – Ref. IUCVI-13149

The DNEL calculator cannot run if the toxic effect type selection (either dose-dependent or concentration-driven) has not been indicated in the relevant summary(-ies). As a consequence, the users that previously calculated systemic DNELs with the DNEL calculator, will have to set the toxic effect type before performing the calculations again. The supporting documentation has been updated as well.

28.4.3 Fee calculator

FIX Fee Calculator: Error occurs when sorting by "Fee amount" in last step of wizard. Ref. IUCVI-11983



28.4.4 Help system

IMP The manual *Functionalities of IUCLID in the web interface* has been updated for IUCLID 6.3.1.

Ref. IUCVI-13203

IMP The built-in help system has been updated for IUCLID 6.3.1. This includes the document *Functionalities of IUCLID 6*, and the ECHA manuals on how to create dossiers.

Ref. IUCVI-13319

28.4.5 Report generator

IMP All reports have been adapted to the IUCLID 6.3 format.

IMP The Report generator wizard contains all the in-built reports which ECHA has made available to IUCLID users. The reports available for generation from a **substance dataset or dossier** include:

- Chemical safety report (CSR)
- Literature references report for substance and mixture/product datasets and dossiers
- List of attachments for substance datasets and dossiers
- NEW Classification and labelling report for lead registrants

The reports available for generation from a mixture/product dataset or dossier include:

- Summary of product characteristics (SPC) report
- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in PDF/RTF formats
- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in CSV formats
- Literature references report for substance and mixture/product datasets and dossiers
- List of attachments for biocidal mixture/product datasets and dossiers (in RTF format)
- List of attachments for biocidal mixture/product datasets and dossiers (in CSV format)
- **NEW** List of annotations for biocidal mixture/product datasets and dossiers

All report templates above, as well as other report templates, can be found from the IUCLID 6 website and uploaded into your own IUCLID instance via the IUCLID Report Manager:

https://iuclid6.echa.europa.eu/reports

28.4.5.1 Summary of new reports

List of annotations for biocidal mixture/product datasets and dossiers

This report is used primarily by assessors from national authorities, and lists the annotations made to IUCLID documents. Each row of the report represents one annotation, and includes all the information entered for that annotation.

Classification and labelling report for lead registrants

This report is used primarily by lead registrants to support the submission of joint registrations under Article 11 of REACH. The report contains classification and labelling information, plus

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basic substance identity information, which can be sent from a lead registrant to a member registrant of the same SIEF.

28.4.5.2 All reports (except for the CSR)

List of attachments for biocidal mixture/product datasets and dossiers (in CSV format)

• All unnecessary line breaks should not appear in the .CSV report from version 6.3 onwards

List of attachments for biocidal mixture/product datasets and dossiers (in RTF format) / List of attachments for substance datasets and dossiers / List of attachments for biocidal mixture/product datasets and dossiers (in CSV format)

• These reports now include the attachment information for the following fields:

FLEXIBLE_RECORD.ChemicalSafetyReport.CSR.CSRDocument

FLEXIBLE_RECORD.ChemicalSafetyReport.CSR.ExportFileDocument

List of annotations for biocidal mixture/product datasets and dossiers

• No Access does not prevent the generation of the Annotations report, and all No Access data should be removed from the report output

28.4.5.3 Other improvements in current reports

- Dossier header information is now fetched for the relevant reports
- The Literature reference and Attachment reports can now handle exceptionally large datasets and dossiers, and generate without failure
- The customised stylesheet used by several reports and available from the IUCLID 6 website, now contains the possibility to use specify different font colours in the report FTL
- FIX DocBook conversion to .rtf fails when .png images are present Ref. IUCVI-11962

28.4.5.4 Known issues and future improvements

- The IUCLID Web interface allows a report to reference and make a link to a specific IUCLID entity. To accommodate this and make it truly customisable using an FTL report template, the reporting engine will be modified to fetch the Server URL (hostname/port). In future, reports can then easily link back to the entity which is being made reference to in a report: Ref. IUCVI-13012
- If one of the FTL files is encoded in UTF-8 with byte order mark, then report generation fails: Ref. IUCVI-11784
- The IUCLID web interface currently accommodates the generation of the Chemical Safety Report. In a future release, all in-built report templates will be available to users from the web interface. Ref. IUCVI-13178



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• In a future release of the IUCLID web interface, advanced options will be available to allow users to pre-select which documents are taken into consideration for report generation, and if confidential information should be displayed

28.4.5.5 Chemical Safety Report (CSR)

Fixes and improvements

General

- The hash sign [#] has been replaced by a string text (for example Annex III) for the hyperlink made to the relevant annex.
- A hyperlink has been made between each study summary linked to an assessment entity and the assessment entity description.

Chapter 1

• 1.3 (1.4 if assessment entity exists): The information related to the physicochemical properties has been reorganised in the related table in order to improve its readability.

Chapter 3

• 3.1: Classification according to GHS is now correctly printed.

Chapter 4

• 4.3.3: The information related to the endpoint summaries 5.3.1 and 5.3.2 is now also reported even if the summary in section 5.3 is not available.

Chapter 5

- 5.3: In vitro skin irritation data waiving information is now correctly displayed when needed.
- 5.7.1.1: changes have been made in a table header to align with its content

Chapter 7

• Improvement of the readability of all endpoint summaries.

Known issues

General

- Page numbers are not available in the table of content generated as .RTF. Please press the "CTRL+ A and F9" to update the ToC.
- Word wrap doesn't work properly when generating .PDF report, however this works with an .RTF report (Ref. IUCVI-8995)
- Rich-text field issues (Ref. IUCVI-9018)
 - Currently, when a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
 - When text is numbered, the numbering is not sequential, with each number remaining as "1."
 - Not all changes to the font in a rich-text field are reflected in the generated CSR, affecting for example the display of the font size and style

 Styles in the .rtf document are missing. As a consequence, the ToC cannot be recreated automatically once one (or more) header is deleted in the document (Ref. CHRIII-1226, IUCVI-9619). However a workaround is described in Q53 "I cannot print or generate a report from IUCLID, what should I do?" available at https://iuclid6.echa.europa.eu/faq

Annexes

- References: All references mentioned in the CSR are reported in the Annex I and ordered according to how they appear in the CSR and not alphabetically (Ref. IUCVI-9203)
- Test material information: currently the indication of which endpoint study the test material is linked to is missing. (Ref. IUCVI-9204)
- The Reference entries in the Annex I are not separated in the CSR when it is generated as a .PDF. However, in the .RTF they are correctly displayed (Ref. IUCVI-9019)

28.4.6 Validation assistant

NEW quality rule QLT173 implemented. Rule checks that pre-registration or inquiry number is provided in section '1.3 Regulatory identifiers' in initial dossiers.

NEW business rule BR220 checks that all lead registrants have provided 'Boundary composition'.

NEW Implemented two new rules for 'BPR Active substance application (representative product)' and 'BPR Biocidal product authorisation', these validations were previously implemented as part of the dossier creation wizard in the IUCLID interface.

NEW Includes first beta-version of validation rules for 'CLP Poison centres notification'.

NEW First beta-version of validation checks created for the new submission type 'AU Industrial Chemicals Certificate Application'. The scenarios have been configured to run on selected existing business rules, completeness check rules and quality rules. New rules TCC_NICNAS_01 and TCC_NICNAS_02 added.

Known issues and future improvements

- Due to the new possibility to add several endpoint records in section 1.3 Regulatory identifiers, some business rules checking content in that section do not work properly if several endpoint records are created.
- The ordering of the failures or warnings reported in the web interface of IUCLID is different from the ordering of the issues in the classic user interface. This will be corrected in future releases.

28.5 Integration with other tools / API

28.5.1 IUCLID Public API

The API documentation is maintained on the IUCLID 6 website:



https://iuclid6.echa.europa.eu/public-api

The following changes (extensions) are introduced with this IUCLID version:

- Copy a template into a dataset
- Customization of the export archive endpoint (exclude stylesheets, empty elements)
- Dossier comparison
- Dossier filtering
- Export a dataset / dossier to PDF
- Link/unlink a template into/from a dataset
- Link/unlink annotation to a document/dossier
- Section document reordering in datasets

28.5.2 Chesar

IUCLID 6.3.1 is fully compatible with Chesar 3.4 that will be published early November 2018. For more details on the Chesar release, see the news section on the <u>Chesar website</u>.

28.6 Miscellaneous

IMP and FIX Various security and performance fixes and improvements

Ref. IUCVI-10660, IUCVI-11562, IUCVI-11814, IUCVI-11815, IUCVI-11812, IUCVI-11838, IUCVI-11883, IUCVI-11885, IUCVI-11895, IUCVI-11906, IUCVI-11908, IUCVI-11929, IUCVI-11960, IUCVI-11972, IUCVI-11994, IUCVI-11999, IUCVI-12026, IUCVI-12038, IUCVI-12049

IMP Files linked to deleted documents are now deleted from the database as well.

