IUCLID for SPC – Training on 24.10 – Questions and Answers

1. TRAINING MATERIALS

Q1: Where can I find the SPC training materials (presentation, exercise instructions...?)
A1: The SPC training information is available from the IUCLID website at https://iuclid6.echa.europa.eu/training-material

Q2: I tried to import SPC part 3 i6z training dossier into our IUCLID network distribution but got an error message. Work IUCLID 6 v 6.27.7, build of 24/02/23.
A2: All the files needed for the exercise have been prepared using IUCLID 6 v.7, therefore are not compatible with the IUCLID 6 v.6 including 6.27.7. Both files can be imported to the IUCLID versions released on 22nd of May 2023 and later. However, to profit from all the functionalities listed in the exercises we recommend that you install the version of IUCLID published on 30th of October 2023.

Q3: The list of SPC-relevant validation rules will be shared and be available together with the updated submission manual. So, when will that manual be available?
A3: The manual will be published 2-3 weeks before the go-live (the exact date is not yet decided). The day of go-live will be announced on the ECHA website at least one month in advance.

2. GO-LIVE

Announcement: ECHA has rescheduled the go-live of the SPC Editor into IUCLID to the first quarter of 2024 due to technical issues. We will communicate the new date for the launch at least one month before the go-live to make sure you have sufficient time to prepare for the transition.

Q4: How and when the exact date of the SPC go-live will be released by ECHA?
A4: The day of go-live will be announced on the ECHA website at least one month in advance.

Q5: Can the finalization of existing SPC still be done in SPC Editor or will this tool be dismissed totally at the beginning of December 2023?
A5: Before the switch to IUCLID, SPC in XML format should be submitted. After the switch, only IUCLID files will be accepted. SPCs under preparation in the SPC Editor will be able to be imported to IUCLID to be finalised.

Q6: Can the SPC files generated with the SPC Editor be opened correctly even after the decommissioning of the SPC Editor?
A6: After the switch to IUCLID the SPC Editor will not be available. However, all SPCs

created previously (XML files stored locally) will be able to be imported to IUCLID.

Q7: Can we already prepare SPCs in this manner in current IUCLID or do we need to wait until another update (in December)?
A7: Currently, R4BP 3 is accepting the SPC prepared in the SPC Editor. However, if you are planning to submit soon after the go-live, you can start preparing the SPC in IUCLID, knowing that you will not be allowed to submit it until the go-live, and then you need to have IUCLID updated to the latest version (during the IUCLID update to the latest version, all the files are migrated to the newer version).

Q8: Can we import the already existing SPCs in the IUCLID Cloud?
A8: Yes, SPC in XML format, created with the SPC Editor can be imported to IUCLID today. They are imported as dossiers. Using the 'Extract to dataset' option you will be able to obtain an editable version of the SPC, make changes and create a new version of the SPC if needed.

Q9: Can you import XML files, from the SPC Editor, into IUCLID?
A9: Yes, SPC files in XML format, generated from the SPC Editor can be imported into IUCLID.

Q10: How long do you expect the migration to be implemented? Will R4BP3 be closed in that period?
A10: The migration is still under testing and the exact timing cannot be estimated precisely. However, it should not be longer than few days. The downtime will include one weekend, when actions are at the minimum.

Q11: How will the SPC be migrated in the specific case? I mean from IUCLID dossier available into R4BP3 or from SPC XML available into R4BP3?
A11: Existing SPC XML files available in R4BP3 will be converted to IUCLID files during the migration process before the switch to the IUCLID format for the submission of SPCs.

Q12: In which format the SPCs will be disseminated via the website?
A12: The switch to the IUCLID format for the submitted SPC will not affect the dissemination process. There will be no change at this level and the disseminated SPCs will remain in the current format.

Q13: Translator companies are not familiar with IUCLID but with SPC Editor. Would it be possible to keep SPC Editor as a working tool?
A13: The SPC Editor will not be available anymore after the transition of SPC into IUCLID. The ECHA team is available to discuss different possibilities to better support the transition to IUCLID, particularly for the necessary adaptations to the translation process.
Companies might consider providing translators with an SPC report in .rtf format, because this report already contains the automatic translations (for example picklists, labels). It is also in editable format, compatible with MS Word or OpenOffice.

Q14: When do we have to stop using the SPC Editor (i.e., is it straight after go-live)? What about ongoing applications: do we send a new IUCLID file after go-live?
A14: Once confirmed by ECHA, R4BP 3 will accept only SPCs in IUCLID format. SPC in XML format generated by the SPC Editor will not be accepted anymore. All existing SPCs submitted (ongoing and completed cases) will be migrated automatically to the IUCLID format in R4BP3.

