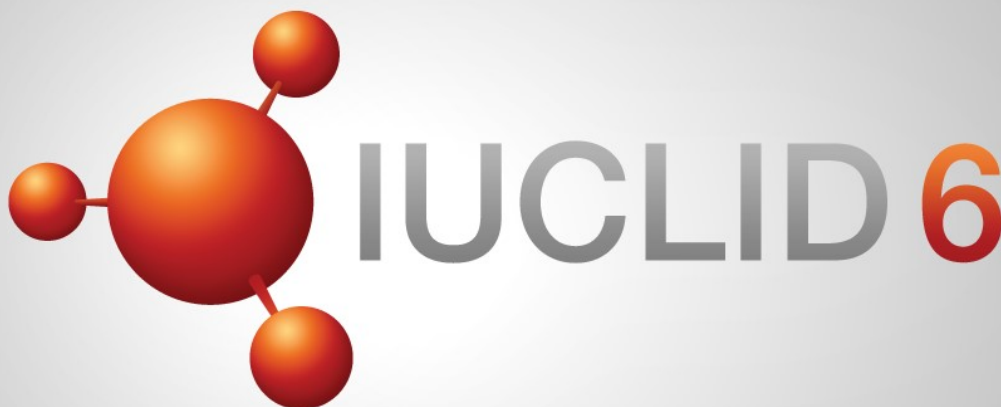


IUCLID 6

Webinar IUCLID 6 – Questions and Answers

Advanced users (part 2) – IUCLID 6 version 1.1.0

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 **ECHA**
EUROPEAN CHEMICALS AGENCY

 **OECD**

IUCLID 6 is developed by the European
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1. INTRODUCTION

This IUCLID 6 webinar took place on the 7th of September 2016. It was intended for advanced users of IUCLID.

It covered:

- The presentation of the key improvements and fixes included in the first service release of IUCLID 6 (version 1.1.0) made available on 30th September 2016, including the presentation of new features (replace during import, inventory management, comparison tool)
- Changes in reporting information in IUCLID 6

Presentations were followed by a question and answer session. The content of this session is reported in this document.

2. QUESTIONS AND ANSWERS

2.1. Validation Assistant

Q1: When will the Technical Completeness Check in IUCLID 6 be aligned with the TCC in REACH-IT? Currently a 'pass' in IUCLID 6 can result in a 'fail' in REACH-IT. Specifically for Section 1.2, there may be other fields which are affected.

A1: The Validation assistant in IUCLID 6 is fully aligned with the completeness check in REACH-IT when it comes to the rules that are automatically run on dossiers. However, in addition to these checks, there are additional manual checks by ECHA staff. Please read more about these manual verification checks on the ECHA website, under Support \ Manuals.

2.2. Migration

Q2: What means finalisation of the migration of the test materials on slide 17?

A2: Due to a glitch in the migration tool certain Test Material information (the ones in templates inherited by several substances) were not fully migrated. The DB patch tool is going to fix these partially migrated test materials.

Q5: Will IUCLID 6 files remain compatible within different updated versions of IUCLID 6?

A5: The IUCLID 6 files will always be compatible with the latest version of IUCLID 6. Like for IUCLID 5. However, if changes are made to the format (only in the October releases, starting in 2017), a file generated from the latest IUCLID 6 version might not be compatible with an older version of IUCLID 6.

Q59: Migrating from I5Z to I6Z results in the attachments becoming corrupted. The files can be viewed and opened within the imported dataset but REACH-IT will reject the dossier because the files are corrupt. Only workaround is to reattach the files. Any fix?

A59: The issue came from IUCLID 5 where the attachments were already corrupted. Now IUCLID 6 and REACH-IT 3 do not accept these corrupted files anymore. The database patch tool provided at the end of the month will identify these files in IUCLID 6 and replace them with temporary files. The database patch tool report will list the issues detected so that they can be fixed correctly by the user.

2.3. Replace during import

Q7: Replace during import: what is the difference between overwrite and replace?

A7: In brief, import can only add new documents, or replace existing documents. It never deletes documents. The replace functionality is a full replace of the existing object and removes documents if not present anymore in the object that is being used to replace.

