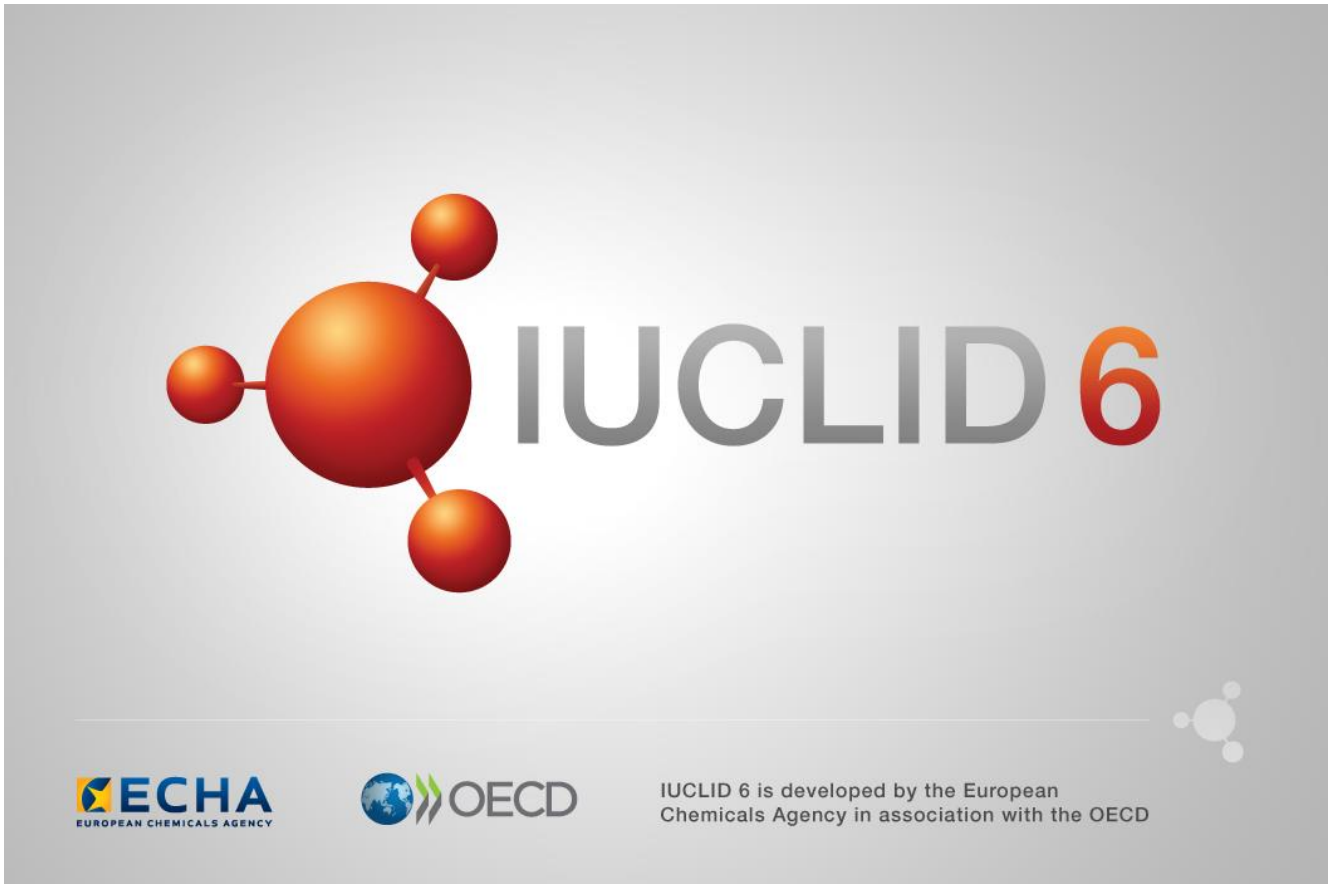
IUCLID 6

Webinar IUCLID 6 – Questions and Answers

IUCLID 6.7.0.1

09/06/2023



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1. INTRODUCTION

This IUCLID 6 webinar for the May release took place on the 8th June 2023. It was intended for users of IUCLID 6.

More information from the release can be found on the IUCLID website.

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

Please also have a look at the latest update of the Frequently Asked Questions page on the IUCLID 6 website: https://iuclid6.echa.europa.eu/faq.

2. INTERFACE

Q1: During the presentation it has been shown a comparison between datasets. Can I make the same type of comparison between dossiers?

A1: The comparison tool can also be used to compare Dossiers and Individual IUCLID documents (also known as records). See the IUCLID manual, section 8.5, for more details: https://iuclid6.echa.europa.eu/documents/1387205/1809908/iuclid_functionalities_html_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395?t=1635259628684

3. CLOUD

Q2: Can you confirm when all instances of IUCLID Cloud will be updated by?

A2: We can confirm that there are 3500 cloud instances left to be migrated to v7 as of 08/06/2023. It is expected that by next Monday 12/06/2023, all the instances are migrated to 6.7. The update process requires migrating the data to a new format and we are doing the migration in batches.

4. INSTALLATION AND UPGRADE

Q3: What do I have to do to work with the new version of IUCLID 6 (version 6.7) online? Because this morning I've tried to see the same things that the relators has showed, but I didn't find them, infact I've the version 6.6 of IUCLID.

