

IUCLID 6

Webinar IUCLID 6 – Questions and Answers

IUCLID 6 version 1.2.0

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EUROPEAN CHEMICALS AGENCY

 **OECD**

IUCLID 6 is developed by the European
Chemicals Agency in association with the OECD



Table of Contents

| | |
|--|----------|
| 1. INTRODUCTION | 2 |
| 2. QUESTIONS AND ANSWERS..... | 3 |
| 2.1. IUCLID features | 3 |
| 2.2. IUCLID installation and update..... | 4 |
| 2.3. IUCLID and Chesar | 4 |
| 2.4. Issues with IUCLID..... | 4 |
| 2.5. IUCLID Public API..... | 4 |
| 2.6. DNEL Calculator | 4 |
| 2.7. Report Generator | 5 |
| 2.8. Validation Assistant..... | 6 |
| 2.9. Misc. | 6 |

1. INTRODUCTION

This IUCLID 6 webinar took place on the 2nd of February 2017. It was intended for users of IUCLID 6. It presented the content of the IUCLID 6 update published on 31st of January 2017. It built on feedback received from users after previous IUCLID 6 releases and addressed the most frequently asked questions and reported issues.

It covered:

- Information on IUCLID 6 version 1.2
 - Fixes for known issues
 - New features (DNEL generator, hyperlinks, IUCLID Public API)
- Advanced feature of the Report generator
- Tips for registrants

The 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. IUCLID features

Q1: When the Advanced search Plugin will be available?

A1: The advanced search options are being developed now as a new application that will provide powerful search possibilities to Oracle databases users. Our intention is to start a beta testing phase with interested parties before summer.

Q2: Can you now print only selected endpoints/sections, as currently the option is to only print a whole file/substance data set.

A2: The print functionality is enable at record and dataset or dossier level. This is the case since IUCLID 6 1.0.0. You are able to print individual endpoints by going to the 'TOC' tab, selecting the records in the section tree and choosing print. There is no possibility to print multiple selected endpoints in a single document. The possibility to select which information from a dataset should be printed is not available currently. As a workaround, it is possible to use the advanced settings of the dossier creation wizard in order to select which information should be included in the dossier; then it is possible the create the generated dossier in full.

Q6: Category-based dossiers with limited content: what is exactly meant with "test summaries" on the respective slide (ca. #15)?

A6: Mainly the content of sections 4 to 13 (endpoint study records and endpoint summaries) is included in dossiers for category members. Uses and GHS information for example are included only for the main (registered) substance.

Q9: Will there be a fee calculator plugin in the future or is it cancelled entirely?

A9: The fee calculator has currently been deprioritised for development. As soon as we have a better idea when this feature can be made available we will inform all users.

Q16: In the previous version, there are a number of tables for which only a few lines are displayed. You need to scroll to view the others. Will this be fixed in a next version?

A16: This has not been addressed in version 1.2.0 of IUCLID 6 but this improvement is planned for the October 2017 version.

Q17: Does the button "update all references" work in the new version?

A17: This has not been addressed in version 1.2.0 of IUCLID 6 but this improvement is planned for the October 2017 version.

Q20: Was there an update in the TMI management?

A21: There was no specific improvement to the Test Material Information management in version 1.2.0. However, an inventory manager is available since version 1.1.0. More information can be found in the IUCLID functionalities manual (section 18).

Q25: Is it possible to print an html version of an endpoint study record? This option was available in previous versions of IUCLID but seems to be not available in current version.

A25: The Endpoint study records can only be printed in .pdf format.

2.2. IUCLID installation and update

Q3: is it possible to update IUCLID6 1.0 directly to version 1.2.0, leaving out 1.1.0?

A3: Yes, you can update directly to 1.2.0.

2.3. IUCLID and Chesar

Q11: From the next release will IUCLID and Chesar be released at the same time so that there will be no delay when upgrading both applications.

A11: IUCLID and Chesar releases are planned following an agreed release plan. The intention of ECHA is to keep both tools compatible as much as possible, like IUCLID version 1.2.0 and Chesar 3.1.1 for example.

Q23: Could you please indicate where exactly in section 3.5 of IUCLID 6 the RCRs generated in Chesar would appear?

A23: The IUCLID section 3.5 contains fields for reporting the exposure estimations. However, no specific fields are defined for reporting the RCRs values as these can be calculated based on the exposure and hazard information already stored in IUCLID.

Q24: Will this new version be compatible with the old Chesar version of 2.3

A24: IUCLID 6 is not compatible with Chesar 2. The latest version IUCLID 6 v1.2.0 is compatible with Chesar 3.1.1

2.4. Issues with IUCLID

Q4: We experience a printing problem of pdf files (doesn't work) in version 1.1.0 is that also solved in version 1.2.0?

A4: Known issues related to printing (creation of pdf) have been addressed. In case you are facing these issues the first step should be update to 1.2.0.

2.5. IUCLID Public API

Q5: What means the abbreviation API?