Q15: Will there be a transitional period in R4BP accepting SPCs in XML format in December 2023 as well?
A15: There will be no parallel submission of SPC in XML and i6z format. After the switch to IUCLID, only SPC in IUCLID format will be possible.

Q16: Will all the existing SPC in R4BP3 be converted to i6z files by ECHA?
A16: All SPCs currently available for download in the dedicated SPC component in ongoing and closed cases, and in existing assets will be converted into IUCLID format during the migration exercise. Note that, SPCs attached to ad-hoc communications, will not be migrated.

Q17: Will it be possible to edit the SPC in IUCLID, if it was originally created in SPC Editor and the XML file was imported to IUCLID?
A17: Yes, SPC files in XML format (in the SPC Editor) can be imported to IUCLID and modified. However, if you want to start or continue an existing application (e.g., NA-MRS), you will need to download the SPC from R4BP (it will be already migrated to IUCLID format i6z).

3. PREPARATION OF THE SPC DOSSIER FOR DIFFERENT APPLICATIONS

Q18: Are the fields mentioned on page 29 of the exercise the only fields that need to match the initial dossier? Will it fail based on extra spaces, capitalisation etc.?
A18: Yes, those are the only fields that need to match the initial dossier. The names must be identical to a reference dossier (they should not be modified at all, so no extra spaces etc.).

Q19: Can an applicant submit only one IUCLID file containing the dossier and the SPC via R4BP3, rather than submitting an IUCLID plus a separate SPC file?
A19: The applicable submission requirements when it comes to the number of files submitted in R4BP 3 have not changed with the new solution: for application types requiring a Biocidal Product Authorisation dossier and a SPC (such as NA-APP), users will be required to submit two separate IUCLID files.

Q20: Do we have to import / create the SPC in the different languages?
A20: An SPC dossier will have to be created for each required language (i.e., one dataset/dossier per language).

Q21: Does the rule "no changing of document names" from exercise page 29 also apply to same biocidal product applications when the reference product is already authorised?
A21: Yes, when starting a new application, you will need to download an SPC from the reference asset and update it before submitting. The document names listed at page 29 of the exercise instruction should not be changed.

Q22: How to make an SPC for an SBP-application, for which no IUCLID must be submitted in R4BP3?
A22: Once implemented, only SPCs in IUCLID format will be accepted in R4BP 3. To start you will need the SPC dossier/dataset in IUCLID format of the SPC available in the reference application. Create a new mixture and use the "Copy data from" functionality to select relevant documents to create a single product SPC or a reduced or complete biocidal product family from the SPC available in the reference application. Very important is to remember to ensure that the document names of each mixture composition item are preserved across the two SPCs.

Q23: In SPC Editor the preparation occurs in different ways for SBP, change-renewal or simplified authorisation (choosing between different drafts). Same case in IUCLID?
A23: The SPC in IUCLID format requires only that you extract to dataset a SPC available in an asset. Then, create a new mixture and use the "Copy data from" functionality to select relevant documents to create a single product SPC or a reduced or complete biocidal product family from the SPC available in the reference application. Very important is to remember to ensure that the document names of each mixture composition item are

preserved across the two SPCs.

Q24: In the case of simplified authorisation, how do we create SPCs for notifications?
A24: The SPC for SN-NOT should be prepared by cloning the dataset of the reference SA SPC and editing the relevant information. If a product family, by reporting the same information of the product subject to SN. Always consider prerecording the identity of the document name for the entries in the section "Family, meta SPC, product" (as explained on page 29 of the exercise instruction).

Q25: Is it fine to indicate the concentration of the mixture in the components section and the concentration of the substance contained in the mixture as per SDS in the source of the mixture?
A25: The SPC in IUCLID allows any flexible combination of concentration input for substances. Given this, the correctness of the indication is a regulatory issue, which is beyond the scope of this exercise. A mixture cannot be as such a component of an SPC composition.

Q26: The October version of IUCLID has options to select ECHA BPR Active substance from the list of reference substances. Must older dossiers be updated to these new reference substances? Because they can have different UUID and content. Example CAS 7173-51-5
A26: There is no need to update the reference substances in previously prepared dossiers as long as they were correctly validated by R4BP3.

