IUCLID 6

Webinar IUCLID 6 – Questions and Answers

IUCLID 6.5.15

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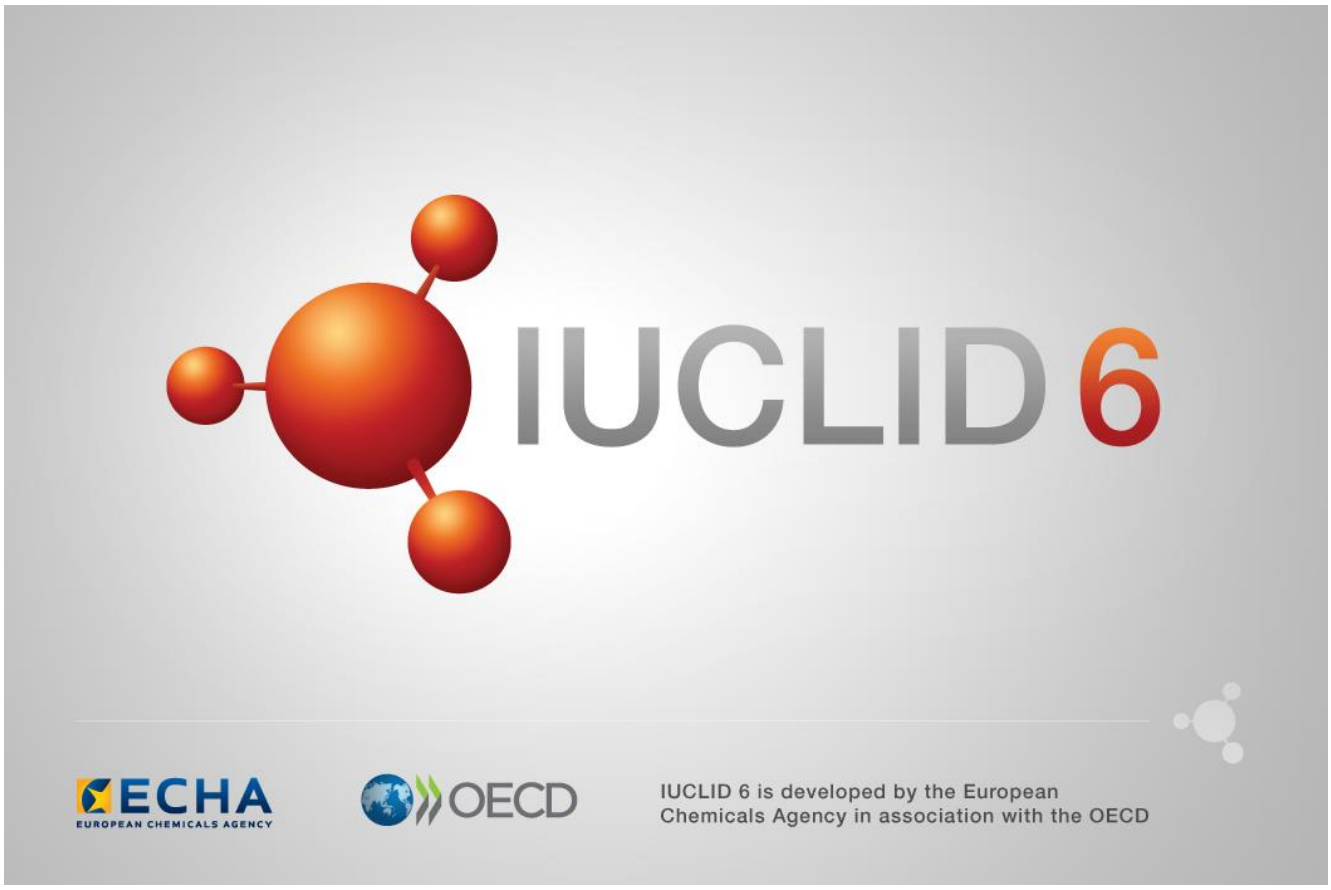

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1. INTRODUCTION

This IUCLID 6 webinar took place on the 12th of May 2021. 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. CLASSIC INTERFACE

Q1: Is it no longer possible to submit dossiers prepared and exported from the classic interface? We did this today and the dossier was rejected in the pre-validation step.

