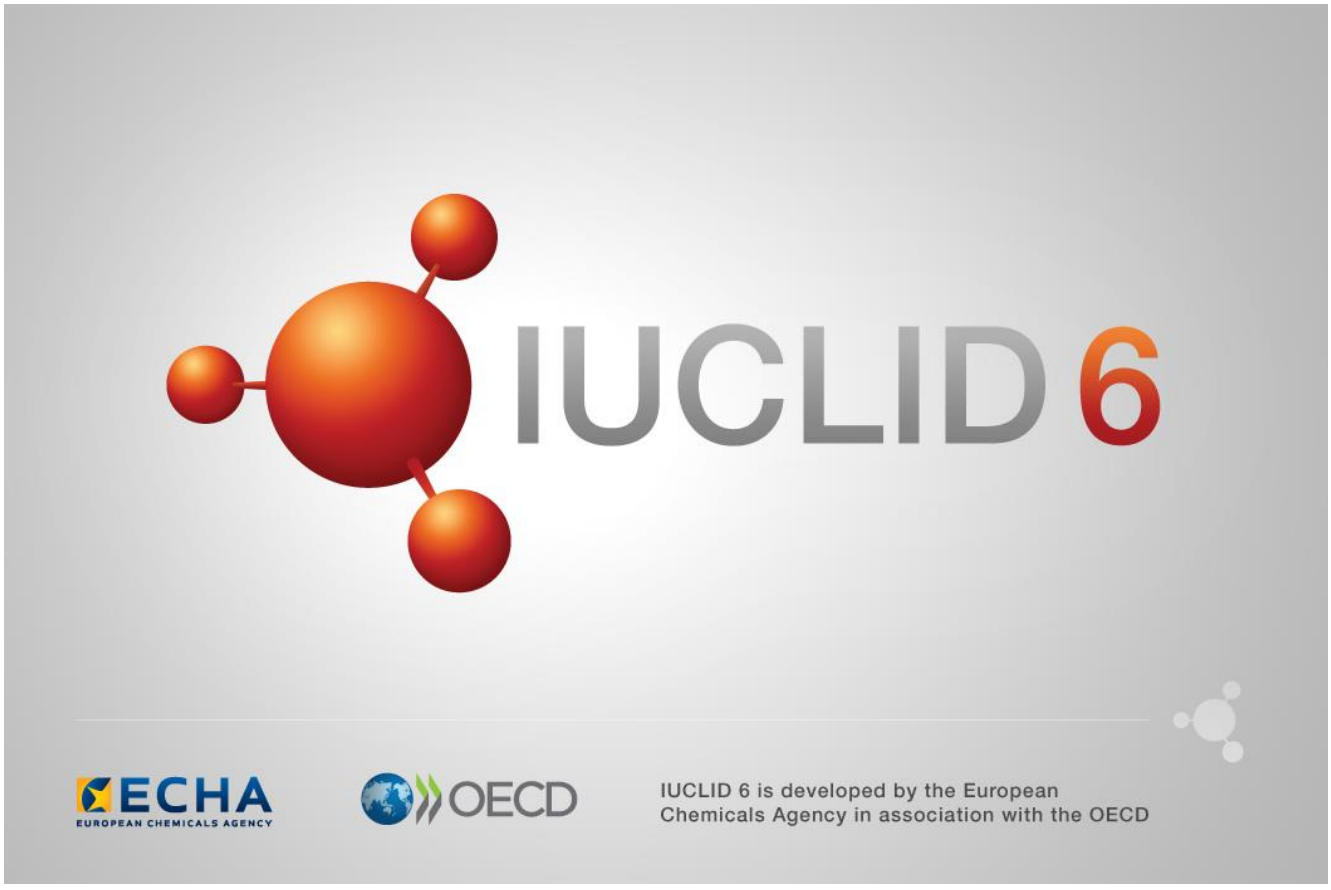
IUCLID 6

Release notes

Version 2.0.0

15/11/2017



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1. 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:

- Fee calculator
- 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

1.1. 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.

1.1.1. 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

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

1.1.2. 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

1.1.3. 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

Ref. IUCVI-11031

IMP Optionality of documents in DU reports

Ref. IUCVI-11010

1.1.4. CLP

No changes

1.1.5. 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

1.2. IUCLID functionalities

1.2.1. Attachments

FIX Attachments to records (in the information panel) should be able to be deleted according to the user's permissions

Ref. IUCVI-11405

1.2.2. 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

1.2.3. 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

1.2.4. Document dynamic content

IMP 7.3.2 eye irritation conditional formatting

Ref. IUCVI-11470

1.2.5. 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

1.2.6. Printing

IMP As a user I would like to print studies without confidential fields or reference to the parent entity

Ref. IUCVI-11404

1.2.7. Search

FIX Reference substance browse search results are not correct

Ref. IUCVI-11154

1.3. IUCLID modules

1.3.1. Dissemination preview

IMP Improve Dissemination Preview results - use IUCLID tree to sort "Document name" column