Q8: Will there be an option in importing process like 'ask user' as in IUCLID 5?

A8: This is not planned currently. We recommend instead to use Always overwrite and to select the documents that should be imported. This is possible in the 'Advanced options' of the import assistant.

Q9: Replace during import: a feature is needed so that you can decide during import which objects are overwritten / replaced and which not. If you import a substance with many connected reference substances from IUCLID 5.6 all the reference substances are overwritten.

A9: During import, you can use the advanced options in order to select the elements of your dataset you want to import and deselect the ones you do not want to import. This option is unfortunately not available when importing a IUCLID 5.6 file.

Q10: It would be interesting to have a kind of table with the different options (replace/newer/always...) highlighting the differences among all these options. It is not straightforward to understand the consequences of each option (replacement/updates).

A10: Thanks for this idea. We will see how this could be included in the Help System.

Q29: Please could you explain the consequences of the different possibilities when we import a dataset (always, ask user, if newer than existing, never). Where could these explanations be found?

A29: This information is in the IUCLID user manual available at:
<https://iuclid6.echa.europa.eu/documentation>.

2.4. Comparison

Q11: Will the comparison tool only work with dossiers, or substance datasets also?

A11: The comparison will be available only for dossiers.

Q13: Is it possible that two separate dossiers exist in the IUCLID database with the same UUID?

A13: Each dossier in IUCLID has a unique identifier. However, two dossiers can be created based on the same substance. By comparing two dossiers you can see the changes made in different parts of the datasets which was used as a basis for the dossiers creation.

Q14: Comparison tool: is the tool working only for dossier with the same UUIDs? Is it possible to compare two dossiers created in different days for the same product?

A14: The comparison is meant to be used with two different dossiers, created from the same dataset (substance or mixture). So, yes, you will be able to create two dossiers created for the same product. The changes between the two 'versions' of the dossier will then be highlighted by the tool.

Q53: Will the 'dossier compare function' be available with the new release in September?

A53: Yes, the dossier comparison function will be available in the service release of IUCLID on 30th September.

2.5. Data reporting in IUCLID 6

Q17: what about use as intermediate but not strictly control condition, shall we use the REACH art. 17/18 indicator?

A17: Use as Article 17/18 intermediate should only be indicated when the intermediate use takes place under strictly controlled conditions.

Q22: Why do we have to enter the results of the source again into the target entry, this is usually the same information; same for summary and conclusion, as the justification for read-across is usually in a separate document.

A22: As explained in one of the last slides, the source and target information in the analogue read-across are in many cases not identical. The source information relates to the experimental study, and the target information to the outcome of applying read-across.

Q44: For reporting skin sensitising potential in vitro, is a single in vitro or cheminformatics record sufficient to pass the Technical Completeness Check or are multiple records required (in accordance with the AOP Approach)?

A44: The completeness check will require the presence of one complete endpoint study record addressing the in vitro / in chemico requirement.

Q45: If I select article 10 for intermediates under 10 t/y and run the validation tool, it shows an error because I have not informed about the service life. However, I cannot select it, as it is inactive. How can this be resolved?

A45: This is a known conflict between the Dynamic content validation and the completeness check rule. It will be fixed in the September release of IUCLID 6. If you need to send your dossier before the fix, you can, in this particular case, leave the Subsequent service life field empty, and ignore the Technical Completeness Check failure. It will not cause a failure at the TCC stage in REACH-IT.

Q50: Does the validation assistant reflect the changes to the skin sensitisation requirement?

A50: The Validation assistant included in the September 2016 release will reflect the change to the skin sensitisation requirement.

Q61: Related to skin irritation / eye irritation / skin sensitisation - is it not counter-intuitive to report both a key study and data waiving for the same endpoint? Where does it say in the guidance that this is the procedure to follow?

A61: The completeness check is designed to check that the current information requirement is fulfilled. Since the information requirement is the in vitro study, at least one endpoint study record must be included addressing this requirement. The manual on How to prepare registration dossiers and PPORD, available on the ECHA website, under Support > Manuals, contains an example of this situation (examples on how to fill in endpoint study records).

Q64: How come the verification tool then approves a record where only an in vivo is provided (if I select other: in vivo and provide a justification)?

