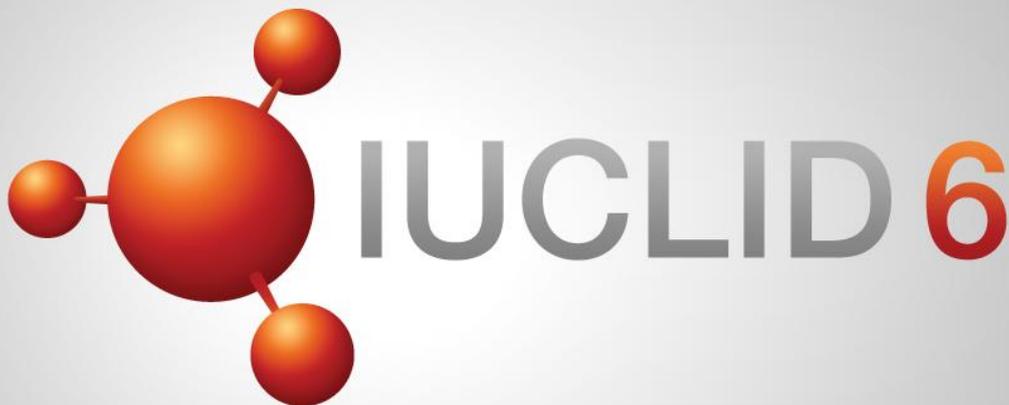


IUCLID 6

Webinar IUCLID 6 – Questions and Answers

IUCLID 6.2

15/11/2017



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



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1. INTRODUCTION

This IUCLID 6 webinar took place on the 15th of November 2017. It was intended for users of IUCLID 6. It presented the content of the IUCLID 6 update published on 15th of November 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 version 6.2
- Compatibility between IUCLID versions
- Installation and update
- Fee calculator
- Update on ECHA Cloud Services and IUCLID Cloud

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 installation, update and migration

Q1: Is version 6.2 of IUCLID already available?

A1: Yes, IUCLID 6.2 can now be downloaded from the [IUCLID website](#).

Q2: Is the new version of IUCLID mandatory?

A2: It is not mandatory for submission of information to ECHA. You still have the option to use it in case you are interested in the improvements included.

Q3: Is IUCLID Cloud needed for an update from version 6.1 to 6.2? Do I have to export all of the data before migration and then import them in a new version?

A3: If you have IUCLID 6 v1.x.x Desktop, you can upgrade to IUCLID 6 2.0.0 using the upgrade tool. Export/import is not needed but backup before upgrade is recommended. If you have a IUCLID Cloud account, the update to the latest version will be done automatically (the week of the 20th of November).

Q4: Can our IT department update the 6.2 version without first using a separate server as a test environment?

A4: This is related to your company IT policies. Testing is a good policy but not mandatory. It is only mandatory to take valid backup of your data before upgrade.

Q5: How can I do a backup?

A5: In the Desktop version there is a backup tool (see the available [video tutorial](#)). In addition to this, the upgrader also creates a backup. In case you have a server installation and are using your own database, a backup of your database should be done separately as well.

Q6: Are there any plans for a server version of IUCLID for a Mac server?

A6: There is no plan to support this configuration. Most likely the existing server version would work with Java JDK for Mac however this has not been tested specifically.

Q7: If CSR and non CSR assessment reports are attached in section 13 of IUCLID 6.1.3, will these be transferred correctly to the structure 13.1 and 13.2 in IUCLID 6.2.0.?

A7: Yes, the migration recognises the type of report. Chemical Safety Reports are migrated to the correct section and the other reports stay in the other report section.

Q8: I have the feeling that the migration between versions will generate an overload of work in checking the fields where the information has been included.

A8: The migration to the IUCLID 6.2 is limited in scope and is not particularly complex. The list of changes are listed in the IUCLID 6.2 release notes and you can of course check how some of your data were migrated. The way the migration is implemented ensure the consistent outcome of the migration across all datasets and dossiers.

