IUCLID 6

Release notes

Version 1.2.0

31/1/2017

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1.   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
- o   IUCLID hyperlinks
- o   Printing and report generation fixes and performance improvements

1.1.   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

1.2.   Attachments

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

Ref. IUCVI-9921

1.3.   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

1.4.   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

1.5. 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IMP The check box 'Add report as an attachment to the filtered document' is not displayed anymore as the function is obsolete.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

1.6. DNEL generator (NEW)

New feature described in the IUCLID 6 functionalities manual (section 20). 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

1.7. Document selection (export / import)

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

 Ref. IUCVI-9488, IUCVI-10409

1.8. 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

1.9.   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

1.10.   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

1.11.   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

1.12.   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

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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

1.13.　Inventory manager

FIX Replacing an already selected entity caused an error.

Ref. IUCVI-10232

1.14.　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

1.15.　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

1.16.   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

1.17.   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

1.17.1.   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*)

1.18.   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

1.19.   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

1.20.   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)

2. VERSION 1.1.0 (30 SEPTEMBER 2016)

2.1. 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**.

2.2. 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

2.3. IUCLID functionalities

2.3.1. 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

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2.3.2. 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

2.3.3. 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

2.3.4. 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

2.3.5. 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

2.3.6. GHS (section 2.1)

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

Ref. IUCVI-1109

2.3.7. 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

2.3.8. 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

2.3.9. 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

2.3.10. 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

2.3.11. Print

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

Ref. IUCVI-5166

2.3.12.   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

2.3.13.   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

2.3.14.   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

2.3.15.   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

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2.3.16. 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

2.3.17. 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

2.3.18. 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

2.3.19. 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

2.4. IUCLID modules

2.4.1. 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

2.4.2. 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

2.4.3. 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.

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2.4.4. Report generator

2.4.4.1.   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

2.4.4.2. 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

2.4.4.3. 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)

2.4.5. 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).

3. VERSION 1.0.2 (21 JUNE 2016)

3.1. 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.

3.2. IUCLID functionalities

3.2.1. Dossiers

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

3.2.2. 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.

3.2.3. Migration

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

3.3. IUCLID modules

3.3.1. Report generator

3.3.1.1. *Chemical Safety Report*

3.3.1.1.1. General

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

3.3.1.1.2.   Chapter 1

Nanomaterial information has been added to the CSR.

3.3.1.1.3.   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.

3.3.1.1.4.   Chapter 3

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

3.3.1.1.5.   Chapter 9 and 10

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

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

3.3.1.1.6.1.   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:

- o Currently, when a table is created or pasted into a rich-text field in IUCLID, it may not be correctly displayed in the CSR
- o When text is numbered using the button, the numbering is not sequential, with each number remaining as "1."
- o 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

3.3.1.1.6.2.   Chapter 1

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

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3.3.1.1.6.3.   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.

3.3.1.1.6.4.   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.

3.3.1.1.6.5.   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".

3.3.1.1.6.6.   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.

3.3.2. 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.

3.3.3. Help system

The content of the help system has been updated.

3.3.4. Chesar communication module

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

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4. VERSION 1.0.0 (29 APRIL 2016)

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

4.1. 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

4.1.1. 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.

4.1.2. 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.

4.1.3. REACH (version 2.5)

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

4.1.4. CLP (version 2.5)

CLP contains the specific documents used for the CLP Regulation.

4.1.5. BPR (version 2.6)

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

4.2. IUCLID functionalities

4.2.1. 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.

4.2.2. 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.

4.2.3. Clipboard manager

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

4.2.4. 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.

4.2.5. 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).

4.2.6. 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.

4.2.7. Migration

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

4.2.8. Printing

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

4.2.9. 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.

4.2.10.   User management

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

4.2.11.   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.

4.3. IUCLID modules

4.3.1. 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.

4.3.2. 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.

4.3.2.1.   *Chemical Safety Report*

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

4.3.2.1.1.   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:

4.3.2.1.1.1.   *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

4.3.2.1.1.2.   Chapter 1

- Nanomaterial information has been added to the CSR

4.3.2.1.1.3.   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

4.3.2.1.1.4.   Chapter 3

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

4.3.2.1.1.5.   Chapter 9 and 10

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

4.3.2.1.2.   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.

4.3.2.1.2.1.   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

4.3.2.1.2.2.   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"

IUCLID 6

4.3.2.1.2.3.   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

4.3.2.1.2.4.   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

4.3.2.1.2.5.   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

4.3.2.1.2.6.   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)

4.3.2.1.2.7.   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

4.3.2.1.2.8.   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

4.3.3. 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'

4.3.4. Fee calculation

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

4.3.5. 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.

4.3.5.1.   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.