IUCLID 6

Webinar IUCLID 6 – Questions and Answers

IUCLID 6.4

08/11/2019

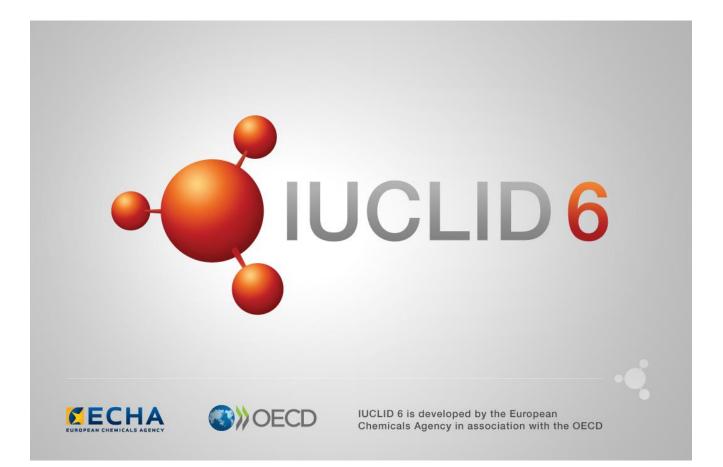


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1. INTRODUCTION

This IUCLID 6 webinar took place on the 8th of November 2019. It was intended for users of IUCLID 6. It presented the content of the IUCLID 6 update published on 30th of October 2019. The webinar built on feedback received from users after previous IUCLID 6 releases and addressed the most frequently asked questions and reported issues.

The webinar covered:

- Changes to the REACH Regulation, including new data fields for reporting nanoforms as well as the latest amendments (ATPs) to the CLP Regulation
- New features for the upcoming database on substances of very high concern in articles (SCIP) and supports the needs of several regulatory authorities, in particular the European Food Safety Authority (EFSA), and the authorities managing chemicals in Australia and New Zealand
- The web user interface with new improvements such as direct navigation to referenced documents in dossiers, advanced printing options and a more compact document view.

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: <u>https://iuclid6.echa.europa.eu/faq</u>



2. INSTALLATION AND UPDATE

Q1: Can I update directly from IUCLID 6.2 to 6.4 or do I have to first update to IUCLID 6.3 and then 6.4?

A1: Yes, you can update directly to IUCLID 6.4 from 6.2. We recommend that you use the updater when updating to the new version. You can find more information about how to update to the latest IUCLID 6 version by watching this <u>video tutorial on the IUCLID updater</u> tool. You can also refer to the Chapter 9 of the <u>installation manual</u>.

Q2: Could you confirm that the possibility to have desktop and server installation will remain with the transition to the web interface? Or is the web interface a first step towards a full cloud service?

A2: There are no plans to phase out the downloadable applications (Desktop and Server distributions). The primary motivation behind creating the web interface has been to overcome certain technical limitations of the classic interface.

Q3: Can the previous IUCLID 6 version database backup files be used with IUCLID 6.4?

A3: Old versions of IUCLID 6 databases cannot be used as such with IUCLID 6.4. The database must be upgraded first.



3. IUCLID FEATURES

Q4: Is the template system still limited to endpoints only (IUCLID sections 4 to 7) or can we use templates for other sections (e.g. use information in section 3.5) as well?

A4: The template was expanded with the development of IUCLID 6, so now you can manage much more complex scenarios with templates.

Q5: When can you see the export option within the new web interface as it is currently all greyed out from the dashboard?

A5: A greyed-out button means that you do not have access to the functionality. The access is set by the administrator of IUCLID. User management settings can only be changed, currently, using the classic interface.

Q6: Is there an option to import Harmonised Classification and Labelling information directly into IUCLID rather than typing it in?

A6: This is not available in IUCLID yet indeed however this is in our list of requirements and we will analyse this option in 2020.

Q7: Will the new category object be able to accommodate UVCB categories in a more manageable way.

A7: The Category object is not yet available in the web interface, it is available only in the classic interface and has not been changed since IUCLID 5. More information on reporting category information is available in the linked guidance document. Please contact the ECHA Helpdesk to share your feedback on managing UVCB categories.

Q8: Classification and labelling calculator will only be available for use in IUCLID?

A8: Yes, the C&L calculator will be available only in the IUCLID web interface.