Q27: SPC of an SBP-application: 1. upload SPC, 2. extract to dataset 3. modify relevant parts (e.g., legal entity, name product), 4. create the dossier. Is it ok?
A27: Yes, you would need to use the reference SPC as indicated in steps 1 to 4. For step 3, only administrative changes based on the existing reference application apply. The authorisation details, including the legal entity, need to be removed before creating an SPC for SPB application. It is very important to remember that names of the documents in the section "Family, meta SPC, product" must remain identical (as explained on page 29 of the exercise instruction).

Q28: UUID changes every time the dataset is extracted from the SPC IUCLID dossier. Current practice foresees the same UUID for those SPCs linked between them (MRP).
A28: The current practice of having the same UUIDs between SPCs in related cases will be replaced by a different approach. Instead of having the same UUIDs, the "related" SPCs will need to have the same document names under the "Family, meta SPC, product" section. For an example, please review page 29 of the exercise instruction.

Q29: When creating an SPC for mutual recognition, which parts need to be translated?
A29: If the SPC is required to be available in another language, it should be translated in all parts. To facilitate this, SPC in IUCLID provides automatic translations of headers and pre-defined picklists, while it is up to the applicant to ensure that free-text field content is properly translated. However, names of the documents in the section "Family, meta SPC, product" must remain identical (as explained on page 29 of the exercise instruction).

Q30: When you mentioned that all SPC's must have the same document name to be linked, do you mean they must have the same "Family or single product SPC name"?
A30: No, we mean names of documents displayed in the Navigation tree on the left, in the section 'Family, meta SPC, product'. If you check the exercise instruction on page 29, there is a screen shot illustrating which names must remain identical as in a reference SPC.

4. TRANSLATIONS

Q31: Can you provide the paths to all translation relevant content within the i6z file of an SPC?

A31: The Translations of IUCLID SPC Submission type are handled in technical properties files. We do not have a consolidated file that aggregates all translations next to the source. Currently, this is not available for public users.

Q32: In a cloned dataset, do we have to create new entries in the composition for active substance/SoCs when the names change due to a different language?
A32: No, the creation of new entries in the composition for different languages will not be required. When filling in active substance information based on the ECHA BPR Active substances list, you will find that the translations for the active substances are provided under the Synonyms section in the REFERENCE_SUBSTANCE Document. Those will be used by the report, if the specific translation is not available, the English Common name of the substance will be printed.
When filling in information for non-active substances, users can provide the translation under the Synonyms section again (manually). This way they can avoid duplication of data in their IUCLID database.

Q33: In the German translation of the SPC report, non-active substances are called "Non-nicht wirksamer Stoff", although it should only be "Nicht wirksamer Stoff".
A33: Thank you for your feedback. Indeed, this is the correction to be done, and it will be addressed in the next version of IUCLID.

Q34: The chosen drop-down options within H&P sentences (e.g., get medical *advice*) are not translated when changing the language. Will this remain like this?
A34: For H&P sentences which contain parameters (such as medical "advice", etc), the user will need to manually update those after changing the language of the User interface from the IUCLID Dashboard. For the go-live this approach will remain. We are exploring improvements to this for the longer term.

Q35: Translations: Do we just link a new substance dataset with a translated common name for the active substance while the linked reference substance for it stays English?
A35: No, for the go-live we are working on an improvement to have the report print the translated substance name based on the available Synonyms List. When filling in active substance information based on the BPR Active substances list, you will find that the translations for the active substance are provided under the Synonyms section in the REFERENCE_SUBSTANCE Document. Those will be used by the report, if the specific translation is not available, the English Common name of the substance will be printed.
When filling in information for non-active substances, users can provide the translation under the Synonyms section again (manually). This way they can avoid duplication of data in their IUCLID database. In conclusion, regardless of the language of the SPC, users will be able to re-use the same substance dataset (with the linked reference substance).

Q36: Will the translated active substance common name for the MS in the synonyms list of ECHA BPR active substances (i.e., Iodine) be considered in the SPC report in the future?
A36: Yes, for the go-live we are working on an improvement to have the report print the translated substance name based on the available Synonyms List. When filling in active substance information based on the BPR Active substances list, you will find that the translations for the active substance are provided under the Synonyms section in the REFERENCE_SUBSTANCE Document. Those will be used by the report, if the specific translation is not available, the English Common name of the substance will be printed.
When filling in information for non-active substances, the users can provide the translation under the Synonyms section again (manually). This way they can avoid duplication of data in their IUCLID database.

Q37: Will there be a functionality for automatic translation of SPCs to all EU languages?
A37: The translation features are similar in the SPC Editor and IUCLID. Field labels and most picklist contents are automatically translated. As before, any free text fields will have to be translated manually.