2.2. Compatibility between IUCLID versions

Q9: Will the tool to export to previous major version cover all IUCLID 6 versions published until now?

A9: Yes, you will be able to backward export to all IUCLID 6 versions.

Q10: What will happen if I update my IUCLID to version 6.2 but one of my clients has not (we are not aware of the differences between versions of our software)? Will I get a failure report?

A10: When you import a IUCLID 6.2 file in a 6.1 database the import will fail. The error message will indicate that the version is not compatible. In case of doubt you can export your data in the 6.1 format when exchanging it with other companies.

Q11: As this update has occurred so close to the deadline, will ECHA be putting a notice on ECHA's website to alert all registrants about the differences in versions compatibilities and possible issues with data sharing within the SIEF?

A11: We are preparing a short video tutorial to illustrate the export options. We can indeed create a news item on our website to promote this and inform the SIEF members at the same time.

2.3. IUCLID and Chesar

Q12: Is IUCLID 6.2 compatible with Chesar 3.2?

A12: Chesar 3.3 has been released already. We strongly recommend that you use Chesar 3.3 with IUCLID 6.2 since compatibility of Chesar 3.3 with IUCLID 6.1 has not been widely tested. For more information please check the [Chesar Q&A page](#).

2.4. Fee calculator

Q13: Are there any plans to introduce a fee calculator for submissions under the BPR?

A13: At the moment there are no plans for that.

Q14: Will the hazardous or PBT classification impact the fee calculator for intermediate registration?

A14: Yes. The hazardousness of the substance will affect the registration fee if a confidentiality in the IUPAC name is claimed in an intermediate registration. For example, a non-hazardous substance used only as an intermediate will not receive the fee for the IUPAC name

confidentiality claim. On the other hand, if the intermediate substance is hazardous then the fee will be issued.

Also, the substance hazardousness and the PBT status will affect the registration fee if a confidentiality is claimed on the Safety Data Sheet (SDS) information.

When using the calculator answer correctly to the questions when the hazardous substance indicator or the safety data sheet indicator appear. The indicators will only appear if they are relevant for calculating the registration fee and if the required information is not already included in the dossier. The indicators will therefore appear more often in member dossiers as these are not required to have information related to the hazardousness of the substance (in section 2.1 of the dossier).

Q15: Can the user run the fee calculator before the registration?

A15: Yes, the idea behind the fee calculator is that you run the calculator on your dossier before submitting it in REACH-IT to see the estimated fee for that registration. For example, if you see that you chose the wrong tonnage band or claimed confidential information from your dossier that you were not intending to claim then you can use your substance dataset and create a new dossier. Remember to run again the fee calculator on the newly created dossier.

Q16: Can we enter company information such as balance sheets etc. to prove SME status in the extended Legal Entity section?

A16: Our Finance department does not use the information from your IUCLID dossier to verify your SME status. You should provide that information in the 'Company size' section of REACH-IT. You can access it by clicking on the Menu and then on the top right part.

2.5. Report Generator

Q17: Where can we find more information on the export function from IUCLID 6.2 to the SPC-Editor?

A17: More information on this subject you will find from the IUCLID 6 webpage, and this [document](#). The export functionality is available using a right-click on your product dataset or dossier, then select report generator and choose the SPC export option. The XML file that will be exported from IUCLID and saved locally can then be imported to the [SPC Editor](#).

2.6. Validation Assistant

Q18: May the structure loss while migrating data between different versions of IUCLID 6 cause validation failures?

A18: We have built the backward migration in a way that it does not impact the validation of the dossiers performed by ECHA.

Q19: Are the different manual checks outcomes due to different IUCLID versions?

A19: The manual check is done in ECHA based on the IUCLID 6.2 version since the 6th of November. All dossiers will be treated in the same way.

2.7. IUCLID Cloud Services

Q20: Will the IUCLID Cloud be available for non-SME/large companies?

A20: The IUCLID Cloud for SME is targeted functionality and size wise to the needs of smaller companies and the funding provided by the commission to develop it was targeted to SMEs. After the registration deadline ECHA will assess and decide about the future.