Q9: Does the new version of IUCLID generate an SPC.xml file compatible with the SPC editor and with R4BP 3?

A9: A draft SPC XML file can be generated using the report generator of IUCLID 6 and uploaded into the SPC Editor for further editing. Note that this option is limited to single products (i.e. not product families). The SPC XML files generated by IUCLID cannot be directly submitted through R4BP 3. They must be finalised using the SPC editor first.

Q10: Some of the sections in IUCLID dataset referring to the biocidal active substance cannot be edited (for example section 2.8 Manufacturing process).

A10: To complete section 2.8 for BPR dossiers, you need to use section 2.9, as indicated in section 2.8 'Cf. 2.9'. This is the same as in the classic interface. This was done in order for the user to have a complete overview of the information requirements, in the order provided by the regulation, even if in some case the same IUCLID form is used to record the data.

Q11: Will the report tools developed and included on the IUCLID website be included in the report generator in the new version or do we still have to import them manually?

A11: Nearly all report templates are available automatically in IUCLID, such as the CSR report, attachment reports, literature references report etc. There are a couple which are not included, these are: a specific use report in CSV format developed by DOW chemicals, and a cross-references report for BPR users.

4. TRANSITION TO THE WEB INTERFACE

Q12: Is it possible to continue preparing and exporting REACH dossiers for submission with the classic IUCLID user interface?

A12: Yes, you can still use the classic interface. The only functionality that has been removed from the classic interface is dossier comparison as the comparison report was improved recently, only for the web interface.

Q13: Does the Web Interface include all functionalities as the native database in 6.4 now? If not, could you please give an overview which functionalities are not covered?

A13: Not all the functionalities have been implemented in the web interface. A high-level summary of the missing functionalities is published under <u>FAQ #69 on the IUCLID website</u>.

Q14: Is there a timeline for phasing out the old interface of IUCLID?

A14: Please see the webinar presentation for more details. In summary, the current plan is to phase out the classic interface by October 2020. This will depend on feedback we get from stakeholders as to the suitability of the web interface for all users.

Q15: Is there a webinar that gives an overview of where everything is in the cloud version?

A15: The interface used in the cloud is the same interface that is delivered with the IUCLID application available on the IUCLID website. In the user manual for the web interface, chapter 2 describes to where functions have been moved in the new interface. See the <u>IUCLID website</u> for videos and webinars on IUCLID functionality.

Q16: Will it be possible to copy and paste several documents (bulk copy/paste) at the same time (similar to the classic version with clipboard manager)?

A16: Yes, the bulk feature is on our to do list for 2020.

Q17: Some users will not use the new interface as they keep having to swap between both and would sooner just use classic until the new one is live. Will more of the new interface be implemented already in the April 2020 release?

A17: Yes, every release will include more and more features adapted to the web interface. We recommend to start using the web interface already now as it contains the main features of data entry and dossier creation for example.

Q18: Phase out of the Classic Interface - will there be detailed guides on how to migrate our data into the Web Interface?

A18: The use of the Classic or the web interface has no impact in the data you have, therefore there is no need to migrate any data. When you install IUCLID today, you have two interfaces you can use to browse your database. In the future we will keep only the web interface but it will continue to connect to the same database.



Q19: The performance of the web interface is much slower than the classic interface (server version). It takes up to 10s after mouse click to get a reaction. Do you have a recommendation for this?

A19: The user experience with the web interface may differ from the classic interface, but the response times should be acceptable and comparable to the classic interface. If you have a specific scenario where the response time of IUCLID via the web interface is much worse than via the classic interface, please contact the ECHA Helpdesk providing all the details where the issue takes place.

Q20: Do I need to upgrade my classic interface to 6.4.2.1 or simply switch everything over to using the web interface?

A20: The Web interface and Classic interface are the same product. You will see the same data in both web and classic interfaces.

Q21: As consultant we work on a large number of Legal Entities using the classic interface, in one installation. Is it possible to change between 'working' LE in the web interface?

A21: It is currently not possible to change the working legal entity in the web interface. You will need to use the classic interface for this. However, next year, when user management is implemented, you will be able to use the web interface for this too.

Q22: Did I get it right that classical and web interface have a different set of functionalities and none of them is complete?