A1: This might probably have been caused by a known issue linked to the fact that hierarchical phrase groups are not implemented in the classic interface. We have detailed this case in an FAQ on the IUCLID website: https://iuclid6.echa.europa.eu/faq#q95

Q2: Why can´t you make the new interface similar to the "classic" interface? The new interface is hardly readable (for example CLP-section). Another example export of a single study endpoint record is difficult /impossible.

A2: The web interface is using a completely different technology as the classic interface. Achieving the same look and feel as the classic is consequently difficult to achieve. We are progressively improving some of the aspects of the web interface to make the data easier to read and enter. For example, we have improved considerably the navigation tree since the first release of the web interface. As you indicate there is still some work to be done and we are currently working on further improvements. We will consult users via the IUCLID LinkedIn group (https://www.linkedin.com/groups/12043483/) in relation to some of them if you would like to share additional feedback with us.

Q3: Will there be an instruction about how to show the classic interface?

A3: Yes, the instructions to access the classic interface can be found from this page: https://iuclid6.echa.europa.eu/web/iuclid/learn-to-use-the-new-interface. They are available after answering a brief survey.

3. ECHA CLOUD SERVICES

Q4: In the case of a Consulting who helps a company with the Reach registration dossier of their substances, what is the best configuration of the users and roles in the Manage menu of IUCLID cloud?

A4: In the cloud we only have two roles. Full and reader. So, depending of the need (Update and create vs Reading) you can choose. Another option, is if the company does not want to share the other data with the consultant, is that the consultant does the work in their "IUCLID Cloud" and allow read access to the customer (or then export and import the data from one instance to another).

Q5: Is it still so that when I did a PCN dossier in the IUCLID cloud I have to download it as a i6z-file locally and then upload it in the ECHA Submission portal in the CLP section? And what is then the difference to the blue button "proceed to submission" in the IUCLID cloud when opening a dossier?

A5: When you use the IUCLID ECHA Cloud Services to create your PCN dossier, you indeed have the option to directly 'Proceed with submission'. The option is available at the end of the dossier creation or also when you open a dossier. This will automatically direct you to the submission portal and preload your dossier which can then be submitted in one click. The submission will be made under the user account you are using in the ECHA Cloud services.

Q6: On the ECHA server or cloud services, data is stored online, which external parties can have access to this data prior to submission?

A6: Thank you for the question. Access to your Cloud instance/data is restricted to you. Nobody, including ECHA staff, has access to it. For more information, check our ECHA Cloud services security statement at https://echa.europa.eu/documents/10162/23111019/echa_cloud_services_security.

Q7: We have many legal entities for which we submit REACH dossiers. If we would be using the ECHA IUCLID cloud service would we need to have as many ECHA IUCLID cloud accounts as we have legal entities? Or could we have one ECHA IUCLID cloud account for all our legal entities?

A7: A IUCLID Cloud user can switch the working legal entity within the same IUCLID Cloud instance using the new User Management settings in the web interface, so long as the User has the permission rights to do this. Importantly, to submit to REACH-IT a dossier with the correct legal entity, you must first export the dossier and upload this to REACH-IT. If you use the direct link between IUCLID Cloud and REACH-IT, the legal entity you signed up with to subscribe to IUCLID Cloud will be used. So, in answer to your question, you do not need to create separate IUCLID Cloud subscriptions per legal entity, but you will need submit dossiers as described above to allocate the correct legal entity to any one submission.

Q8: When could BPR applicants use ECHA Cloud and its services?

A8: Currently the Terms and conditions do not allow the ECHA Cloud Services to be used for BPR purposes indeed. We are not able to provide you with more information at this stage.

4. EU PLANT PROTECTION PRODUCTS (EFSA)

Q9: For basic substance dossier, where do we register studies about human health, ecotoxicology? Do we split these studies like in the old template for basic substance dossier such as chapter 8 for "Effect on non-target organisms"?

A9: For EU PPP, please refer to the EFSA website and the corresponding Helpdesk: https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation-training-programme

Q10: For EU PPP, basic substance in the "working context" disappeared. What is the new "working context"?

A10: The information requirements for EU PPP basic substances have been simplified and all the information has to be provided at the level of the Mixture dataset.

Q11: Since the ECHA portal for submission is restrictive with respect to file size, only light version of the dossier (sanitised study reports) will be acceptable for PPP submission?

A11: The Cloud instances of IUCLID have been upgraded to allow more storage of data. The submission portal is also accepting larger dossiers that will allow the submission of all relevant information. In the case of EU PPP dossiers, the full study report should be provided, and a sanitised version added in case the first one contains confidential data.