Ref. IUCVI-11597

IMP Glassfish server upgrade to v4.1.1



29 VERSION 2.0.0 (15 NOVEMBER 2017)

Please also refer to the Frequently Asked Questions on the IUCLID 6 website.

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

In the next sections, improvements are identified with IMP and bug fixes with FIX.

Here are the main new features (NEW) introduced by the update:

- o Fee calculator
- o Export to the previous IUCLID 6 version

A presentation of this release is available on the IUCLID 6 website:

https://iuclid6.echa.europa.eu/videos

29.1 IUCLID legislations

Format changes are documented below.

The format information is available on the IUCLID 6 website:

https://iuclid6.echa.europa.eu/format

The page above contains all information concerning the most recent version of the IUCLID 6 format as well as the documentation of the previous format versions.

In order for the users to be aware of the differences between two versions of the format, a series of Release Notes are made available, per group of documents, so-called 'legislation'.

Some of the main changes made to the format are listed hereafter.

29.1.1 CORE

IMP Relabeling of 'Description of composition'

- Ref. IUCVI-10964
- IMP Changes in section 11 'Guidance on safe use'
- Ref. IUCVI-10969
- **IMP** Addition of 'free text' templates (guidance on safe use)
- Ref. IUCVI-10968
- **IMP** New field in Dossier Header substance evaluation
- Ref. IUCVI-11007
- IMP New structure of SUBSTANCE entity, in the context of v2.0.0
- Ref. IUCVI-11494

IMP Endpoint summary section 7 'Explanation for hazard conclusion' to be moved outside the collapsible block 'DNEL related information'

Ref. IUCVI-9166

IMP Introduce lower/upper limit information in document definitions



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Ref. IUCVI-11401

- IMP Section 5.4.1 endpoint summary Removal of LogKoc
- Ref. IUCVI-11022
- IMP Documents 5.2.1 and 5.2.2 differentiation between freshwater and marine water
- Ref. IUCVI-11016
- IMP Change field 'Category rationale' from text area to text template (category)
- Ref. IUCVI-11005
- **IMP** ENDPOINT_SUMMARY.Datatox under section 7: fields with missing label
- Ref. IUCVI-10894
- IMP 2.1 Self vs harmonised classifications
- Ref. IUCVI-10986
- IMP 3.2 'Remarks' field
- Ref. IUCVI-10989
- IMP 2.1 Inactivity of 'Not classified' checkbox
- Ref. IUCVI-10982
- IMP 3.3 Site with multiple legal entities
- Ref. IUCVI-10990
- IMP GHS Adaptations due to GHS revisions and CLP ATPs
- Ref. IUCVI-10987
- FIX Section 3.5 Alignment of PROC and PC names
- Ref. IUCVI-11029
- IMP Section 6 endpoint summary New picklist entry
- Ref. IUCVI-11020
- IMP Endpoint summaries No negative values allowed
- Ref. IUCVI-11018
- **IMP** Legal entity Extension of identifiers
- Ref. IUCVI-11023
- IMP Updates in Literature references, in the scope of v2.0.0
- Ref. IUCVI-11125
- **IMP** 1.1 Picklist review type of substance micro organism
- Ref. IUCVI-11028

29.1.2 OECD

IMP 7.8.2 - Removal of redundant fields Ref. IUCVI-11003 **IMP** 4.22 - Replacement of picklist (phrase group) value

Ref. IUCVI-10995

FIX 7.8.2 picklist - Overall developmental toxicity has wrong picklist.

Ref. IUCVI-11002

IMP Update wording of phrase 212 (Melting point / freezing point document)

Ref. IUCVI-9692

FIX Correct wording of data waiving phrase in section 4.11 'Flash point'

Ref. IUCVI-9711

IMP Text template added to field 'Justification for type of information'

Ref. IUCVI-11275

FIX Sections 4.24 and 4.26 - Block 'Overall remarks, attachments' missing in two sections (OECD templates)

Ref. IUCVI-11102

IMP Add values to section 7.6.1 field Type of assay

Ref. IUCVI-11001

NEW New dossier header for submission type: Exchange of experimental data

Ref. IUCVI-11616

NEW and IMP Update of pesticide templates (OHTs) 85-1 to 85-10

Ref. IUCVI-11043

IMP Improve the text template of the Confidential details on TMI

Ref. IUCVI-11033

FIX 4.15 - Removal of picklist value

Ref. IUCVI-10994

IMP 7.3.2 - Table headings

Ref. IUCVI-10998

IMP Endpoint Study Records - Alignment of justification phrases (section 7)

Ref. IUCVI-11015

29.1.3 REACH

IMP 14 - Conditional formatting DU report

Ref. IUCVI-11011

NEW Downstream user REACH art. 66 document and new submission type

Ref. IUCVI-11013, IUCVI-11032

NEW Inclusion of 'OHT Endocrine disrupter testing in aquatic vertebrates – in vivo' in REACH dossiers

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Ref. IUCVI-11031

IMP Optionality of documents in DU reports Ref. IUCVI-11010

29.1.4 CLP

No changes

29.1.5 BPR

IMP 14.3.6 - New picklist values

Ref. IUCVI-10976

IMP 14.3.9 - Changes in picklist

Ref. IUCVI-10977

IMP 4.6 - mapping of section 4.6 to 4.11

Ref. IUCVI-10996

FIX Duplication of information in Biocides templates

Ref. IUCVI-10965

- IMP BPR submission types: Endpoint summary 'Terrestrial toxicity' added
- Ref. IUCVI-11167

FIX 14.3.2 - Wrong picklist

Ref. IUCVI-10975

FIX BPR: wrong reference in section 6.8 (mixture/product only)

Ref. IUCVI-11232

FIX BPR Basic information (mixture): incorrect numbering

Ref. IUCVI-11168

29.2 IUCLID functionalities

29.2.1 Attachments

FIX Attachments to records (in the information panel) should be able to be deleted according to the user's permissions

Ref. IUCVI-11405

29.2.2 Clipboard manager

IMP Clipboard Manager: Mention of missing elements during paste all Ref. IUCVI-11152



FIX Error when pasting Fixed Record that is referenced in an Endpoint Study Record Ref. IUCVI-10921

FIX An exception message appears when the user tries to copy all documents from a dossier Ref. IUCVI-11182

FIX Clipboard Manager: Error when pasting very large number of documents

Ref. IUCVI-11107

FIX Clipboard manager: The name of the element is not correct if you rename a new record Ref. IUCVI-11155

29.2.3 Confidentiality flags

IMP Separation of Confidentiality flags and Restriction checkboxes (user interface level) Ref. IUCVI-11006

IMP Data Protection (Confidentiality) fields should explicitly define which fields they are protecting

Ref. IUCVI-10913

29.2.4 Document dynamic content

IMP 7.3.2 eye irritation conditional formatting Ref. IUCVI-11470

29.2.5 Dossier and export

IMP Simplify the flow between the dossier creation and the export or validation assistant actions for example

Ref. IUCVI-10950

FIX List dossier is not possible on distributed Linux environment

Ref. IUCVI-11359

FIX Modification history contains the working legal entity of the User despite the fact the user selects excluding legal entity during the dossier creation

Ref. IUCVI-11066

29.2.6 Printing

IMP As a user I would like to print studies without confidential fields or reference to the parent entity



29.2.7 Search

FIX Reference substance browse search results are not correct *Ref. IUCVI-11154*

29.3 IUCLID modules

29.3.1 Dissemination preview

IMP Improve Dissemination Preview results - use IUCLID tree to sort "Document name" column

Ref. IUCVI-10927

29.3.2 Fee calculator

IMP Release of the fee calculator

29.3.3 Help system

IMP Update of the help system for version 2.0.0 of IUCLID 6. The main changes are indicated at the beginning of the manual.

Ref. IUCVI-

29.3.4 Report generator

FIX Full CSR: Text entered in rich text boxes with new lines and exported to IUCLID is not displayed

Ref. IUCVI-11185

FIX Full CSR: Hazard pictograms are printed twice when generating from Chesar

Ref. IUCVI-11183

FIX Generate report for a substance fails if it is linked with a reference substance which has only a name

Ref. IUCVI-10959

FIX When the character "&" is in an attachment, the reporting engine fails to generate

Ref. IUCVI-11518

IMP Add ordering buttons in Output table of "Edit report" form



29.3.4.1 New reports

There are a set of new reports (report templates are available to download from the <u>IUCLID 6</u> <u>website</u>) which are now in-built into the Report generator wizard, and are found under 'Type of report' when running the Report generator wizard:

- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in PDF/RTF formats
- Biocidal Products Regulation Confidentiality Report (BPR Article 66) in CSV format
- Literature References report for substance and mixture/product datasets and dossiers
- List of attachments for biocidal mixture/product datasets and dossiers (in RTF format)
- List of attachments for substance datasets and dossiers
- List of attachments for biocidal mixture/product datasets and dossiers (in CSV format)

Notes on new reports

- "Biocidal Products Regulation Confidentiality Report (BPR Article 66) in PDF/RTF formats": this report is used primarily by assessors from national authorities, and has been extended to include an updated disclaimer, a hyperlink to the document containing the confidentiality claim, an additional column for ECHA assessment, as well as a summary box at the end of the report for national authority assessors to summarise their assessment.
- "Biocidal Products Regulation Confidentiality Report (BPR Article 66) in CSV format": this report is a simple CSV table (opened in MS Excel) of relevant confidentiality claims under Article 66, and does not contain the introduction and disclaimer which the report "Biocidal Products Regulation - Confidentiality Report (BPR Article 66) in PDF/RTF formats" contains.
- "Literature References report for substance and mixture/product datasets and dossiers": this report can be generated from either a substance or mixture/product datasets and dossiers. The mixture/product report contains additional information specifically to assist national authorities in their work under the Biocidal Product Regulation. A hyperlink is included to go directly to a specific IUCLID document (when using a server version of IUCLID).
- "List of attachments for biocidal mixture/product datasets and dossiers (in RTF format)": the report contains additional information specifically to assist national authorities in their work under the Biocidal Product Regulation. A hyperlink is included to go directly to a specific IUCLID document (when using a server version of IUCLID).