A22: The classic interface contains all the usual functionalities for IUCLID (except for the comparison tool, which is now only available via the web interface). Many of the existing functionalities are already available in the web interface and you can perform most of your work with it since last year. However, we plan to develop all the relevant functionalities for the web interface by October 2020 so that we can phase out the classic interface.

Q23: How to register new users in the new version without using the classic version?

A23: Users and roles cannot be managed via the IUCLID web user interface at this moment. To create new users or manage user's roles at least the user manager or system administrator needs to use the IUCLID classic interface.



5. ECHA CLOUD SERVICES

Q24: Is there still a limitation in storage space in the cloud IUCLID instances managed by ECHA and how much is it?

A24: Yes, there is limit on storage space: 100 MB for IUCLID Trial service and 1 GB for IUCLID Cloud service.

Q25: Is it possible to get additional storage in the IUCLID Cloud version? I expect that 1 GB will not be sufficient for us.

A25: Currently there is a warning displayed informing about exceeding the storage limit, but the service is still usable. If there is a need to continuously use a larger storage space you need to contact the ECHA Helpdesk and justify the need.

Q26: Is it possible to handle around 100 substances as REACH and CLP users in the Cloud services?

A26: Yes, you can use IUCLID Cloud services but beware that it comes with up to 1 GB of data storage.

Q27: I am already a user of the Cloud services. Do I have to do something special to get the new version?

A27: The new IUCLID version is automatically updated for all IUCLID Cloud users. This normally happens some days after the official release. You do not need to do anything.

Q28: How to obtain administrator access to IUCLID cloud? We have several legal entities to cover in our company. How can we easily login with the legal entity we want on IUCLID cloud?

A28: The standard topology in the IUCLID cloud is that there is one IUCLID per Legal Entity. If you want to work for many Legal Entities you will have to use separate IUCLID Cloud instances. You can connect them via the foreign user concept in ECHA Accounts. Additionally, if your target is to manage multiple legal entities in one IUCLID, this can at the moment only be done in the Classic User Interface.

Q29: What is the difference between web interface and IUCLID cloud? Does it mean that in the future we all have to move to IUCLID cloud services?

A29: There is one IUCLID product, which currently has two interfaces, the classic and web interfaces. The IUCLID Cloud utilises the web interface more prominently but users downloading IUCLID can choose whether to use the classic or the web interface. At the moment there are no plans to stop the distribution of the desktop and the server version and moving everyone to the cloud.



6. POISON CENTRES NOTIFICATIONS

Q30: I am not able to see the work performed by my colleague in IUCLID6. I refer to the 'guided dossiers' section for the Poison Centre Notifications. Could you please guide me how to change this?

A30: We do not have any specific access rights relevant to the Guided dossier approach so we are not sure how we can help easily. Please verify that you are working in the same IUCLID database and check if your colleague sees your changes.

Q31: When is it expected the next release of IUCLID? In particular the one that will implement the changes related to the first amendment of Annex VIII for PCN notification?

A31: We will communicate specific information about Poison Centres Notifications on the Poison Centres website.

Q32: Does IUCLID 6.4 already support the new PCN 2.0 format? We had Issues in our first attempts with PCN 2.0 and IUCLID 6.4.

A32: IUCLID 6.4 does support the updated PCN format. Please contact the ECHA Helpdesk in case of specific issues.

Q33: When can the industry expect major changes and improvements related to the PCN dossier preparation as things are currently not optimal?

A33: The PCN dossier preparation tool is constantly improving. A new release is expected early 2020. Additional improvements will continue next year as well.

Q34: Is there a need for a IUCLID account for System to System PCN notifications? Where can we find more details about S2S?

A34: You can find information on the S2S service on the <u>poison centres website</u>. Additional documentation about the technical aspects of the service as well as how to get access to it will be made available in the next weeks. Please follow the website for the latest news.

Q35: Will PCN dossiers generated with IUCLID 6.4 still be compatible with IUCLID 6.5?

A35: Yes, every IUCLID release ensures compatibility with the previous versions.



7. IUCLID FORMAT AND COMPATIBILITY

7.1. Introduction

Q36: When exporting from IUCLID there is now a new field 'export to previous major version'. What is the function of this field?

A36: This field existed in the classic interface. Now, it is available in the web interface as well during the export of datasets. By checking the field, it allows you to export your dataset in a format compatible with the last major version of IUCLID. You can for example export a 6.3 compatible dataset from IUCLID 6.4.