Q12: Will you do a demo for EU PPP basic substances dossier registration?

A12: For the preparation of dossiers for EU Plant Protection Products, EFSA is providing trainings and support materials to users. You will find more information on the EFSA website: https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation-training-programme

5. FORMAT

Q13: Are there any significant changes concerning the OHTs (new OHTs, new flexible records/summaries, new fields/pre-defined tables in the different OHTs) already planned for the October release? Where could we find more information regarding this and how long in advance prior to the official release?

A13: The changes to the format are being collected and analysed now. Draft changes will be communicated as soon as possible on the IUCLID website: https://iuclid6.echa.europa.eu/format

Q14: The OHTs and more info can also be found on OECDs webpage: https://www.oecd.org/ehs/templates/

A14: Yes indeed. Thanks for the information. You will find on the OECD site the latest official versions of the templates.

6. FUNCTIONALITIES

6.1. Dossier and submission

Q15: When do I need to include the Legal Entity while creating a dossier (especially under working content REACH)? By default, the Legal Entity is not included if I understand correctly.

A15: Yes, this is correct. For REACH dossiers, the Legal Entity is not included by default as ECHA relies on the submitting Legal Entity specified in REACH-IT in that case. For other dossier types, like Poison Centres Notifications, the Legal Entity is included by default as it is required to be submitted via the ECHA submission portal. The default behaviour is adjusted in IUCLID to the dossier type.

Q16: After having changed the context from "REACH registration" to "Inquiry" then created an Inquiry dossier, data not required for the inquiry (e.g. yearly volumes) were present in the inquiry dossier. If possible, how can it be avoided?

A16: The section 'Estimated quantities' is set as 'optional selected by default' for the REACH Inquiries. These sections can be unselected though if you use the advanced options and document selection when creating a dossier.

Q17: The working context and the information in the dossier header is lost when a dataset is imported. Shall this feature be improved in the upcoming releases?

A17: The working context is, indeed, not transferred as part of the export/import process since datasets may be used for different purposes. I thank you for sharing your feedback as it helps us to improve IUCLID.

Q18: Which versions of IUCLID 6 can be uploaded in REACH-IT? Does it accept still v6.3?

A18: REACH-IT accepts files in the i6z format that are created using IUCLID 6. It therefore accepts files created with v6.3. However, if you wish to check and comply with the latest Technical completeness checks (TCC) made by ECHA (e.g. for nanoforms), you should use and submit in the 6.5 format.

6.2. Clipboard / Copy data from

Q19: Are you planning to reintroduce the "clipboard" feature also in the new web interface? The current copy method for the web interface is very counterintuitive and difficult to use, especially when a company has to manage many substances.

A19: The possibility to copy records between datasets has been implemented in the web interface via the 'Copy data from' option. This is indeed a different approach that in the classic interface. The user should be in the target dataset and use the copy option to select the dataset and records that should be copied. As we have now added the possibility to open several datasets in different tabs, you should be able to browse for the data to be copied while you still have your target dataset opened. We will check however how the copy flow could be improved in the future if this is an issue shared with other users too.

Q20: I agree with a previous question that the classic clipboard functionality needs to be reproduced. It was heavily used for copying multiple end points between related substances. It's essential when managing a large portfolio of related substances.

A20: Thank you for sharing your feedback. It will help us improve IUCLID.

Q21: In the new version, did the option of "Copy from existing" for endpoint records disappear?

A21: Yes, with the implementation of the new navigation tree and the 'Copy data from' feature, the 'Copy from existing' is not available anymore. If you need to copy one record, select 'Copy data from' and you can quickly select the relevant dataset and record to copy.

Q22: Suggestion: could the option to copy rows in the repeatable block fields be implemented in future releases? This would help in case of tables with many rows that contain some repetitive information.

A22: Thanks for the suggestion. We have had this idea suggested in several stakeholder forums in the past, particularly for duplicating rows in the Effect levels block common to many OHT Endpoint Study Records. We have planned to have this feature implemented this year and should be available with the next public release of IUCLID.

Q23: Where do I find the "copy data from" feature? It only shows me "New document".

A23: "copy data from" is accessed from the menu under the button with three dots which is located towards the top right of the interface. First, select the document into which data is to be copied. See section 23 of the document "Functionalities of IUCLID in the web interface".