Known issues for new reports



IUCLID6

- "List of attachments for biocidal mixture/product datasets and dossiers (in CSV format)": this report has formatting issues which sometimes causes blank spaces between data and data which is shifted outside of the cell. Otherwise, the data in the CSV file is complete and, if necessary, the format adjusted inside the CSV file.
- "List of attachments for biocidal mixture/product datasets and dossiers (in RTF format)", "List of attachments for substance datasets and dossiers", "List of attachments for biocidal mixture/product datasets and dossiers (in CSV format)": these reports do not currently include the attachments for the following fields:
 - o FLEXIBLE_RECORD.ChemicalSafetyReport.CSR.CSRDocument
 - FLEXIBLE_RECORD.ChemicalSafetyReport.CSR.ExportFileDocument

29.3.4.2 Chemical Safety Report (CSR)

Changes compared to the previous version of the CSR generated by IUCLID:

General

- Adaptation to the format changes of IUCLID 6.2
 - "Type of water" has been introduced to related picklist entry after the "Value used for CSA" both for the discussion (screening testing) and the discussion (Simulation testing) (section 4.1.2.1.3).
 - "Log KOC" value has been removed from the CSR "Key value" for chemical safety assessment.
- Readability improvements:
 - No labels are printed for corresponding IUCLID fields without given information.
 It applies among others to endpoint summary labels, "Data waiving / Test material" information, Annex II;
 - o Removal of question marks appearing on test material information;
 - General readability of the report has been improved by introducing additional spaces between headers and normal text, and by adding coloured table headers.

Chapter 1

 Structural formula image has been introduced in chapter 1.1. "Name and other identifiers of the substance". The formula can be uploaded into IUCLID in .jpg, .jpeg, .gif and .png formats. • "Data waiving" and "Test material" labels are not printed if no information is provided in any endpoint records.

Chapter 2

- ERCs and PROCs default descriptions are now displayed in all contributing activities/techniques, when no name is defined by the user.
- "Subsequent service life relevant for that use" now is correctly appearing in the document

Chapter 3

• Pictograms along with corresponding descriptions are now available in the CSR.

Chapter 5

- The studies in the results table are now sorted according to the "Species", "Type of study", "Endpoint", "Type of genotoxicity" or "Route of administration"
- New sections for additional toxicological effects were added:
 - o 5.10.1.4. "Additional toxicological effects"
 - o 5.10.3. "Summary and discussion of other effects"

Chapter 7

• "Atmospheric compartment" section is now always printed

Annexes

• Annex III containing information on "Mode of action / Human relevance Framework" has been introduced.

Known issues

- Page numbers are not available in the table of content generated as .rtf. Please press the "CTRL+ A and F9" to update the ToC.
- Word wrap doesn't work properly when generating .pdf report however works with .rtf (Ref. IUCVI-8995)
- Rich-text field issues (Ref. IUCVI-9018)
 - Currently, when a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
 - When text is numbered using the button, the numbering is not sequential, with each number remaining as "1."
 - Not all changes to the font in a rich-text field are reflected in the generated CSR, affecting for example the display of the font size and style



 Styles in the .rtf document are missing. As a consequence, the ToC cannot be recreated automatically once one (or more) header is deleted in the document (Ref. CHRIII-1226, IUCVI-9619)

Annexes

- References: All references mentioned in the CSR are reported in the Annex I and ordered according to how they appear in the CSR and not alphabetically (Ref. IUCVI-9203)
- Test material information: currently the indication of which endpoint study the test material is linked to is missing. (Ref. IUCVI-9204)
- The Reference entries in the Annex I are not separated in the CSR when it is generated as a .pdf. However, in the .rtf they are correctly displayed (Ref. IUCVI-9019)

29.3.5 Validation assistant

NEW Implemented new completeness check rules (TCC) to verify that the new data waiving justification phrases based on the amended REACH Annexes are backed up by appropriate data (sections 7.2.3, 7.3.1, 7.3.2, 7.4.1)

IMP Improved completeness check rules (TCC) to verify that data waiving in section 4 based on that the substance is flammable, explosive, pyrophoric, self-reactive or organic peroxide is substantiated by the appropriate classification

IMP Improved completeness check rule TCC_0102_20 which checks that UVCB substances contain a composition or a justification for deviations

IMP Improved completeness check rule TCC_ESR_A62 which checks that data waiving of the sub-chronic toxicity study in section 7.5 is substantiated by the appropriate classification and short-term study

IMP Adapted all business rules and completeness check rules that check section 13 to the new IUCLID 6 v.2.0.0 format

IMP Implemented new and improved business rules (BR) for the submission types Substance in article notification and downstream user report

NEW Implemented new quality rules (QLT) for hazard endpoints (sections 7.3.1, 7.3.2, 7.4.1, 7.6.1, 7.8.1, 7.8.2)

NEW Added a new validation scenario for the new submission type 'Exchange of experimental data' (outside the REACH or CLP regulatory context). The scenario has been configured to run the existing business rules, completeness check rules and quality rules that apply to the data in such a dossier and that are not directly linked to REACH/CLP concept.

IMP The default sorting of the Validation assistant UI report should follow the column 'Section number'

Ref. IUCVI-11531

29.4 Integration with other tools / API

29.4.1 Chesar

FIX Error on export of Uses from Chesar to IUCLID (Client's transaction aborted) *Ref. IUCVI-11455*

29.4.2 Public API

IMP Public REST API does not return "Remarks" and "Version" content from dossier header
Ref. IUCVI-11383
FIX Fail to create new document/entity with top-level attachments
Ref. IUCVI-11596
FIX IUCLID API fetch and display wrong (outdated) phrases for phrase group B07
Ref. IUCVI-11687
IMP Public REST API should support the retrieval of Categories linked to an entity
Ref. IUCVI-11634

29.5 Miscellaneous

IMP Date / time representation improvement
Ref. IUCVI-10843
FIX Integers migrated as decimals
Ref. IUCVI-11017
IMP As a user I would like to see more rows of a table in IUCLID, by default
Ref. IUCVI-10928
IMP Multiple selection of Users is not possible in Group management
Ref. IUCVI-10500



30 VERSION 1.3.0 (28 APRIL 2017)

Please also refer to the Frequently Asked Questions on the IUCLID 6 website.

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

No changes have been made to the IUCLID format in this version and full compatibility is maintained across IUCLID 6 versions (i.e. all IUCLID 6 files can be exchanged with all IUCLID 6 versions).

In the next sections, improvements are identified with IMP and bug fixes with FIX.

Here are the main new features (NEW) introduced by the update:

- o PNEC calculator
- o Dossier header re-use
- o Advanced features of the report generator

30.1 Background job

NEW After an import of a IUCLID file, it is now possible to navigate directly to the imported data using an option in the background job window.

Ref. IUCVI-8868

30.2 Clipboard

FIX A paste as reference should not be allowed for fixed records. *Ref. IUCVI-10877*

30.3 Comparison tool

IMP The dossiers to be compared can now be retrieved using their UUIDs.

Ref. IUCVI-10579

30.4 Data edition

IMP When editing a text field in a pop up window, when maximising the window, the edition zone should also be maximised.

Ref. IUCVI-10636

FIX An incorrect message was displayed when deleting a fixed record (e.g. section 1.3 record) linked to another record.



FIX A non user friendly message was displayed when uploading an image with an unsupported file format.

Ref. IUCVI-10881

NEW A new submission type has been added in order to support the 'Exchange of experimental data' outside any regulatory context. This submission type is a prototype and is subject to further validation with the IUCLID users' community. That is the reason why the dossier creation using this submission type is not yet enabled.

Ref. IUCVI-10896

FIX Save and clear of multi-line invalid data in a document freezes the IUCLID client.

Ref. IUCVI-10766

FIX The user is not able to add an attachment which has the characters {} in the file name. *Ref. IUCVI-10874*

30.5 Database patch tool

IMP The database patch tool is now able to detach incorrect references to fixed records.