A3: IUCLID Cloud instances hosted by ECHA are currently upgraded to version 6.7. We expect that all instances will be upgraded latest by 12/06/2023. If you use a IUCLID instance that is hosted by your own organization or was installed on your local machine, then it needs to be upgraded by your IT support. The updater tool can be downloaded from the IUCLID website (https://iuclid6.echa.europa.eu/download). Note that the Updater will be re-published on the week beginning 12/06.2023 in order to fix an issue with Endpoint Summary migration. If you experience any issue during or after update, please contact ECHA Helpdesk (https://comments.echa.europa.eu/comments_cms/Contact_IUCLID6.aspx).

5. INTERNATIONAL

Q4: Could you precise more where IUCLID 6.7 is not accepted?

A4: We currently do not have any information about a regulatory authority not accepting IUCLID 6.7. However, there is a possibility that time is needed for regulatory authority systems to be updated to be compatible with the latest version of IUCLID. It is recommended to check with the recipients of IUCLID files whether they are accepting the latest version already. In EU, submissions of IUCLID dossiers in the new version of IUCLID to ECHA and EFSA is already possible.

Q5: If I need to use IUCLID for both EU REACH and UK REACH should I upgrade now given that the extension for UK REACH is only for testing in IUCLID 6 version 7?

A5: Indeed, the new extension created for UK REACH in IUCLID 6 v7 is for testing purposes only. The recommendations given by UK HSE should be followed in terms of preparation of IUCLID files. ECHA is already accepting the latest version but please check with the relevant UK authority whether they accept the latest version too, before upgrading. ECHA is also still accepting previous IUCLID versions. Another option, if you decide/prefer to upgrade, is to export your dossiers using the 'previous major version' option. This will create a dossier in the previous format that can be submitted to all authorities who are still using IUCLID 6 v6.

6. FORMAT

Q6: Could you please explain why the section 2 for the EU PPP Microorganisms working context is still blocked and does not allow it to be filled properly?

A6: The document which covers information requirements for points 2.1, 2.2 and 2.4–2.9 is provided directly under section 2 (you need to click on the section 2 title and then a plus sign which appears on the right). Sections 2.1 – 2.9 are displayed in grey, italic as they are only references to the documents in sections 2 and 3.1. However, if you cannot create a document under section 2, please report it to the EFSA help desk https://www.efsa.europa.eu/en/applications/askaquestion.

Q7: When creating a "BPR SPC" working context from a "BPR Product" working context, the endpoint Composition remains as in the original "BPR Product" working context. This is an issue since the complete composition must be reported for a Product dossier, and only as and SoCs are reported in an SPC.

A7: We are aware of this difference, and we are analysing possible solutions to implement before the transition from the XML Editor to IUCLID at the end of the year.

7. WEBINAR

Q8: Will this webinar be published on the IUCLID website?

A8: The Webinar will be published on the IUCLID youtube channel shortly after the event: https://www.youtube.com/channel/UCYpcZKod97aYXv8U7WaLxxg. We will also publish the Q&A and the slides on the ECHA Webinar page: https://echa.europa.eu/-/iuclid-6-2023-format-changes-release

8. IUCLID UPDATE AND REGULATORY DEADLINES

Q9: Does the upgrade interfere significantly with any e.g. REACH or BPR dossiers that are in the process of being prepared, i.e. should such dossiers be finalised before performing the upgrade? What should be taken into account?

A9: You can submit your IUCLID 6 file to ECHA (for REACH/BPR) in IUCLID 6.6 still. However, you should bear in mind the time it will take to update your IUCLID instance to 6.7 and if you have any pressing regulatory deadlines and obligations. Note that for the Validation assistant, If you must submit a new dossier before you have finished updating your IUCLID, you may still consider preparing it in the old IUCLID version. To avoid issues with the new TCC rules, you may check the affected dossier areas manually before you submit the dossier. Information on the new and updated TCC rules in available on this page: https://echa.europa.eu/-/completeness-check-of-reach-registration-dossiers-what-changes-in-2023-and-how-you-can-prepare. Should it happen that your dossier fails TCC upon submission, you will receive a list of failures with instructions on how to correct them and a standard deadline of four months to update the dossier.

9. VALIDATION ASSISTANT

Q10: Are the new validation rules implemented only in the validation assistant in IUCLID 6.7? In other words: if I run the validation assistant in a previous IUCLID version, is the outcome still valid after the new requirements enforced as of 1st June 2023?

A10: If you must submit a new dossier before you have finished updating your IUCLID, you may still consider preparing it in the old IUCLID version. To avoid issues with the new TCC rules, you may check the affected dossier areas manually before you submit the dossier. Information on the new and updated TCC rules in available on this page: https://echa.europa.eu/-/completeness-check-of-reach-registration-dossiers-what-changes-in-2023-and-how-you-can-prepare. Should it happen that your dossier fails TCC upon submission, you will receive a list of failures with instructions on how to correct them and a standard deadline of four months to update the dossier.

Q11: I created a WoE endpoint and filled in the following sections: Justification for type of information / Cross-reference / results and discussion and conclusion but I still have an alert: Completeness check rule (TCC_ESR_02) Can you tell me which part I need to fill in for this new endpoint?

Q11: The latest list of new and existing Validation rules can be found here: https://echa.europa.eu/documents/10162/20188284/list_of_new_and_amended_completeness_check_rules_en.pdf/90f64c1a-6e5d-5a88-f454-ad8aeca6371b?t=1681881629490

For this particular TCC rule, please ensure that all records with the 'type of information' set to 'weight of evidence justification/conclusion' contains the following:

1) A justification in the field ‘Justification for type of information’. It includes a template to support you in building the justification;

2) Weight of evidence source documents linked in the ‘Cross-reference’ table;

3) Information in the ‘Results and discussion’ table.