6.3. Import

Q24: How does the import work in case of importing an updated dataset for the same substance from another IUCLID database; is it overwriting the old dataset having the same substance name or is a new substance dataset created (how is this dataset identified)?

A24: If the dataset you import already exists in the database, you can decide which overwrite mode to apply: if newer (default), never, always, replace. You can also use the advanced import options in order to see the list of included documents before the import.

Q25: In case of importing an updated dataset; the overwriting mode: if newer (default), never, always, replace only allows only one copy of the dataset in the IUCLID database (UUID specific). Is it possible to retain both the old and the new updated version of the same dataset?

A25: A document has a Unique Universal Identifier (UUID). Only one document with a particular UUID can exist in a IUCLID database. To have two versions of a document present at the same time you need to have two separate documents and manage the content yourself.

6.4. Miscellaneous

Q26: Can reports be searched by their authors, or titles, or only by their UUID (as so far experienced)? E.g. in order to search literature references.

A26: Searching literature references by Author or Title is possible in the inventory of reference substances, using the Advanced search options. This allows you to select the correct literature reference when recording the information in an endpoint study record for example. However, you currently cannot search substances, mixtures or dossier by literature references. These advanced search features are only available for Text analytics users (cf. https://iuclid6.echa.europa.eu/text-analytics).

Q27: Does end point history (creation, import, edit dates and who did the actions) still exist?

A27: Yes, the modification history is available in the web interface. When you see the content of a document, on the top right corner there is an icon with a clock. Click the icon and the Modification history related to the displayed document will be shown.

Q28: In addition to the dossier, the annotation feature for commenting is also available for substance and mixture dataset. However, the export annotations feature is only available for a dossier. Will this export annotations feature be incorporated to datasets as well?

A28: For datasets, the annotations can be exported together with the dataset itself. When you export the dataset, you can use the advanced exports settings including document selection and you will see the annotations being included in the export file.

Q29: In the new version I cannot find the field where I can upload an inherited template of a study record into the data set.

A29: In the web interface, open your substance and mixture dataset. Scroll down to the end of the section tree and you will see 'Inherited templates'. When you hover over this section a chain link will appear on the right side. Click the link and you will be able to select an inherited template to link to your dataset.

Q30: Is it possible to switch endpoints study records on the left side of the tree of IUCLID to organize the studies in a logic way. It looks that it works only downside (but not always) and not upside.

A30: Yes, it is possible to reorganise the records per type under each section. This is done by using a drag and drop feature. Please note that endpoint summaries for example are grouped together and presented before the endpoint study records.

Q31: Suggestion: Could you consider making the free-text field adjustable in the next IUCLID release? Now the field can be adjusted in the height but not in the width. Nowadays we have wider monitors, and this will be very helpful to use the available screen space.

A31: Thank you for your suggestion. This type of improvement is already being planned for the future IUCLID releases.

Q32: The web interface shows sometimes errors (e.g. when importing files) but it does not say what the error was. Is it possible to find out what the error was? Some log file or something?

A32: The web interface does provide error handling and messages when an i6z file fails to import. You will see 'error' next to the 'x' in the dashboard import widget. By clicking on 'error', a text file is downloaded which contains the error message.

Q33: Why isn't the old main page for a substance/mix -that showed all available endpoints- available any longer but instead when selecting a substance, you are automatically sent to the "name" part? It was way easier to navigate than the left navigation bar and also the "copy from" feature is missing.

A33: Thank you for your feedback. The idea behind the change is to have only one way to manage a dataset and we will try to improve further the navigation tree to make the management easier. The 'Copy data from...' option is available in the three-dot button on the top right corner of the screen.

Q34: With the previous update, when exporting a dataset by selecting only some fields (i.e. to send the LR dataset to a new co-registrant) the i6z file created contained also the attachments related to unselected fields (i.e. the identification lab report). Has this issue been solved?

A34: During export, all attachments linked to a selected document will be included (except when attachments are selected to be entirely removed from the advanced settings). We are not aware of

any issue in this area. Could you please contact the Helpdesk so that we can investigate further? https://echa.europa.eu/contact

Q35: You showed a new functionality to order items in a table like for the OECD guidelines in endpoints. Is it now possible to order constituents in the composition section?