A64: Do you refer to skin sensitisation? The skin sensitisation amendment has yet to be officially published. It is included in the Validation assistant released in September 2016.

Q68: Why does your table on reporting read-across, in the webinar presentation, differ from Table 3 in the guidance issued April 2016 (how to prepare registration and PPORD dossiers)?

A68: I on purpose left out some fields in my slide that can be used in the source endpoint study record (e.g. Justification for type of information, Cross-reference), but are not often relevant. This was to more clearly illustrate that they are mandatory in the target record.

2.6. Users' feedback

Q3: Contrast needs to be improved. Very important!

A3: Yes, indeed. The issue was brought by several users via the Helpdesk. Please try the next service release and let us know whether the contrast has been improved enough or not.

Q15: I have been having issues with creating dossiers, though not every time. In dossier creation, the word 'executing' appears on the screen for a few seconds and then disappears. The dossier creation process does not complete but no error message is visible

A15: If the issue always happen for the same substance(s), this might be due to a bug we identified and fixed in the September update. You can check the known issues we have published on the IUCLID 6 website in order to see how to deal with this issue for now: <https://iuclid6.echa.europa.eu/faq#q36>.

Q57: Will it be possible to import information from IUCLID export files to the clipboard as in IUCLID 5?

A57: This will not be possible in IUCLID 6, but you can import the file and copy the content to the clipboard then re-use it through the paste function of the clipboard.

2.7. Chesar integration

Q4: Is the intention to ultimately have Chesar updates to the same schedule as IUCLID (April & October), or will there always be this compatibility gap?

A4: Regarding releases dates: the future release dates of Chesar will be aligned with IUCLID release dates but it is foreseen that there will be a couple of weeks difference between the two products release dates (IUCLID being the first one).

Regarding compatibility: compatibility between Chesar and IUCLID might be broken maximum ones per year in case it is needed. In other words: it is not foreseen that every new release of IUCLID will require a new release of Chesar.

Q6: Just to be clear, we should not update IUCLID 6 (30th September 2016) if we use CHESAR 3, until the CHESAR 3 update is released in October?

A6: Indeed, Chesar users should upgrade both IUCLID 6 and Chesar 3 in October when the update of Chesar 3 is made available.

Q16: you spoke about Chesar 3 and IUCLID 6. Not sur to have well understood. Can we upload Chesar 3 on IUCLID 6?

A16: Chesar 3.0 (published in June) is compatible with IUCLID 6 v1.0.2 (published in June). Chesar 3.1 (planned to be published in October) will be compatible with IUCLID 6 v1.1.0 (to be published in September). Chesar 3 can communicate with IUCLID 6 in order to retrieve substance properties and can also populate the uses in IUCLID 6 section 3.5.

Q42: You indicated to wait for the update of Chesar3 in October before updating Iuclid6. Can you explain?

A42: IUCLID 6 v1.1.0 will not be able to communicate with Chesar 3.0 (currently released). If you are not planning to load substance data from IUCLID into Chesar or upload use and exposure data from Chesar to IUCLID then there is no need to wait until October.

2.8. Miscellaneous

Q21: Is there a IUCLID webinar for beginners?

A21: There will be a webinar on how to prepare a registration dossier under REACH, using IUCLID 6 and REACH-IT 3 as part of the 2018 roadmap work. You will find more information at https://echa.europa.eu/view-webinar/-/journal_content/56_INSTANCE_DdN5/title/reach-2018-prepare-your-registration-as-a-iuclid-dossier.

Q33: If I notice errors in IUCLID 6, such as the waiver in the drop-town list for surface tension is wrong, who should I notify?

A33: You can report these findings to the ECHA Helpdesk (IUCLID support).

Q47: Will it be possible to download several reference substances at once from the IUCLID 6 website or is it only possible to download reference substance one by one.

A47: In addition to the individual download of reference substances from the IUCLID 6 website, a package of around 3,700 commonly used reference substances is available for download. All reference substances downloaded from the IUCLID 6 website can then be imported in bulk in IUCLID 6 (Cf. <https://iuclid6.echa.europa.eu/get-iuclid-data>).