Ref. IUCVI-10876

30.6 Dissemination preview

IMP Implementation of a new rule for the filtering of nanomaterial information.

Ref. IUCVI-10758

IMP The ordering and sorting of the dissemination preview report has been improved. All columns can now be sorted and the default sorting is done on the 'Section name' (numeric sorting).

Ref. IUCVI-10762

FIX The copy of the full report is now possible to Excel.

Ref. IUCVI-10691

30.7 Dossier creation

NEW Described in the <u>IUCLID 6 functionalities manual</u> (section 7.1.4). During the dossier creation there is now the possibility to load the information that was previously entered in the dossier header (administrative data related to the submission of information) of dossiers created for the same substance.

Ref. IUCVI-6026

FIX The inquiry section is now indicated as mandatory for 'REACH Inquiry'.



FIX Attachments added to the dossier should be considered as dossier information in the database and the .i6z files.

Ref. IUCVI-10821

30.8 Help system

IMP Update of the help system for version 1.3.0 of IUCLID 6.

Ref. IUCVI-11036

30.9 Import / export

FIX The import mechanism should ignore i6d documents placed under the attachments folder.

Ref. IUCVI-10767

FIX An exception message appears if the user tries to import the EC inventory using the replace mode.

Ref. IUCVI-10433

FIX Document selection produces validation error in some cases as related documents selection is not updated accordingly.

Ref. IUCVI-10413

IMP The performance has been improved for the document selection during import, export and dossier creation.

Ref. IUCVI-10090

30.10Information panel

FIX A 'Null' value was displayed in the annotations tab in the information panel when empty values existed.

Ref. IUCVI-10418

FIX Error while loading the attachment tab when the document contains several attachments.

Ref. IUCVI-10866

30.11 Installer and updater

NEW A IUCLID Desktop updater is now available for Mac OS. The first Mac installer was published with IUCLID version 1.2.0. This is the first time an updater is needed for this operating system. It can be downloaded from the <u>IUCLID website</u>.

Ref. IUCVI-10651

FIX Due to a change made to the installer in order to support High DPI screens, the installation of IUCLID was sometimes blocked by Antivirus systems. A new installer which does not include the High DPI screen fix is now available on request to the <u>Helpdesk</u>.

Ref. IUCVI-10610

IMP The installer memory setup mechanism has been amended in order to allow external parametrization of the maximum heap size allocated. This takes place via a configuration file that is placed in the same level with the iuclid6-installer.exe file. This will be documented on the <u>IUCLID website</u>.

Ref. IUCVI-10889

30.12Instance based security (IBS)

IMP The performance of bulk change of ownership has been improved.

Ref. IUCVI-10501

30.13Navigation

FIX 'No access' appeared for legal entities for read-only users without Instance Based Security activated.

Ref. IUCVI-10435

30.14PNEC calculator (NEW)

NEW Described in the <u>IUCLID 6 functionalities manual</u> (section 20). The aim of the PNEC calculator is to support the derivation of Predicted No-Effect Concentrations for the aquatic, sediment and terrestrial environmental protection targets based on ECHA Guidance on Information Requirements and Chemical Safety Assessment. It also populates automatically the 'Ecotoxicological information' summary record in section 6 of IUCLID.

30.15Printing

IMP Assessment entities are now printed together with the substance dataset.

Ref. IUCVI-10392

FIX Error printing a reference substance that contains an invalid formula image.

Ref. IUCVI-10872

30.16Public REST API

IMP The linking of attachments to documents is now supported. *Ref. IUCVI-10739*



IUCLID6

IMP It is now possible to determine the type of entity (e.g. dossier, substance or mixture dataset) imported using the Public REST API import endpoint.

Ref. IUCVI-10747

30.17Report generator

NEW Described in the <u>IUCLID 6 functionalities manual</u> (section 23). The Report generator now contains a Report manager that allows the user to upload additional report templates and make them available to all the users of the same IUCLID database. Examples of report templates are available on the <u>IUCLID website</u>.

Ref. IUCVI-10551

FIX The report generation was failing when invalid XML characters were present in a dataset.

Ref. IUCVI-10820

FIX The report generation was failing when the dataset contained a reference substance with an image and a customised stylesheet was used.

Ref. IUCVI-10890

IMP The report generator engine is extended to support access to the modification history per document.

Ref. IUCVI-10880

30.17.1 Chemical Safety Report (CSR)

Changes compared to the previous version of the CSR generated by IUCLID

- General
 - The information in Part A should be provided in section 13 of IUCLID before proceeding with the generation of the CSR
 - The creation of a Joint or Own CSR is now defined in section 13 of IUCLID.
 This section includes the picklist options "all uses" "own CSR" or "joint CSR" which trigger the corresponding CSR generation type
 - Information triggered from the CSR report generator has been updated according to the new IUCLID format
 - Table numbers are numbered according to the related chapter and not consecutively as in the previous versions of the CSR generator
 - In all study result tables the column "References" has been removed and the references put in the "Results" one.
 - Basic assessment entity information is available in the CSR generated
- Chapter 1
 - Nanomaterial information has been added to the CSR

- Chapter 2
 - Changes have been made to the layout of the tables related to all uses so as to better accommodate the new information captured from IUCLID
- Chapter 3
 - Classification and labelling according to DSD/DPD has been removed from the generated CSR
- Chapters 4-8
 - In all study result tables the column "References" has been removed and the content put in the "Results" one.
 - \circ $\;$ Justification for type of information available in all result tables
 - In all result tables, the result flagged as "key result" is displayed always as first entry.
- Chapters 9 and 10
 - o No information is available in these sections besides the Chapter headers

Fixes and improvements

- General
 - Improvements on the format: endpoint summaries: removal of labels if no information is available in the corresponding field
 - o Improvement in the display of the footer of the CSR
- Chapter 1: "data waiving" and "test material" labels now not appearing if no information is provided in any endpoint records
- Chapter 2: improvement in the display of information in the tables: beside the related identifiers, now the ERC/PROC name is appearing if no "name of the activity/technique" is provided. Labels are not appearing in the tables from 2.1-2.6 if no information is available
- Chapter 7: removal of the "assessment factor" labels in section 7.5
- Chapter 8: labels and sections are not printed if no information is available

Known issues

- General
 - Page numbers are not available in the table of content generated as .rtf. Please press the "CTRL+ A and F9" to update the ToC.
 - The Reference entries in the annex 1 are not separated in the CSR when it is generated as a .pdf. However, in the .rtf they are correctly displayed (*Ref. IUCVI-9019*)



- Few labels are still printed in the CSR even if no information is available in the corresponding IUCLID fields
- o Extra empty lines are available in all tables of the CSR
- Rich-text field issues (*Ref. IUCVI-9018*)
 - Currently, when a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
 - When text is numbered using the ¹=¹ button, the numbering is not sequential, with each number remaining as "1."
 - Not all changes to the font in a rich-text field are reflected in the generated CSR, affecting for example the display of the font size and style
- Styles in the .rtf document are missing (Ref. CHRIII-1226)
- Chapter 5
 - The studies in the results table are not sorted according to the "Species", "Type of study", "Endpoint", "Type of genotoxicity" or "Route of administration"
- Annexes
 - References: All references mentioned in the CSR are reported in the Annex I and ordered according to how they appear in the CSR and not alphabetically (*Ref. IUCVI-9203*)
 - Test material information: currently the indication of which endpoint study the test material is linked to is missing. (*Ref. IUCVI-9204*)

30.18Restore

FIX Launching IUCLID did not work after a restore under a Linux or Mac environment. *Ref. IUCVI-10947*

30.19Server version

IMP The launch of the IUCLID client is now automated. There is no need to click 'Start application' in order to start the launch process of the client when using the IUCLID 6 Server version.

Ref. IUCVI-10597

FIX Incessant error messages were logged when the client lost the connectivity to the server.

30.20Validation Assistant

FIX Fixed bug in quality rule QLT069 which checks the consistency between the degree of purity and the concentration of an impurity

IMP Improved quality rule QLT098 to also consider the late pre-registration number format as valid

NEW Quality rules (QLT) implemented for classification and labelling (section 2.1)

NEW Quality rules (QLT) implemented for hazard endpoints (sections 6.3.1, 6.3.2, 6.3.3, 7.3.1, 7.3.2)



31 VERSION 1.2.0 (31 JANUARY 2017)

Please also refer to the Frequently Asked Questions on the IUCLID 6 website.

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

No changes have been made to the IUCLID format in this version and full compatibility is maintained across IUCLID 6 versions (i.e. all IUCLID 6 files can be exchanged with all IUCLID 6 versions).

In the next sections, improvements are identified with IMP and bug fixes with FIX.

Here are the main changes introduced by the update:

- o DNEL generator
- IUCLID hyperlinks
- Printing and report generation fixes and performance improvements

31.1 Annotations

FIX dossier export failed when the included Legal Entity contained an annotation.

Ref. IUCVI-9918

FIX The status of an annotation is now displayed in the 'Annotations' tab of the information panel.