A35: Thank you for the question. Yes, it is possible to re-order blocks of data in numbered lists like the constituents/impurities/additives table rows as well as in the Table of Content. This is only available for datasets, not for dossiers. You can find more information about it in chapter 3.6.16 of the IUCLID functionalities manual at https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_html_en.pdf

7. INSTALLATION

Q36: Is there an updater for the new release which I can use with the previous version?

A36: There is a software application available on the IUCLID website that updates any version of IUCLID 6 to the latest one. On the downloads page see "IUCLID 6 updater". The address is https://iuclid6.echa.europa.eu/download.

Q37: Ok for the PostgreSQL proposal, as in the past, :-) hoping that it will be included a backup tool or a set of instructions to execute it appropriately.

A37: If PostgreSQL becomes supported, the configuration of IUCLID to use PostgreSQL will be added to the installation manual for IUCLID 6 Server. To back up a PostgreSQL database it is recommended to use methods that are independent of IUCLID and are documented by the source of PostgreSQL.

Q38: On the IUCLID Software Download page it is stated "The latest version of IUCLID 6 published for all users on this website is 5.15.0. " Does this mean that the update software listed under "Available Updates" also applies to updating from the previous version (Oct 2020) to the April 2021 version?

A38: There is a software application available on the IUCLID website that updates any version of IUCLID 6 to the latest one. On the downloads page, see "IUCLID 6 updater": https://iuclid6.echa.europa.eu/download

8. PERFORMANCE

Q39: Compared to the classic view - speed is the main issue with the web interface. Substantial improvement is urgently needed! Any news on that?

A39: Thank you for your feedback. While the Derby database has some limitations, IUCLID is able to handle correctly several thousands of datasets and dossiers on the condition to use Oracle as database as indicated on the system requirements page on the IUCLID website (https://iuclid6.echa.europa.eu/system-requirements). We are currently analysing the issue and collecting more information from the users who are having a similar experience. Please contact us at the ECHA Helpdesk to share more information about it: https://echa.europa.eu/contact

Q40: Does the new version improve the loading speed for large databases? Since PCN notifications have started, our - already large - substance database has increased enormously and the loading time when changing page (but also when returning to the previous one) is so long that is impossible to work

A40: We have received reports about this situation at our Helpdesk. The web interface is indeed slow with a large number of datasets or dossiers when a Derby database is used. We are currently analysing the issue and collecting more information from the users who are experiencing this. Please contact us at the ECHA Helpdesk to share more information about your experience: https://echa.europa.eu/contact

Q41: It seems that the problems in the IUCLID web interface are not related to the approach to it but to its performance.

A41: With the increase of the use of the web interface and the increase of the database size, this is indeed an issue that is becoming more frequent and we will concentrate on finding solutions to this. Thank you for your feedback.

Q42: So, before October, there will be no new update that improves the speed for the non-cloud users? Currently the new version is not fast enough to be able to use it (minimum of 30 seconds to charge one endpoint record or to change between them).

A42: If your installation of IUCLID 6 is not working quickly enough, please create a ticket at the IUCLID helpdesk so we can investigate and try to help you to improve it.

Q43: Working with the web interface is really slowing down my work so I prefer to work on my IUCLID desktop classic interface, then download the dataset and upload it on my client's IUCLID Cloud in order to create the dossier from their web interface IUCLID. Do you see problems in this procedure?

A43: A different approach would be to complete all steps in the Desktop installation and to export the dossiers in order to submit them to ECHA for example.

Q44: You replied: 'A different approach would be to complete all steps in the Desktop installation and to export the dossiers in order to submit them to ECHA'. I prefer to create the dossier on the client IUCLID CLOUD because it is more updated compared to desktop version, hope it is correct!

A44: In that case I would suggest you use only the Desktop installation: the Classic interface to work on the dataset and the Web interface to finalise the dossiers. With the Desktop version you can easily switch between the two interfaces and the data will be stored in one place, on your computer.

9. REPORT GENERATOR

Q45: Does the Doc M report generator for PPP also extract the information from the attachments included in the endpoint study records?

A45: Doc M generated from the report generator will not include data from attachments. For EU PPP related questions, please additionally refer to the training materials available on the EFSA website (https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation-training-programme) and to the EFSA Helpdesk.

Q46: Is there a new functionality to generate DU-CSR or is it planned to implement this?