Q37: Will there be also an update of the inquiry types that were linked to the phase in status?

A37: Yes, the inquiry types were updated in IUCLID 6.4 to remove the connection with the phase-in status. Please find more information in the manual on how to prepare Inquiry dossiers available on <u>ECHA webpage</u>.

Q38: Will it still be technically possible (until end of 2019) to make a co-registration following a pre-registration once one has updated to this most recent version of IUCLID?

A38: Yes, you can still use your pre-registration number until the end of the year. This does not depend on the version of IUCLID 6, but we recommend using the most recent version.

Q39: I would like to ask you whether you intend to publish special table comparing endpoints in IUCLID 5 and in IUCLID 6 especially in case that plain text field in IUCLID 5 changed in drop-down menu with choosing options.

A39: Typically we publish the format changes compared to a previous major version of IUCLID e.g. the changes between IUCLID 6.4 and IUCLID 6.3. Currently there is not format change comparison report between IUCLID 6.4 and IUCLID 5.6 or earlier.

Q40: Also for next IUCLID 6.5, will you guarantee the compatibility with IUCLID 6.4?

A40: Yes, IUCLID 6.4 will be compatible with version 6.5, i.e. you will be able to import 6.4 files to 6.5 and export 6.4 compatible files from 6.5.

7.2. Technical Completeness Check and nanomaterials requirements

Q41: Have the new nanoform fields been added into the IUCLID 6.4 classic version or only the web version?

A41: Both interfaces have the new fields for reporting nanoforms.



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Q42: Any recommendation how nanomaterials dossiers shall be submitted in time if it can only be done with IUCLID 6.4 and if boundary compositions need to be aligned with co-registrants not aware of the required fields?

A42: This question has been addressed in the specific webinar for registration of nanoforms on 12th November 2019. Please consult the <u>webinar page</u>. We are aware that this deadline is very tight. We advise you to make all the efforts possible to prepare and submit your registration dossiers in time. It is always possible to update the dossier later if you become aware of new/improved information. If you have any more specific or substance related question, we are ready to help you via our <u>helpdesk service</u>.

Q43: Will there be added guidance on how to enter information under section 1.2 for nanoforms of registered substances?

A43: Please refer to the Annex 8 of the manual '<u>How to prepare registration and PPORD</u> <u>dossiers</u>'. ECHA has also published the <u>webinar</u> for registration of nanoforms.

Q44: Is the validation assistant available in IUCLID 6.4, in both classic and web-interfaces?

A44: Yes, both interfaces have the latest Validation assistant.

Q45: I will have to send an inquiry and to update several dossiers in November / December, one as lead registrant. The dossiers are not for nanoforms. I would prefer to use the old version (6.3), do you think it will be possible or I will have problem?

A45: If you are registering a substance covering nanoforms, you must use IUCLID version 6.4 or above to submit your registration successfully. If your registration does not cover substances in nanoforms, you can submit the dossier with an older IUCLID 6 version. However, keep in mind that the Validation assistant of a IUCLID version older than 6.4 is not up to date with the completeness check performed on the submitted dossier. For example, since the 1st of November 2019 it has become mandatory to specify the 'State/form' of each composition in IUCLID section 1.2.

Q46: Do you think it can be possible that I run the Technical Completeness Check locally, everything is fine and then have the dossier rejected for other reasons than the manual checks performed by ECHA?

A46: If your registration does not cover substances in the nanoform, you can submit the dossier with an older IUCLID 6 version. However, the Validation assistant of a IUCLID version older than 6.4 is not up to date with the completeness check performed on the submitted dossier. In particular, since 1 November 2019 it has become mandatory to specify the 'State/form' of each composition in IUCLID section 1.2 also for registrations that do not cover nanoforms.

Q47: Are any of the changes to the OECD Harmonised Templates (OHTs) relevant for Technical Completeness Check under REACH?

A47: The completeness check has been extended to OHTs relevant for nanomaterials such as sections 4.28.8 – Nanomaterial dustiness and 5.7.1 – Dispersion stability of nanomaterials. All new checks are described in the updated version of registration manual 'How to prepare registration and PPORD dossiers' and reflected in the Validation assistant that comes with IUCLID 6.4.

Q48: Are there any new business rules?