5. PLANNED IMPROVEMENTS

i. Where to find information

Q38: Can we have more information about plans to improve IUCLID?
A38: You can see an overview of the planned improvements in future IUCLID releases on the IUCLID website at: https://iuclid6.echa.europa.eu/planned-releases. There are two main releases per year, one in October (recent one was on the 30.10) and one in April, which are followed by a presentation webinar organised by ECHA (the next webinar is scheduled for 21st of November).

ii. Bugs and improvements reported during the exercise

Q39: EUH phrases are missing in SPC (single product) by report generator for both pdf/rtf format for the "single product". While it is correct for "product family"
A39: Thank you for reporting this problem. We intend to fix it before the go-live.

Q40: Multiple users in a same company of IUCLID cloud: impossible contemporaneous usage due to dashboard language.
A40: Thank you for your feedback. Indeed, we have confirmed an unexpected behaviour of the user interface language selection in the ECHA Cloud Services. The language is reset to English when refreshing the page of your browser (using the F5 keyboard key for example). We will work towards the resolution of this issue. In the meantime, after the selection of the language, you can avoid refreshing the page to continue to work in the desired language.

Q41: The full composition is not required for the SPC, only SoCs and the active substance Why is there a business rule then in the validation for the specific composition?
A41: The word 'specific' means here 'relevant to the SPC' (active substance(s), substance(s) of concern, releaser(s), other substance(s) knowledge of which is essential for proper use of biocidal products), however we have realised that this wording might be misleading, and we will change it, both in the IUCLID document and the validation rule message to 'Composition of the product' in the next IUCLID release. Thank you for pointing out the problem.

Q42: Created the SPC dossier in server Feb release. Exported that dossier and import to desktop v. 7.10.1. General directions in SPC dossier not in .rtf, .pdf docs?
A42: We have not been able to reproduce this problem in 7.10.1, therefore we would ask you to contact ECHA help desk and provide us with the i6z file that you have generated a report from.

iii. Reuse of a biocidal product authorisation dataset for an SPC

General information from ECHA:

The IUCLID version released on 30th of October contains the format that can be used to prepare the SPC in IUCLID. For the go-live the main goal was to ensure that IUCLID will cover the functionalities and format that are present in the SPC Editor.
Now, when IUCLID is ready for the go-live, we can focus on the analysis and improvements that will allow users to reuse the same dataset between two working contexts: *BPR Biocidal product authorisation* and *BPR Summary of product characteristics (SPC)*.
Although, we had in mind the potential reuse of these datasets when working on the transition from the SPC Editor to IUCLID, we did not avoid some constraints that need to be addressed before users will be able to reuse the same datasets. Those limitations are

related to the product composition. We aim to solve them in the next IUCLID release, in April 2024.
Before this day, there are two ways to create an SPC file and benefit from the data that have been already inserted to IUCLID (in a biocidal product authorisation dataset):

Option 1: by using functionality "Clone" functionality:

1. Find the dataset prepared for the biocidal product authorisation.
2. Clone the dataset ("Clone" functionality has been explained on page 31 of the exercise instruction).
3. Select the working context 'BPR Summary of product characteristics (SPC)'.
4. Adapt content of the dataset to the needs of the SPC by deleting/modifying not needed data and adapting the composition to the requirements specified for an SPC:
    - all substances that are not active substance require link to a reference substance entity, and not to a substance.
    - mixture is not allowed in a composition.
    - only substances relevant to an SPC should be reported, i.e.
        - active substance(s)
        - substance(s) of concern
        - releaser(s)
        - other substance(s) knowledge of which is essential for proper use of biocidal products.

It is very important to understand that this is not a 'reuse' of a dataset, but creation of a new dataset; deleting is irreversible.
The data present in the BPR Biocidal product authorisation dataset, which has not been actively deleted by the user, will not be displayed in the BPR Summary of product characteristics (SPC) dataset, but will remain there, hidden (for example toxicity data will be visible if BPR Biocidal product authorisation is selected again). This data (not relevant to the SPC and not displayed in the SPS working context) will not be transferred to a dossier (non-editable version of data to be submitted to R4BP3) and will not be retrieved by the SPC reports (rtf/pdf).

Option 2: by using "Copy data from" functionality:

1. Create new mixture/product dataset.
2. Select the working context 'BPR Summary of product characteristics (SPC)'.
3. Under three-dot menu, select "Copy data from…" and select a biocidal product dataset from which you would like to copy data ("Copy data from" functionality has been explained on page 34 of the exercise instruction)
4. Copy required data (by selecting relevant documents); copied record will appear in the table of contents with an addition to a name "COPY".