A5: API means application programming interface. It is of interest for programmers only. However this offers possibility that you may integrate IUCLID with other applications you may have... if you need to.

2.6. DNEL Calculator

Q7: Is the use of ECHA provided DNEL calculator mandatory?

A7: No, the use of DNEL calculator is not mandatory. However, we encourage you to use it as it might improve consistency in the data and transparency on how DNELs have been derived.

Q8: Will there be an equivalent PNEC generator in the future?

A8: Yes, an equivalent PNEC calculator is foreseen for a future IUCLID release.

Q26: If registrant have DNELs, should he recalculate them using the new plugin and use new values?

A26: The DNEL calculator can be used to cross-check the DNELs already calculated with the DNELs result of applying ECHA Guidance. Although the use of the DNEL calculator is not mandatory, we encourage you to use it as it might improve consistency in the data and transparency on how DNELs have been derived.

Q27: Are you going to extend the DNEL calculator in order to cover the short term or local effects?

A27: We are exploring the possibility of extending the DNEL calculator to other DNELs in a future release of IUCLID.

Q28: If registrant performed already qualitative analysis in Chesar 3.1 because of lack DNELs, should he calculate DNELs in new IUCLID and to do qualitative analysis?

A28: The DNEL calculator will not work if DNELs cannot be derived. Therefore, in such a case you could proceed with a qualitative assessment using Chesar.

Q29: With DNEL calculator tool and the future PNEC calculator, it is also planned to develop a tool to calculate RCR's and MOS's for formulated product with exposure date included by us?

A29: At the moment it is not foreseen the development of a tool to calculate risk characterisation ratios (RCR) or margins of safety (MOS). Nevertheless, we encourage you to use Chesar as it will help you to carry out the chemical safety assessment (and prepare the CSR) in a structured, harmonised, transparent and efficient manner. You can find more information at: <https://chesar.echa.europa.eu/>

2.7. Report Generator

Q10: Can you please repeat what SPC stands for?

A10: Summary of product characteristics. The SPC report is used for product authorisations under the BPR regulation

Q12: Will it be possible to generate a IUCLID file by importing an SPC .xml (which was prepared in SPC Editor)?

A12: No, this is not a feature that was foreseen

Q13: Where can we find the documentation on how to create / change report stylesheets for the report generator?

A13: Currently, there is no IUCLID support for creating stylesheets. We will publish on the IUCLID 6 website the default stylesheet we use. You can use this to help create and customize your own stylesheets. We will do this before the end of the week.

Q30: Maybe I just missed this part, but is there documentation on how to create report templates?

A30: Yes, on the IUCLID 6 report generator page: <https://iuclid6.echa.europa.eu/reports>. We will be providing more information on this in the future.

2.8. Validation Assistant

Q14: How can I be sure that Validation Assistant is up to date? In old version IUCLID 5 there was the message on the left bottom that V.A is up to date

A14: The latest version of the Validation assistant is always included in the latest IUCLID version. By keeping your IUCLID version up to date, you can ensure to always have the latest VA installed. The user can choose to be notified of when new versions of the IUCLID application or its components are available. For more information regarding the update check feature, please access the IUCLID Help System (F1 key) and refer to section 15.1.2.5 of the *Functionalities of IUCLID*). You can also refer to the release notes of a new IUCLID version to see a summary of the changes made to the Validation assistant.

Q15: Do the manual checks include a review of the submitted analytical data (attachments) as would be performed in the inquiry process?

A15: No. The manual checks do not verify the quality of the submitted information including the analytical data. They check that a relevant justification is included if you have not provided the required results for analytical information.

Q18: Does ECHA check manually if all the analytical and spectral data as required in annex VI and if not is the dossier rejected? And in case where some analysis are not applicable to the type of substance?

A18: See A15.

Q19: The quality checks are planned to be developed as part of the validation assistant?

A19: Quality rules are being developed continuously, their aim is to improve the overall quality of the dossier. The currently available quality rules can be found under the 'Quality checks' tab of the Validation assistant report. Please note: the warnings issued under the 'Quality checks' tab are not related to the Technical completeness check. Technical completeness check failures are reported in the 'Submission checks' tab; however failures that are identified during the manual checks by ECHA staff cannot be detected with the Validation assistant.

Q22: When creating dossier from DS, does LE matter still (is it a BR failure) or can you work in any LE now, as it does not appear in the dossier header anymore?

A22: With IUCLID 6 it is not mandatory not include a legal entity in the dossier. The absence of a legal entity will not cause a business rules failure. If you decide to include a legal entity in the IUCLID dossier and the REACH-IT account you submit the dossier with has a different legal entity, you will get a warning about this when you upload your file for submission. You can however choose to ignore it.

2.9. Misc.

Q21: Are there practical examples of dataset to be used as probe?

A21: An example dataset has been made available on the Chesar website:
<https://chesar.echa.europa.eu/support/library>

Q31: Are there any plans to make IUCLID 6 and OECD QSAR toolbox compatible?

A31: Yes, this is planned for version 4 of the Toolbox, scheduled to be made available at the beginning of April 2017.