Ref. IUCVI-10927

1.3.2. Fee calculator

IMP Release of the fee calculator

1.3.3. 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-

1.3.4. 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

Ref. IUCVI-11042

1.3.4.1. New reports

There are a set of new reports (report templates are available to download from the IUCLID 6 website) 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

- “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:
    - FLEXIBLE_RECORD.ChemicalSafetyReport.CSR.CSRDocument
    - FLEXIBLE_RECORD.ChemicalSafetyReport.CSR.ExportFileDocument

1.3.4.2. 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;
    - 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:
  - 5.10.1.4. “Additional toxicological effects”
  - 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)

1.3.5. 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

1.4. Integration with other tools / API

1.4.1. Chesar

FIX Error on export of Uses from Chesar to IUCLID (Client's transaction aborted)

Ref. IUCVI-11455

1.4.2. 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

1.5. 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

2. 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:

- PNEC calculator
- Dossier header re-use
- Advanced features of the report generator

2.1. 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

2.2. Clipboard

FIX A paste as reference should not be allowed for fixed records.

Ref. IUCVI-10877

2.3. Comparison tool

IMP The dossiers to be compared can now be retrieved using their UUIDs.

Ref. IUCVI-10579

2.4. 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.

Ref. IUCVI-10878

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

2.5. Database patch tool

IMP The database patch tool is now able to detach incorrect references to fixed records.

Ref. IUCVI-10876

2.6. 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

2.7. Dossier creation

NEW Described in the IUCLID 6 functionalities manual (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'.

Ref. IUCVI-10906

FIX Attachments added to the dossier should be considered as dossier information in the database and the .i6z files.

Ref. IUCVI-10821

2.8. Help system

IMP Update of the help system for version 1.3.0 of IUCLID 6.

Ref. IUCVI-11036

2.9. 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

2.10. Information 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

2.11. 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 IUCLID website.

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 Helpdesk.

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 IUCLID website.

Ref. IUCVI-10889

2.12. Instance based security (IBS)

IMP The performance of bulk change of ownership has been improved.

Ref. IUCVI-10501

2.13. Navigation

FIX 'No access' appeared for legal entities for read-only users without Instance Based Security activated.

Ref. IUCVI-10435

2.14. PNEC calculator (NEW)

NEW Described in the IUCLID 6 functionalities manual (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.

2.15. Printing

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

2.16. Public REST API

IMP The linking of attachments to documents is now supported.

Ref. IUCVI-10739

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

2.17. Report generator

NEW Described in the IUCLID 6 functionalities manual (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 IUCLID website.

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

2.17.1. 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.
    - 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
    - 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
    - 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
- 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 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*)

2.18. Restore

FIX Launching IUCLID did not work after a restore under a Linux or Mac environment.

Ref. IUCVI-10947

2.19. Server 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.

Ref. IUCVI-10814

2.20. Validation 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)

3. 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:

- DNEL generator
- IUCLID hyperlinks
- Printing and report generation fixes and performance improvements

3.1. 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

3.2. Attachments

FIX Errors were happening when attaching files to IUCLID fields, particularly as part of a dossier creation.

Ref. IUCVI-9921

3.3. 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

3.4. 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

3.5. 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

3.6. DNEL generator (NEW)

New feature described in the IUCLID 6 functionalities manual (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

3.7. Document selection (export / import)

FIX 'Document Selection' was not working properly in 'Entities list' panel when exporting a record.

Ref. IUCVI-9488, IUCVI-10409

3.8. 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

3.9. 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

3.10. Hyperlinks (NEW)

New feature described in the IUCLID 6 functionalities manual (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

3.11. 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

3.12. Installer, 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

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

3.13. Inventory manager

FIX Replacing an already selected entity caused an error.

Ref. IUCVI-10232

3.14. Navigation 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

3.15. Print

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.

Ref. IUCVI-10191

3.16. Public (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: https://iuclid6.echa.europa.eu/public-api

Ref. IUCVI-9153

3.17. 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

3.17.1. 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*)

3.18. Server 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

3.19. User 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

3.20. Validation 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)

4. VERSION 1.1.0 (30 SEPTEMBER 2016)

4.1. Introduction

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.

Improvements are identified with **IMP** and bug fixes with **FIX**.

4.2. 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

4.3. IUCLID functionalities

4.3.1. 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.

Ref. IUCVI-4389

4.3.2. 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

4.3.3. 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

4.3.4. 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

4.3.5. 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

4.3.6. GHS (section 2.1)

IMP Pictograms are now displayed together with their codes under the Labelling section of the GHS information.

Ref. IUCVI-1109

4.3.7. 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

4.3.8. 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

4.3.9. 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

4.3.10. 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

4.3.11. Print

FIX When accessing rich-text fields in IUCLID, there is now the possibility to print the content.