Q21: Does the IUCLID Cloud have the same API functionality as locally installed IUCLID? Does it allow users to enter/extract data from their own system?

A21: Technically yes, as we are running the same IUCLID application, but we are yet to expand the API to manage the user accounts and access rights handled by the ECHA Account system. We will notify users once this function has been concluded and verified.

Q22: What about the structure of the data in the Cloud generated by using previous versions of IUCLID? In what fields of IUCLID Cloud will it be placed?

A22: IUCLID Cloud and IUCLID (Regular) are using the same format, so the compatibility between Cloud and IUCLID follows the same rules as presented during the webinar. For all IUCLID format changes, you can find these on the IUCLID 6 website.

Q23: Will there be a "Support for REACH 2018 registration" in IUCLID 6 (Regular) version for large size companies?

A23: This is not in our plans. We assume that existing users of IUCLID already has enough experience and knowledge to prepare the dossiers by themselves. The support module is intended to be useful and supportive for first time dossier builders. Nevertheless, would a large company have an interest in the module or would like to train some of their staff via the module, this can be done in the IUCLID Cloud Trial service which is available to everyone.

2.8. REACH and CLP

Q24: Is the upload of data for Classification and Labelling notifications into REACH-IT possible?

A24: The options available for submitting a C&L notification are i) use the REACH-IT online dossier with the nice function of agreeing with other notifiers on a C&L or ii) prepare the notification in IUCLID. In both situation the notifications need to be done and maintained one by one. Upload directly from Excel is unfortunately not possible any more.

Q25: Is it possible to upload bulk CLP Notifications to IUCLID for example using Microsoft Excel?

A25: There is no generic "Excel to IUCLID" function available in IUCLID. The previously existing Excel-based functionality to prepare and submit bulk C&L notifications was discontinued in

REACH-IT last year with the updates of the GHS and the CLP regulation. Most users have opted to use the REACH-IT online dossier for creating and maintaining their C&L notifications. At the moment there is no bulk option available.

Q26: If IUCLID has features allowing users to enter/extract data from their own system, is it not possible to do this, then prepare the notification in IUCLID, then upload the IUCLID dossier into REACH-IT?

A26: Yes, technically this is possible and we assume that there are companies who have chosen to link their own systems with IUCLID. You can find more information on how to integrate IUCLID with other systems, using the IUCLID Public API, on the [IUCLID 6 website](#).

2.9. Miscellaneous

Q27: Is there a way to do a mass export of dossiers, substances or Legal Entities?

A27: Yes - IUCLID comes with a Bulk export functionality to export all your data. Please refer to the [Help section](#) of IUCLID on how to do it if it feels complex.

Q28: Are you already working on a dedicated search plugin? We are looking forward to find datasets or dossiers based on endpoints, endpoint summaries, other fields or even endpoint names.

A28: We are working on an advanced search tool that is a separate application which integrates with IUCLID. The tool will only work with Oracle databases for the time being though. We intend to start a beta testing phase soon. There will be information about this on the IUCLID website and the [LinkedIn group](#).

Q29: Are there any plans to add templates for mechanistic data (separate from adverse effects for ecotoxicology and human health)? Particularly data relevant for endocrine information, with more of a focus on molecular information and biomarkers, rather than apical endpoints e.g. in vitro oestrogen/androgen receptor assays (see OECD Guidance 150, Conceptual Framework Levels 2 and 3).

A29: Thanks you for your question. We will be in contact with the OECD Harmonised Templates Group in order to see if there could be some development in that direction.

Q30: Are there any plans to improve the performance of rich-text fields? The formatting tools do not perform to a sufficient level, this means that dossier preparation is more time consuming and often requires the use of additional software (e.g. MS word).

A30: The rich-text fields allow you to a number of standard format changes to the text. Currently the options available differ between the web user interface available in IUCLID Cloud and the standard IUCLID user interface. We will be looking into options to improve the editing options in the next IUCLID releases.