Ref. IUCVI-10300

31.2 Attachments

FIX Errors were happening when attaching files to IUCLID fields, particularly as part of a dossier creation.

Ref. IUCVI-9921

31.3 Background jobs

FIX A discrepancy was observed between the times reported in different places of the background jobs. The times of the server or the client were reported creating inconsistencies. Now all times are aligned according to the client time zone.

Ref. IUCVI-9848

31.4 Clipboard manager

IMP When copying records which have the default IUCLID name (IUCLID UUID), the naming follows the standard logic (i.e. adding the suffix '-copy').

Ref. IUCVI-9887

IMP When copying record, the suffix '-copy' is only added when there is already an occurrence of the name in the destination IUCLID section.

Ref. IUCVI-9513

IMP Records from the clipboard that cannot be copied to the destination dataset are not blocking anymore the copy process. Instead, a warning is displayed to the user in order to list the records that could not be copied.

Ref. IUCVI-9657

31.5 Dissemination preview

FIX Improvement of the performance of the dissemination preview process.

Ref. IUCVI-9975

IMP The check box 'Add report as an attachment to the filtered document' is not displayed anymore as the function is obsolete.

Ref. IUCVI-8910

31.6 DNEL generator (NEW)

New feature described in the <u>IUCLID 6 functionalities manual</u> (section 21). The aim of the DNEL calculator is to support the derivation of Workers and General Population Derived No-Effect Levels for long-term systemic effects for oral, dermal and inhalation routes based on ECHA Guidance.

Ref. IUCVI-9963

31.7 Document selection (export / import)

FIX 'Document Selection' was not working properly in 'Entities list' panel when exporting a record.

Ref. IUCVI-9488, IUCVI-10409

31.8 Dossier creation / Export

FIX The flag 'substance of concern' was wrongly overriding the 'active substance' status in a BPR dossier.

Ref. IUCVI-9803

FIX The validation of the content of some dossier header fields has been fixed.

Ref. IUCVI-9922

IMP In the case of the dossier creation or export of a substance included in categories, the user can now select, in the advanced options, the level of information to be included for the



category members. By default, only the endpoint study summaries are included during dossier creation and all information is included during export.

Ref. IUCVI-10224, IUCVI-9978

FIX When creating a dossier for a substance linked to a category, the exclusion of the Legal entities was not working as expected.

Ref. IUCVI-10289

31.9 Help system

IMP Update of the help system for version 1.2.0 of IUCLID 6.

Ref. IUCVI-9795

FIX Links from help icons restored.

Ref. IUCVI-9919

31.10Hyperlinks (NEW)

New feature described in the <u>IUCLID 6 functionalities manual</u> (section 1.3.4). The feature hyperlink provides a way of creating a web-based hyperlink to an entity or document within IUCLID 6. Following the hyperlink causes a new instance of the IUCLID 6 interface to be opened. After a User logs in, the entity or document is displayed in the data window. This feature is available only for IUCLID 6 Server.

Ref. IUCVI-7644

31.11 Import

FIX The Replace option is disabled when the action is not relevant.

Ref. IUCVI-10194

IMP Performance of re-import of large IUCLID 6 files (i.e. thousands of documents).

Ref. IUCVI-10233

IMP Performance of import for Derby database has been improved.

Ref. IUCVI-9814

31.12Installer, updater and other IUCLID tools (e.g. migration tool)

IMP Memory configuration to run the installer has now been optimized for 32-bit and 64-bit systems.

Ref. IUCVI-9750, IUCVI-10544

IUCLID6

FIX When a Desktop version is installed without user management, users from a IUCLID 5 database are not migrated.

Ref. IUCVI-9895

IMP IUCLID tools have been updated in order to be able to re-use the Java version provided by IUCLID if they are executed from a IUCLID 6 installation folder.

Ref. IUCVI-10113

31.13Inventory manager

FIX Replacing an already selected entity caused an error.

Ref. IUCVI-10232

31.14Navigation panel

FIX The filtering of the results displayed in the navigation panel for substances did not take into account the reference substance details.

Ref. IUCVI-10319

New feature A Chesar table of content can now be selected to help users filling-in the information relevant to be shared between IUCLID and Chesar. The relevant data can also be selected for export.

Ref. IUCVI-10252

IMP When navigating in a dossier (dossier components) or inside the Table of Content of a dataset, the selected record and the corresponding sections(s) are indicated in bold, helping the user knowing which information is displayed in the data area.

Ref. IUCVI-10050

31.15Print

FIX Improvements have been made in order to prevent the printing function to fail because of 'malformed' rich text fields. The solution is now configurable in order to provide fixes to problematic cases identified in the future, without requiring a new IUCLID release.

Ref. IUCVI-10264

IMP Improvement of the performance of printing large datasets (thousands of documents). Although the printing process still requires enough memory for large datasets, the performance is improved.



31.16Public (REST) API (NEW)

New feature The IUCLID 6 Public REST API, initially published as a beta version in September 2016, has now been finalized and is officially published with version 1.2.0. The corresponding documentation is maintained on the IUCLID 6 website: <u>https://iuclid6.echa.europa.eu/public-api</u>

Ref. IUCVI-9153

31.17 Report generator

IMP The generation of a report including images now succeeds in environments that do not run X Server.

Ref. IUCVI-10275

New feature The possibility to extract the Summary of Product Information under the EU Biocidal Products Regulation is now available for Mixtures / Products.

Ref. IUCVI-9991

IMP It is now possible to generate reports in RTF format from a Mixture / Product.

Ref. IUCVI-10025

31.17.1 Chemical Safety Report (CSR)

Fixes and improvements:

- Improvements on the format: removal of empty lines in the hazard conclusion tables; few spelling mistakes corrected.
- Introduction of hyperlinks in all "References" pointing to the related pages in the Annex
 1 and all "Test material information" pointing to annex 2.
- The name of the substance is now displayed in the header of the CSR
- The creation date and the version of IUCLID from which it is generated is now displayed in the footer of the CSR
- Better communication with Chesar for the generation of a complete CSR (part A and part B section 1-10)
- Chapter 1: "data waiving" and "test material" labels now not appearing if no information is provided in any endpoint records
- Chapter 3: pictograms are now available in the CSR document
- Chapter 4-7: In all result tables, the result flagged as "key result" is displayed always as first entry.



Known issues:

- Page numbers are not available in the table of content generated as .rtf. Please press the "CTRL+a and F9" to update the ToC.
- The Reference entries in the annex 1 are not separated in the CSR when it is generated as a .pdf. However, in the .rtf they are correctly displayed (*Ref. IUCVI-9019*)
- Footers display to be improved (Ref. IUCVI-10425)
- Styles in the .rtf document are missing (*Ref. CHRIII-1226*)
- Improvement on the formatting of the CSR document (*Ref. IUCVI-9131*)
- Rich-text field improvements (Ref. IUCVI-9018)
 - When a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
 - When text is numbered using the button, the numbering is not sequential: each bullet number remaining as "1."
 - Not all changes to the font in a rich-text field are reflected in the generated CSR, affecting for example the display of the font size and style
- ERC/PROC descriptions in all Contributing activities/techniques for the environment is not displayed in the uses table (chapter 2) (*Ref. IUCVI-10517*)
- The label "link to subsequent service life" is printed even if no link is available (chapter 2) (*Ref. IUCVI-10512*)
- The references entries available in Annex I are not ordered alphabetically, but accordingly to their appearance order in the CSR document. (*Ref. IUCVI-9203*)
- The test material information is not linked to the relevant endpoint study(-ies) (Annex II) (*Ref. IUCVI-9204*)
- Creation of an Annex III where to report information on the Mode of action / Human relevance framework (*Ref. IUCVI-10204*)

31.18Server version

IMP The server administrator is now informed (via a message in the log) when the IUCLID 6 server is properly started.

Ref. IUCVI-10188

FIX The upgrade to IUCLID 6 version 1.1.0 led to the following errors in some cases: 'no access' to substances and exception when accessing templates.

Ref. IUCVI-10094, IUCVI-10095



31.19User interface

IMP Relevant action buttons are disabled after execution in order to prevent two requests to be submitted by the user by mistake.

Ref. IUCVI-9867

IMP The user interface is able to scale correctly even on high-resolution screens.

Ref. IUCVI-10395, IUCVI-10262

New feature There is now a possibility to select several sections or records in a dataset in order to delete or copy them in bulk.

Ref. IUCVI-9793

IMP Newly created records in a dataset are now displayed above records stored in an inherited template linked to the dataset.

Ref. IUCVI-10263

IMP Multiple documents can now be removed from a list of linked records.

Ref. IUCVI-9705

FIX The links to the Fee calculator and the Advanced search have been removed from the home page of IUCLID has these features are not currently available.

Ref. IUCVI-10225

New feature It is now possible to sort records in a IUCLID section by drag and drop function.

Ref. IUCVI-9976

FIX Documents could not be opened when they contained specific malformed content (e.g. under section 7.3.2).