Ref. IUCVI-5166

4.3.12. 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

4.3.13. 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

4.3.14. 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

4.3.15. 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

Ref. IUCVI-9614

4.3.16. 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

4.3.17. 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

4.3.18. 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.

Ref. IUCVI-9714

4.3.19. 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

4.4. IUCLID modules

4.4.1. Chesar communication module

This version of IUCLID 6 (v1.1.0) can be used to exchange data with the service release of Chesar 3 which will be published in November 2016. For more details on the release date, see the news section on the Chesar website. 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

4.4.2. 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

4.4.3. 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.

4.4.4. Report generator

4.4.4.1. 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

4.4.4.2. 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
  - 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

4.4.4.3. 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 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)

4.4.5. 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).

5. VERSION 1.0.2 (21 JUNE 2016)

5.1. Introduction

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.

5.2. IUCLID functionalities

5.2.1. Dossiers

(IUCVI-9246) The field 'Linked Contributing activity' in section 3.5 now appears as read-only in dossiers.

5.2.2. 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.

5.2.3. Migration

(IUCVI-9161) Issue with specific dossiers when migrating from a IUCLID 5.6 Oracle database to a IUCLID 6 Derby database.

5.3. IUCLID modules

5.3.1. Report generator

5.3.1.1. Chemical Safety Report

5.3.1.1.1. General

In all study result tables, the column "References" has been removed and the references put in the "Results" one.

5.3.1.1.2. Chapter 1

Nanomaterial information has been added to the CSR.

5.3.1.1.3. 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.

5.3.1.1.4. Chapter 3

Classification and labelling according to DSD/DPD has been removed from the generated CSR.

5.3.1.1.5. Chapter 9 and 10

No information is available in these sections besides the Chapter headers.

5.3.1.1.6. Known issues that will be implemented / resolved in the next version(s) of the CSR generator

5.3.1.1.6.1. 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 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

5.3.1.1.6.2. Chapter 1

Structural formula image is missing from chapter 1.1. “Name and other identifiers of the substance”.

5.3.1.1.6.3. 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.

5.3.1.1.6.4. 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.

5.3.1.1.6.5. 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”.

5.3.1.1.6.6. 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.

5.3.2. 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.

5.3.3. Help system

The content of the help system has been updated.

5.3.4. Chesar communication module

This version of IUCLID 6 can be used to exchange data with Chesar 3.

6. VERSION 1.0.0 (29 APRIL 2016)

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

6.1. 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

6.1.1. 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.

6.1.2. OECD (version 2.20)

OECD contains the set of documents harmonised at the OECD level to report studies done on chemicals to determine their properties or effects on human health and the environment.

6.1.3. REACH (version 2.5)

REACH contains the specific documents used for the REACH Regulation, such as the inquiry or the opt-out information.

6.1.4. CLP (version 2.5)

CLP contains the specific documents used for the CLP Regulation.

6.1.5. BPR (version 2.6)

BPR contains the specific documents used for the Biocidal Products Regulation.

6.2. IUCLID functionalities

6.2.1. 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.

6.2.2. 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.

6.2.3. Clipboard manager

- (IUCVI-8989 & IUCVI-6957) The clipboard manager content should be updated in case a document is deleted.

6.2.4. 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.

6.2.5. 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).

6.2.6. 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.

6.2.7. Migration

- (IUCVI-8642) Error in migration tool when the user selects "Previous" when the migration process has already started.

6.2.8. Printing

- (IUCVI-8981) An error appear if the user deletes a substance that is being printed.

6.2.9. 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.

6.2.10. User management

- (IUCVI-8802) Login fails when the user has a password containing only spaces.

6.2.11. 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.

6.3. IUCLID modules

6.3.1. 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.

6.3.2. 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.

6.3.2.1. Chemical Safety Report

This section of the Release notes relates to the generation of the Chemical Safety Report (CSR) using the Report generator.

6.3.2.1.1. 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:

6.3.2.1.1.1. 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

6.3.2.1.1.2. Chapter 1

- Nanomaterial information has been added to the CSR

6.3.2.1.1.3. 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

6.3.2.1.1.4. Chapter 3

- Classification and labelling according to DSD/DPD has been removed from the generated CSR

6.3.2.1.1.5. Chapter 9 and 10

- No information is available in these sections besides the Chapter headers

6.3.2.1.2. 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.

6.3.2.1.2.1. 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 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

6.3.2.1.2.2. 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”

6.3.2.1.2.3. 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

6.3.2.1.2.4. 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

6.3.2.1.2.5. 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

6.3.2.1.2.6. 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)

6.3.2.1.2.7. 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

6.3.2.1.2.8. 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

6.3.3. 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'

6.3.4. Fee calculation

The Fee calculation plug-in is not available in IUCLID 6 yet.

6.3.5. 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.

6.3.5.1. 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.