A46: Currently Chesar 3 and IUCLID 6.5.15 do not have a specific DU-CSR. However, the current full CSR available to generate from Chesar (which includes sections 9 (exposure assessment) and 10 (risk characterisation), will provide the key information you need to build the DU-CSR. Note that sections 1-8 of the CSR are extracted from IUCLID (including the Use information, section 3.5). So, you will need to install and use Chesar and IUCLID to generate the full CSR, sections 1-10. Also note that other aspects of the DU-CSR are extracted from IUCLID when generating the CSR, such as the Identification of the substance, the classification and labelling, as well as the toxicological and eco-toxicological endpoints.

Q47: The literature reference report which can be generated in IUCLID shall replace doc L (literature reference list for PPP submission)? Is it mandatory to create this report for PPP submission?

A47: For EU PPP related questions, please refer to the training materials available on the EFSA website (https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation-training-programme) and to the EFSA Helpdesk.

Q48: When the MCA/MCP report generator for PPP for the sections different to Physchem and Toxicology will be available? Next IUCLID Cloud release in June 2021?

A48: The Document M reports for Phys-chem and Tox are available in this April release. An extension of the suite of PPP reports will be found in the June Cloud release indeed, including the Document M reports for Env. Fate and Ecotox.

Q49: While using MCA report generator for Tox in IUCLID, the formatting and display of the tables is lost (alignment of the values in cells to the right and distorted values due to merged cells). Is there an improvement planned in the upcoming releases?

A49: Thank you for your comment. Yes, indeed some formatting issues are observed in the report depending on the type of information stored in IUCLID. This is something we are investigating. We have managed to fix some issues but there are still some improvements needed in this area.

10. VALIDATION ASSISTANT

Q50: Can you explain the Quality check notes regarding source substances (test material not same as registered substance) Read across Please explain how this can be handled in IUCLID?

A50: There is currently an issue with QLT176 which gives a warning incorrectly for the studies which are used as the Source study in case of read across. The inconsistency will be fixed in a future IUCLID release. For the time being the warning should be ignored.

Q51: Is validation available for data sets for substances and mixtures under PPP working context, or only for dossiers?

A51: For EU PPP, validation is available for the mixture dossiers and datasets, for the following working contexts only: EU PPP Active substance application (product); EU PPP Microorganisms - active substance application (product); EU PPP MRL application; EU PPP Basic substance application.

11. USER MANAGEMENT

Q52: Are you planning to implement the "Export User" function in the Web UI and also generate PW's automatically as it is now available in the Classic UI? How is the process to activate IBS.

A52: Export and import users from a csv file is currently only supported by the classic interface but this is indeed a feature is planned to be added to the web interface.

Q53: Are you planning to implement the function to generate PW's automatically in the WebUI as it is now available in the Classic UI?

A53: Thank you for your question. This feature has indeed not yet been ported to the web interface and this is something we need to prioritise for future releases.

Q54: Do we have any type of report or overview to view the users and their roles?

A54: There is no automatically generated report for User management. In the latest version of IUCLID 6 (5.15.0), the details for Users, Roles, and Groups are visible in the web interface.

Q55: Does the "SuperUser" have more rights than the role "System Administrator"? Can any of the already existing roles in IUCLID give access to sections, etc. to new roles / users or just the SuperUser is able to do this?

A55: The Role of "System Administrator" provides the same access to data and functionality as SuperUser. However, the system can be configured so that SuperUser cannot be locked, as described in section 5.1.1 of the installation manual for IUCLID 6 Server. This is not available for other Users.

Q56: How can I activate Instance Based Security?

A56: You can find the relevant instructions in the Installation and update manual, section '5.10. Instance Based Security (IBS)', available from the IUCLID website:
https://iuclid6.echa.europa.eu/documents/21812392/21903772/installation_manual_server_en.pdf

Q57: In a completely new IUCLID server 6.5.15 a new role (basic user) has access to REACH, CLP, OECD, CORE, but this use cannot change the working context in substance dossiers. What needs to be adjusted to make this option available for all users?

A57: We would need more detail in order to investigate the issue. For example, it would be good to know the exact definition of the role you created. For example, does the role allow the creation of dossiers? Please contact the ECHA helpdesk in order to follow up on this:
https://echa.europa.eu/contact

Q58: I cannot find the management of different users as on the classic interface. You cannot reset a password for example. Is there a way to manage users like on the classic interface?

A58: Concerning the password reset, please go to the main menu from the Dashboard and select 'User' under 'User management'. Select a user and you will see the 'Change password' option on the right side of your screen under User Profile. You need to be a user administrator to see this option.