Ref. IUCVI-10274

31.20Validation assistant

IMP Improved implementation of checks on testing proposals on the registered substance ['experimental study planned'] vs. testing proposals based on read-across ['experimental study planned (based on read-across)]'

Ref. TCC_ESR_19, TCC_ESR_20

IMP Improved implementation of checks on analytical information

Ref. TCC_0104_01, TCC_0104_02, TCC_0104_03

IMP Quality rules (QLT) implemented for physical and chemical properties (sections 4.4, 4.8, 4.12, 4.13, 4.15)

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32 VERSION 1.1.0 (30 SEPTEMBER 2016)

32.1 Introduction

Please also refer to the <u>Frequently Asked Questions</u> on the IUCLID 6 website.

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

No changes have been made to the IUCLID format.

Improvements are identified with IMP and bug fixes with FIX.

32.2 Migration (import, migration tool and IUCLID 6 database patch tool)

IMP Several performance improvements for the migration to Derby databases (including IUCLID Desktop version).

Ref. IUCVI-9285

FIX NullPointerException in Migration Rule MR6112 when migrating test material records from inherited templates under specific conditions.

Ref. IUCVI-9713

FIX The values of the field 'Doses / concentrations' in the document 'Developmental toxicity / teratogenicity' are now correctly migrated

Ref. IUCVI-9354

FIX Values under 'Toxicological information' in Inquiry records are now migrated correctly.

Ref. IUCVI-9559

FIX The information about which specific uses are linked in 14.3.6 is now transferred as text lines at the top of field "Detailed description of method of application".

Ref. IUCVI-9712

32.3 IUCLID functionalities

32.3.1 Annotations

IMP Multiple selection is now allowed for the annotations tab of a dossier or a dataset and bulk export of annotations is consequently possible.



32.3.2 Clipboard

IMP When a document in the IUCLID clipboard cannot be copied to the selected dataset, an error is displayed to the client (previously nothing was indicated).

Ref. IUCVI-9512

32.3.3 Comparison

IMP New feature in IUCLID 6: a user can now compare the content of two dossiers. More information can be found in the IUCLID 6 manual embedded in IUCLID (activated with the F1 key) or available on the IUCLID 6 website.

Ref. IUCVI-9152

32.3.4 Concurrency

IMP When several users are accessing and editing the same IUCLID document, the first user who saves will have his data stored in the database. The second user who saves will be informed that the data were modified.

Ref. IUCVI-9378

32.3.5 Export

FIX 'Document Selection' is now working properly in 'Entities list' panel when exporting a record and using the advanced options of the export assistant.

Ref. IUCVI-9488

FIX Orphan entities are now unselected automatically in the document selection step of the export assistant.

Ref. IUCVI-9191

IMP A stylesheet is now added in order to render the content of the manifest file when opened in a browser.

Ref. IUCVI-3728

FIX Documents attached to template were not correctly exported together with a substance in some specific cases (this affected the GHS, PBT summary and guidance on safe use documents stored in a template linked to a substance).

Ref. IUCVI-9809

32.3.6 GHS (section 2.1)

IMP Pictograms are now displayed together with their codes under the Labelling section of the GHS information.

Ref. IUCVI-1109

32.3.7 Import

FIX When importing a IUCLID 6 dossier, the content of the dossier is now displayed in the 'References to' panel of the advanced import assistant.

Ref. IUCVI-8955

IMP A new option is available during import: 'Replace'. With this option, the dataset imported, if already present in the database, will completely replace the previously available one.

Ref. IUCVI-8739

32.3.8 Inventory management

IMP A new feature is added to manage the content of the inventories (e.g. contacts or test materials). The tool helps the user replacing one or several inventory entries with a selected one.

Ref. IUCVI-9490

32.3.9 Literature reference

IMP When creating a new literature reference from an endpoint study record under 'Data source', the newly created reference is automatically linked to the record.

Ref. IUCVI-8913

FIX The report date is now saved with the correct value in the database and displayed correctly to the user.

Ref. IUCVI-9594

32.3.10 Logging

FIX 'Wrong file format' log entries, related to the absence of the indication of the system which generated the UUID, are removed.

Ref. IUCVI-9394, IUCVI-9603

FIX Unnecessary log entry removed 'ResourceBundle with the name : 'empty' not found'

Ref. IUCVI-9444

FIX Unnecessary log entry removed 'File /version.xml not found'

Ref. IUCVI-9598

32.3.11 Print

FIX When accessing rich-text fields in IUCLID, there is now the possibility to print the content. *Ref. IUCVI-5166*



32.3.12 Reference substances

IMP In a reference substance, when an inventory entry is selected, the CAS number and molecular formula are automatically pre-filled in case this information was not there initially.

Ref. IUCVI-703

FIX In a reference substance included in a dossier, it is now possible to click 'Go to link target' to display the linked inventory entry.

Ref. IUCVI-8946

32.3.13 References to document

IMP A feature has been added which enables to see the links made to a document that is being viewed/edited.

Ref. IUCVI-5353

32.3.14 Search

IMP Search by dossier template also applies to Biocidal Products Regulation dossier types.

Ref. IUCVI-8965

IMP Search results are now ordered using the 'Modification date'. The last updates (or newly imported elements) are displayed first.

Ref. IUCVI-9577

FIX The search 'by synonyms' has been removed from the basic search options.

Ref. IUCVI-8823

32.3.15 Submission types

FIX BPR data under section 9.2 is made visible again.

Ref. IUCVI-9391

FIX The document 'Additional ecotoxicological information' is added to the BPR submission types.

Ref. IUCVI-9588

FIX Mandatory sections are updated for the following submission types:

- REACH registration 10 100 tonnes: missing mandatory sections: 5.1.2, 6.1.1, 6.1.7, 7.8.1
- REACH registration transported isolated intermediates above 1000 tonnes: missing mandatory sections: 5.2.1

32.3.16 System administration

IMP A new option is available under 'Admin - System administration'. The system administrator can chose to display the last used user name in the IUCLID 6 login window. This change will be applied to all users of the IUCLID 6 installation.

Ref. IUCVI-3592

32.3.17 User preferences

IMP It is now possible to change the font size of IUCLID 6. Three different values are proposed. 11: default font size, 12: 125% and 13: 150%.

Ref. IUCVI-3525

IMP The possibility to configure proxy settings for update notifications has been added to the user preferences.

Ref. IUCVI-9406

32.3.18 User interface

IMP Several improvements have been done to the user interface for Linux and Mac OS users: e.g. fixes were implemented for missing buttons, toolbars, checkboxes not displayed correctly.

Ref. IUCVI-2421

FIX The checkbox can now be ticked only when clicking on them. Previously a click on the same line as the checkbox would change the status of the checkbox.

Ref. IUCVI-7394

FIX The yellow tips displayed when hovering the icons on the bottom right of the application are not blocking the access to the icons anymore.

Ref. IUCVI-8864

FIX The fields from the inventory entries can now be copied to the client clipboard.

Ref. IUCVI-9865

FIX The User Interface becomes unresponsive when loading large documents under section 3.5.

Ref. IUCVI-9242

FIX The appearance of the User Interface is now less dependent on the Windows Theme selected.

Ref. IUCVI-9293

FIX The records that can be selected under the document 'Opt-out' are now ordered alphabetically.

Ref. IUCVI-9704

FIX The values of the multi-select picklists can now be copied to the client's clipboard.



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32.3.19 User management

FIX A role manager is now able to configure the access to the data sections even if he has no access to datasets.

Ref. IUCVI-9022

FIX The access to attachment permission does not affect the attachments in a dossier. Only the permission for Dossier should control the entire content of the dossier.

Ref. IUCVI-9408

FIX Annotations can be saved on a dossier even without R/W permission on dossiers.

Ref. IUCVI-9548

32.4 IUCLID modules

32.4.1 Chesar communication module

This version of IUCLID 6 (v1.1.0) can be used to exchange data with the service release of <u>Chesar 3</u> which will be published in November 2016. For more details on the release date, see the news section on the <u>Chesar website</u>. Chesar users are advised to wait for this service release of Chesar 3 before upgrading to IUCLID 6 v1.1.0, because the communication between IUCLID 6 v1.1.0 and the current version of Chesar 3 does not work.

Ref. IUCVI-9684

32.4.2 Help system

IMP The content of the help system has been updated to include a description of the new features, improve existing documentation. A BPR submission manual has also been added to the list of manuals available.

FIX It is now possible to print the content of the Help system.

Ref. IUCVI-8962

32.4.3 Public REST API

IMP A beta version of the IUCLID Public REST API has been made available in order to allow developers building interfaces between IUCLID and other application. More information can be found on the IUCLID 6 website under Support.

32.4.4 Report generator

32.4.4.1 Chemical Safety Report

Changes compared to the previous version of the CSR generated by IUCLID.