This dataset will not contain data that are not relevant to the BPR Summary of product characteristics, however the composition section still needs to be adapted to the SPC requirements (if copied).

Q43: How can we reuse an existing mixture dataset but keep only the necessary components for the SPC from the mixture composition?
A43: Please see information above. Before April 2024 release, you can choose between two options, and adapt composition section manually.

Q44: In BPR product dossier listed already all countries with product trade names. One entry per country/ product combination. Can this be used in the SPC dossiers?
A44: Please see information above. Before April 2024 release, you can choose between two options, and adapt composition section manually. All the combination of country/trade

name listed in the document "Product" can be kept. However, the components list has to be adapted to SPC requirements.

Q45: In your exercises, all SoCs are entered as reference substances in the composition. Can we also link substance or mixture datasets in the composition instead?
A45: Currently, substances that are indicated with functions other than active substance must be reported using a reference substance entity. We are analysing the possibility to also allow substance datasets in the future.

Q46: Product BPR dossier composition with mixtures in it. The mixtures are not present in the SPC context (.rtf or .pdf)? SPC composition only substances, breakdown?
A46: Mixture cannot be reported as a component in an SPC dossier. All the substances need to be retrieved and reported separately: an active substance as a substance dataset, all other substances as reference substances.

5. IUCLID INSTALLATION

Q47: How can we set the new Windows service after installation of upgrade of IUCLID 6 server? We have tried to do it as in the manual, but it didn't work.
A47: In case you have installation issues, please contact the ECHA Helpdesk at https://comments.echa.europa.eu/comments_cms/Contact_IUCLID6.aspx

Q48: Is it still possible for a consultant to work on an SPC in his own IUCLID cloud and the applicant works on the SPC in parallel in his own IUCLID cloud?
A48: There are several options for different users to work on the same SPC: (1) it is possible to export and import the SPC content between IUCLID installations (2) when using ECHA Cloud Services, an applicant can give access to a consultant to its own IUCLID instance. This is done using the 'foreign user' concept. More details are available under section 7.12 of this manual: https://echa.europa.eu/documents/10162/17247/howto_account_manual_industry_en.pdf
Please note that, in the case of the foreign user, the foreign user will get access to the full content of the company's IUCLID database.

Q49: Is there any option to have a test system? if a couple of employees want to do the training with importing datasets and dossiers the IUCLID will get very full
A49: You have several options in case you would like to distinguish between your production IUCLID database and another IUCLID instance for testing or training purposes: (1) you can install a Desktop IUCLID on your computer, (2) you can setup a test/training IUCLID Server in your company, (3) you can use an ECHA Cloud Services IUCLID instance and use the Trial subscription. More information at https://iuclid6.echa.europa.eu/download

Q50: Using the IUCLID cloud version, is there a fee to pay to ECHA?
A50: The use of a IUCLID instance in ECHA Cloud Services is free of charge if the usage is allowed by the terms and conditions. More information at: https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services

Q51: Will an SPC (IUCLID) issued by ECHA or a CA be directly available to the applicant in the Cloud version? Or need to be downloaded and imported?
A51: Users will be able to download SPCs from R4BP 3 and import them to a IUCLID installation.

Q52: For those that use IUCLID server, is there an action to integrate SPC into IUCLID? We already see the SPC option in our IUCLID.
A52: The SPC support features have been included progressively in IUCLID since several

months. If you already have the IUCLID version from May 2023 you can already use the SPC option for training purposes. The version of IUCLID published on 30th of October 2023 will contain the final update of the SPC-related features. So, it is recommended to update to this version.

6. MISCELLANEOUS

Q53: SPC Section 1.3 - The Authorisation Holder can appear as manufacturer even if the manufacturing sites are under the name of other companies? Thank you.
A53: SPC in IUCLID does not prevent to choose whichever legal entity as manufacturing site owner. This appears to be a regulatory issue, which is outside the remit of this exercise.

Q54: Will the .pdf and .rtf extract formats be polished? I extracted one RTF from one of the exemplary IUCLID files and it looks full of irrelevant information.
A54: We recommend using IUCLID 6 v.7.10 to generate the report. The result should be equivalent to the report produced with the SPC Editor.

Q55: Will the final set of validation rules for the SPC working context be made available? This would be helpful.
A55: Yes, the list of SPC-relevant validation rules will be shared and be available together with the updated submission manual.

Q56: Will we have to manually change the file name of the downloaded SPC i6z to make it more recognisable? Currently we can see market area, language, and time stamp.
A56: When exporting a dossier from IUCLID, the default name is the unique identifier of the dossier (UUID). This can of course be changed when saving the file.