A48: Some business rules were adapted to the end of the phase-in scheme but no new information is checked. All business rules are described in the updated version of registration manual 'How to prepare registration and PPORD dossiers'.

Q49: Will there be more TCC failure messages related to the reporting obligation of nanoforms, apart from the already mentioned "State/form" failure?

A49: The completeness check has been extended to cover the information requirements on nanoforms. For an overview, please consult the <u>webinar for registration of nanoforms</u>. All new information requirements that are checked for nanoforms are also described in a new annex of the updated version of registration manual 'How to prepare registration and PPORD dossiers' and reflected in the Validation assistant that comes with IUCLID 6.4.

Q50: Will there be any migration issues between previously versions of IUCLID 6 (say version 6.1) which will cause TCC errors in IUCLID 6.4?

A50: There have been a limited number of format updates in IUCLID versions after 6.1 which upon migration to version 6.4 may cause completeness check failures. Whether this happens will depend on the content of the dossier. Make sure you run the Validation assistant on the migrated dataset/dossier in IUCLID 6.4 to detect such failures before you submit the dossier.

7.3. SCIP database

Q51: Has the level of access required when SCIP comes online been assessed?

A51: As the Article will be included as a new entity it will re-use the access roles available (like create, delete, etc.).

Q52: Will SCIP users be able to practice in the system prior to mandatory use and create temporary test records to familiarise themselves with the system?

A52: The target is to release a prototype in early 2020. The obligation to submit data for real starts only in January 2021, so there should be enough time to learn how to use the system.

Q53: What exactly was added to the format for enabling SCIP notifications? When the changes will be visible to end-user? When will IUCLID/ECHA release a guidance for SCIP notifications?

A53: For the October release, we included the format, and this is not visible in the IUCLID user interface yet. However companies can use it to start preparing data files for system-to-system submissions. The plan is to release a prototype for data preparation in early 2020. -There is a SCIP workshop on the 12th November that will give more information on this topic if you are interested (recording will be made available).

Q54: Regarding the future SCIP database, will the data entry structure be representative of a flat BOM, tree BOM, or other?

A54: The data structure of SCIP is very flexible and can manage both flat and full tree boms. The member states will be responsible to define the level that the data should be notified on.



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Q55: On the future SCIP database, do you know if a data loader can be used? If so, will ECHA/others be providing that or will we have to develop our own?

A55: System to system notification of SCIP information is planned to be supported and the current IUCLID API (available from the IUCLID website) already allows to build data flows between IUCLID and other systems if needed. IUCLID will be able to be used to create notifications but bulk creation of notifications from another system will have to be developed separately.

Q56: As an equipment producer we, and many of our suppliers, equipment and raw material suppliers, have never used this system before. I would therefore expect there to be an increase in demand for downloads of the software and increased number of users.

A56: The introduction of new initiatives will definitely increase the use of our system and we will monitor closely all aspects from download to Helpdesk support in order to maintain the current service level.

Q57: I would like to know if the next year update of IUCLID (version 6.5) could or not affect the development of the interface between SCIP database and different databases which will be used to submit data.

A57: The format in IUCLID changes only once per year (in the October release). The standard maintenance of the format includes updating of the pick lists, and especially for SCIP where the CN codes are being used, changes can be expected. Additionally, if improvements are identified once the prototype is made available, there might be a need for amendments. Nevertheless, all IUCLID versions are built in a way that allows the export into the previous format and forward migration (6.4-6.5) upon import of data.

8. MISCELLANEOUS

Q58: Is there a release date for the new Chesar version 3.5?

A58: The plan is to have Chesar 3.5 released at the end of this month (November 2019). No specific date has been decided yet.

Q59: Which Chesar version is required for IUCLID 6.4?

A59: Chesar 3.5, which is planned to be released in November, will be fully compatible with IUCLID 6.4. The current version of Chesar (Chesar 3.4) is also compatible with IUCLID 6.4 (with a small limitation which has no impact on the assessment). More details on the compatibility between the two tools can be found in the FAQ "How can I check if Chesar is compatible with IUCLID?" available on the <u>Chesar website</u>. We expect to update this FAQ to include IUCLID 6.4 shortly.

Q60: The Rest API information related to this new IUCLID version is not updated on the website, when will it be updated?

A60: The current API documentation on the website is also applicable for this version of IUCLID 6.4. There has been no update to the API for 6.4.