General

- The information in Part A should be provided in section 13 of IUCLID before proceeding with the generation of the CSR
- The creation of a Joint or Own CSR is now defined in section 13 of IUCLID. This section includes the picklist options "all uses" "own CSR" or "joint CSR" which trigger the corresponding CSR generation type
- Information triggered from the CSR report generator has been updated according to the new IUCLID format
- Table numbers are numbered according to the related chapter and not consecutively as in the previous versions of the CSR generator
- In all study result tables the column "References" has been removed and the references put in the "Results" one.
- Basic assessment entity information is available in the CSR generated

Chapter 1

Nanomaterial information has been added to the CSR

Chapter 2

• Changes have been made to the layout of the tables related to all uses so as to better accommodate the new information captured from IUCLID

Chapter 3

 Classification and labelling according to DSD/DPD has been removed from the generated CSR

Chapters 4-8

- In all study result tables, the column "References" has been removed and the content put in the "Results" one.
- Justification for type of information available in all result tables

Chapters 9 and 10

• No information is available in these sections besides the Chapter headers



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32.4.4.2 Fixes and improvements of this release

- General: Improvements on the format (e.g. change of stiles, empty parenthesis removed, label with no content largely removed, empty tables not displayed, improved readability of TMI annex, ...)
- chapter 1:
 - EC name and CAS number
 - o Nanomaterial information
 - Structural formula in .jpg format
 - Addition of 4 missing endpoints (4.23 Self-reactive substances, 4.24 organic peroxide, 4.25 corrosive to metals, 4.26 Gasses under pressure)
- Chapter 2: PC codes, empty table removed)
- Chapter 3: pictograms images
- Chapters 3-7
 - "Justification for type of information" included in all endpoint tables
 - Eye irritations and skin irritation/corrosion tables

32.4.4.3 Known issues that will be implemented / resolved in the next version(s) of the CSR generator

- Page numbers are not available in the table of content generated as .rtf. Please press the "CTRL+A then F9" to update the table of contents
- Headers and footers information to be improved
- Styles in the .rtf document missing
- Rich-text field
 - Currently, when a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
 - When text is numbered using the ¹= button, the numbering is not sequential, with each number remaining as "1."
 - Not all changes to the font in a rich-text field are reflected in the generated CSR, affecting for example the display of the font size and style
- ERC/PROC description in all Contributing activity/technique for the environment is not displayed in the uses table (chapter 2)
- The label "link to subsequent service life" is printed even if no link is available (chapter 2)
- The studies in the results table are not sorted according to the "Species", "Type of study", "Endpoint", "Type of genotoxicity" or "Route of administration" (chapter 5)
- All references mentioned in the CSR are reported and ordered according to how they
 appear in the CSR and not alphabetically (Annex I)
- currently the indication of which endpoint study the test material information is linked to is missing (Annex II)

32.4.5 Validation assistant

IMP TCC rule modified to reflect changes in Annex VII, 8.3 – skin sensitisation (TCC_070401_A01).

IMP QLT rules implemented for substance identification information (sections 1.1, 1.2, 1.4).

IMP QLT rule implemented to detect presence of attachment placeholders created by the database patch tool (QLT080).

IMP Failure message improvements.

FIX Subsequent service life required for Art. 10 intermediate, but not selectable in IUCLID (TCC_030503_01).



33 VERSION 1.0.2 (21 JUNE 2016)

33.1 Introduction

Please also refer to the <u>Frequently Asked Questions</u> on the IUCLID 6 website. The releases notes are highlighting changes compared to previous versions of IUCLID 6.

No changes have been made to the IUCLID format.

33.2 IUCLID functionalities

33.2.1 Dossiers

(IUCVI-9246) The field 'Linked Contributing activity' in section 3.5 now appears as read-only in dossiers.

33.2.2 Import of IUCLID 5.6 dossiers

(IUCVI-9206) In some cases a problem with the import of IUCLID 5.6 dossiers has been detected when:

- the modification history entries were excluded from the exported dossier
- and the dossier contained a template with a document in section 3.7.1 with a Link to uses in section 3.5 indicating a 3.5 document of a substance dataset.

33.2.3 Migration

(IUCVI-9161) Issue with specific dossiers when migrating from a IUCLID 5.6 Oracle database to a IUCLID 6 Derby database.

33.3 IUCLID modules

33.3.1 Report generator

33.3.1.1 Chemical Safety Report

33.3.1.1.1 General

In all study result tables, the column "References" has been removed and the references put in the "Results" one.

33.3.1.1.2 Chapter 1

Nanomaterial information has been added to the CSR.

33.3.1.1.3 Chapter 2

Changes have been made to the layout of the tables related to all uses so as to better accommodate the new information captured from IUCLID.

33.3.1.1.4 Chapter 3

Classification and labelling according to DSD/DPD has been removed from the generated CSR.

33.3.1.1.5 Chapter 9 and 10

No information is available in these sections besides the Chapter headers.

33.3.1.1.6 Known issues that will be implemented / resolved in the next version(s) of the CSR generator

33.3.1.1.6.1 General

Page numbers are not available in the .rtf TOC. To get the page numbers, please press the following "CTRL+ a and F9"

No table of contents entries found.

Assessment entities are only included in Chapter 1 of the generated CSR.

Labels are always printed in the CSR even if no information is available in the corresponding IUCLID fields. This leads to an increased number of pages in the CSR.

Rich-text field issues:

- Currently, when a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
- When text is numbered using the ¹ button, the numbering is not sequential, with each number remaining as "1."
- Not all changes to the font in a rich-text field are reflected in the generated CSR, affecting for example the display of the font size and style

33.3.1.1.6.2 Chapter 1

Structural formula image is missing from chapter 1.1. "Name and other identifiers of the substance".



33.3.1.1.6.3 Chapter 2

ERC description in all Contributing activities/techniques for the environment is not displayed in the text.

PROC description in all Contributing activity/technique for the environment is not displayed in the text.

Chapter 2.2: Even if "subsequent service life relevant for that use" has value "no", the following "Link to the subsequent service life" is still printed.

33.3.1.1.6.4 Chapter 3

The CSR currently prints all classification tables' headers when no corresponding classification is available in IUCLID.

Currently, no pictogram images are available in the CSR.

33.3.1.1.6.5 Chapter 5

The studies in the results table are not sorted according to the "Species", "Type of study", "Endpoint", "Type of genotoxicity" or "Route of administration".

33.3.1.1.6.6 Annexes

References: all references mentioned in the CSR are reported in the Annex I and ordered according to how they appear in the CSR, not alphabetically.

Test material information: currently the indication of which endpoint study the test material is linked to is missing.

33.3.2 Dissemination preview

Filtering of dossiers containing categories: inherited templates linked to category member substances other than the registered substance are now filtered correctly. Documents in such templates are removed by the Dissemination preview.

The filtering of the information for REACH is now supported for all IUCLID sections.

33.3.3 Help system

The content of the help system has been updated.

33.3.4 Chesar communication module

This version of IUCLID 6 can be used to exchange data with Chesar 3.

34 VERSION 1.0.0 (29 APRIL 2016)

Please also refer to the Frequently Asked Questions on the IUCLID 6 website.

34.1 IUCLID legislations

IUCLID legislations are a new concept introduced in IUCLID 6. The IUCLID database allows storing data according to different entry forms. The content of these forms is managed differently whether they are used by all IUCLID users (CORE legislation) or within the context of a regulation (e.g., REACH Regulation data entry forms are managed in the REACH legislation).

The list of entry forms belonging to each IUCLID legislation is published on the IUCLID 6 website:

http://iuclid6.echa.europa.eu/web/iuclid/documentation

34.1.1 CORE (version 2.25)

IUCLID CORE contains the main documents of IUCLID such as the substance identification, the classification and labelling information or the endpoint summaries.

34.1.2 OECD (version 2.20)

OECD contains the set of <u>documents harmonised at the OECD</u> level to report studies done on chemicals to determine their properties or effects on human health and the environment.

34.1.3 REACH (version 2.5)

REACH contains the specific documents used for the REACH Regulation, such as the inquiry or the opt-out information.

34.1.4 CLP (version 2.5)

CLP contains the specific documents used for the CLP Regulation.

34.1.5 BPR (version 2.6)

BPR contains the specific documents used for the Biocidal Products Regulation.



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34.2 IUCLID functionalities

34.2.1 Annotations

 (IUCVI-8905) Import of IUCLID 5 files containing only annotations is not possible in IUCLID 6. The annotations should be exported with their parent documents from IUCLID 5 in order to be migrated during the import to IUCLID 6.

34.2.2 Assessment entities

 (IUCVI-9005) Assessment Entity for "(group) of constituent" should retrieve only the list of reference substances available in the substance current substance dataset. Currently all available reference substances are listed and IUCLID displays an error message if an incorrect reference substance is selected.

34.2.3 Clipboard manager

 (IUCVI-8989 & IUCVI-6957) The clipboard manager content should be updated in case a document is deleted.

34.2.4 Documents management

- (IUCVI-8994) In IUCLID 5, the data entry forms were differentiating between 'Basic' and 'Details' fields. This was used to filter the content of the documents in the User Interface and to filter the content of the datasets during export and dossier creation. This option is not yet available.
- (IUCVI-8747) Changes without saving can cause an error if the user wants to delete a record.
- (IUCVI-8409) The content of rich-text area cannot be copied using Ctrl+C.

34.2.5 Dossier

- (IUCVI-8946) "Go to link target" in Inventory number field of a reference substance is not available when the reference substance is included in a dossier.
- (IUCVI-8923) The export option should not be activated for single documents in a dossier.
- (IUCVI-9028) When creating a dossier from a mixture / product linking to itself via a composition document, it is not possible to create a dossier of type 'BPR active substance application).

34.2.6 Export

(IUCVI-8983) Steps to reproduce: login as IUCLID 6 user; find a substance; export the substance; open "Background Jobs"; find the background job related to the export of the substance; click on "Report"; click on "Details" tab; try to edit a UUID or Last modified date by double clicking. An error is reported.

34.2.7 Migration

• (IUCVI-8642) Error in migration tool when the user selects "Previous" when the migration process has already started.

34.2.8 Printing

• (IUCVI-8981) An error appear if the user deletes a substance that is being printed.

34.2.9 User interface

- (IUCVI-2421) User interface issues appear when the IUCLID client is used under a Linux environment (e.g., icons are not available).
- (IUCVI-8974) Sections in tabs, like in section 3.5, are not collapsed automatically if the user has chosen this option in his preferences.

34.2.10 User management

• (IUCVI-8802) Login fails when the user has a password containing only spaces.

34.2.11 Search

- (IUCVI-8965) Search by dossier template: BPR mixture dossier types are missing.
- (IUCVI-8823) Search for substance by reference substance using the criterion 'Synonyms' is not working.
- (IUCVI-8424) Search mixture/product by synonyms does not work.
- The advanced search module is not available.



34.3 IUCLID modules

34.3.1 Validation assistant

The Validation assistant contains:

- All automated completeness check (TCC) rules; please note that the Validation assistant does not predict the manual verification checks performed by ECHA during completeness check.
- Those business rules (BR) that rely on IUCLID data only. Business rules that depend on information from the ECHA database (e.g. submission history) are not included in the Validation assistant.

Validation is supported on both dossiers and substance datasets.

Future versions of the Validation assistant will include quality checks to support users in improving consistent reporting of information.

Disclaimer: The Validation assistant simulates the submission checks carried out by ECHA as far as possible. The responsibility remains with the submitter to ensure that their dossier fulfils all the relevant legal requirements.

34.3.2 Report generator

The Report generator in IUCLID 6 allows the user to generate reports based on data stored in a IUCLID 6 dataset or dossier.

34.3.2.1 Chemical Safety Report

This section of the Release notes relates to the generation of the Chemical Safety Report (CSR) using the Report generator.

34.3.2.1.1 Changes compared to previous version

In these release notes, we highlight the changes compared to the previous version of the CSR generated by IUCLID 5:

34.3.2.1.1.1 General

- The information in Part A should be provided in section 13 of IUCLID before proceeding with the generation of the CSR
- The creation of a Joint or Own CSR is now defined in section 13 of IUCLID. This section includes the picklist options "all uses" "own CSR" or "joint CSR" which trigger the corresponding CSR generation type
- Information triggered from the CSR report generator has been updated according to the



new IUCLID format

• Table numbers are numbered according to the related chapter and not consecutively as in the previous versions of the CSR generator

34.3.2.1.1.2 Chapter 1

• Nanomaterial information has been added to the CSR

34.3.2.1.1.3 Chapter 2

• Changes have been made to the layout of the tables related to all uses so as to better accommodate the new information captured from IUCLID

34.3.2.1.1.4 Chapter 3

 Classification and labelling according to DSD/DPD has been removed from the generated CSR

34.3.2.1.1.5 Chapter 9 and 10

• No information is available in these sections besides the Chapter headers

34.3.2.1.2 Known issues and areas for improvement

During our testing we have collected a list of known issues and improvements requested by users that will be taken into account in the next version(s) of the CSR generator. They are identified below.

34.3.2.1.2.1 General

- Labels are always printed in the CSR even if no information is available in the corresponding IUCLID fields. This leads to an increased number of pages in the CSR.
- Remarks are generally indicated in parenthesis. However in cases where no "remarks" have been provided in IUCLID the opening and closing parentheses are always printed as (). For example in the result tables the following may be printed "LD50: >5000 mg/kg bw (male/female) based on: () ()"
- Assessment entities are not currently taken into consideration for the generation of the CSR.
- Rich-text field issues:
 - Currently, when a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
 - When text is numbered using the ¹ button, the numbering is not sequential, with each number remaining as "1."
 - Not all changes to the font in a rich-text field are reflected in the generated CSR, affecting for example the display of the font size and style

34.3.2.1.2.2 Table of Content (TOC)

• Page numbers are not available in the TOC. To get the page numbers, please press the following "CTRL+ a and F9"



34.3.2.1.2.3 Chapter 1:

- EC name information is missing in Table 1. Substance identity
- CAS number (EC inventory) information is missing in Table 1. Substance identity
- Structural formula image is missing from chapter 1.1. "Name and other identifiers of the substance"
- The Characterisation of a nanomaterial in all compositions is wrongly appearing when no information is available in the fields

34.3.2.1.2.4 Chapter 2

- ERC description in all Contributing activity/technique for the environment is not displayed in the text
- PROC description in all Contributing activity/technique for the environment is not displayed in the text
- SU 0, AC02 and AC0 are not printed if the corresponding free text field is not populated. However, when the text field beside them is populated, this free text is correctly transferred to the CSR

34.3.2.1.2.5 Chapter 3

- The CSR currently prints all classification tables' headers when no corresponding classification is available in IUCLID
- Currently, no pictogram images are available in the CSR

34.3.2.1.2.6 Chapter 4

 The "Justification for classification or non-classification" in section 4.14 "Explosiveness", 4.15 "Flammability" and 4.16 "Oxidising properties" are not transferred to the corresponding section in the CSR (6.1 Explosivity, 6.2 Flammability, 6.3 Oxidising potential)

34.3.2.1.2.7 Chapter 5

- The studies in the results table are not sorted according to the "Species", "Type of study", "Endpoint", "Type of genotoxicity" or "Route of administration"
- Skin irritation /corrosion: only the studies having "Category 1 (corrosive) based on GHS criteria", " Category 1A (corrosive) based on GHS criteria", "Category 1B (corrosive) based on GHS criteria", " Category 1C (corrosive) based on GHS criteria" selected in the "interpretation of results" field, are reported in the CSR
- Eye irritation: only the studies having "Category 1 (irreversible effects on the eye) based on GHS criteria", "Category 2 (irritating to eyes) based on GHS criteria", "Category 2A (irritating to eyes) based on GHS criteria", "Category 2B (mildly irritating to eyes) based on GHS criteria" selected in the "interpretation of results" field, are reported in the CSR

34.3.2.1.2.8 Annexes

- References: All references mentioned in the CSR are reported in the first Annex named "References" and ordered according to how they appear in the CSR. The references are not ordered alphabetically
- Test material information: currently the indication of which endpoint study the test material is linked to, is missing

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34.3.3 Dissemination preview

Known issues:

Filtering of dossiers containing categories: inherited templates linked to category
member substances other than the registered substance are not filtered correctly.
Documents in such templates should be removed by the Dissemination preview, and
will not be published on the website.

IUCLID sections for which filtering is not supported in this version (i.e. the dissemination preview will not remove any data in the following sections):

- Section 3.5: Use and exposure information
- Section 3.6: Uses advised against
- Section 4.28: OECD harmonised templates on 'Additional physico-chemical properties of nanomaterials'

34.3.4 Fee calculation

The Fee calculation plug-in is not available in IUCLID 6 yet.

34.3.5 Help system

The IUCLID 6 Help System is intended to enable any user to learn how to use IUCLID 6 without having to refer to the IUCLID Helpdesk, or to seek additional training. It serves as a complete reference manual for all IUCLID 6 features, functions, and options. It is integrated in to the application itself, with access being provided via links in the user interface, and by pressing the function key F1.

The reference manual for all IUCLID 6 features, functions, and options can also be downloaded in .pdf format and is available in different languages from the IUCLID 6 website.

In addition, the Help System integrated in IUCLID 6 also includes manuals on how to use the application for regulatory purposes, including help on entering data into Substance datasets.

34.3.5.1 Known issues

- (IUCVI-8962) When the user selects the option to print, the Print dialog should appear allowing the user to proceed with the printing process. Instead, it has been reported in some cases that no Print dialog appears, and no print activity is indicated to the user.
 Furthermore, an error appears in IUCLID.
- (IUCVI-8028) Steps to reproduce the issue: open the Help System: Press F1 or from menu select Help -> Help; expand section "Functionalities of IUCLID 6" in the tree view pane; double-click on "Changes to this document"; double-click on "9.... Legal entity site". The highlighted selection changes from "9.... Legal entity site" back to "Changes



to this document", instead of remaining on the currently selected topic. This erratic behaviour occurs to all topics/sub-topics within the "Functionalities of IUCLID6" section.