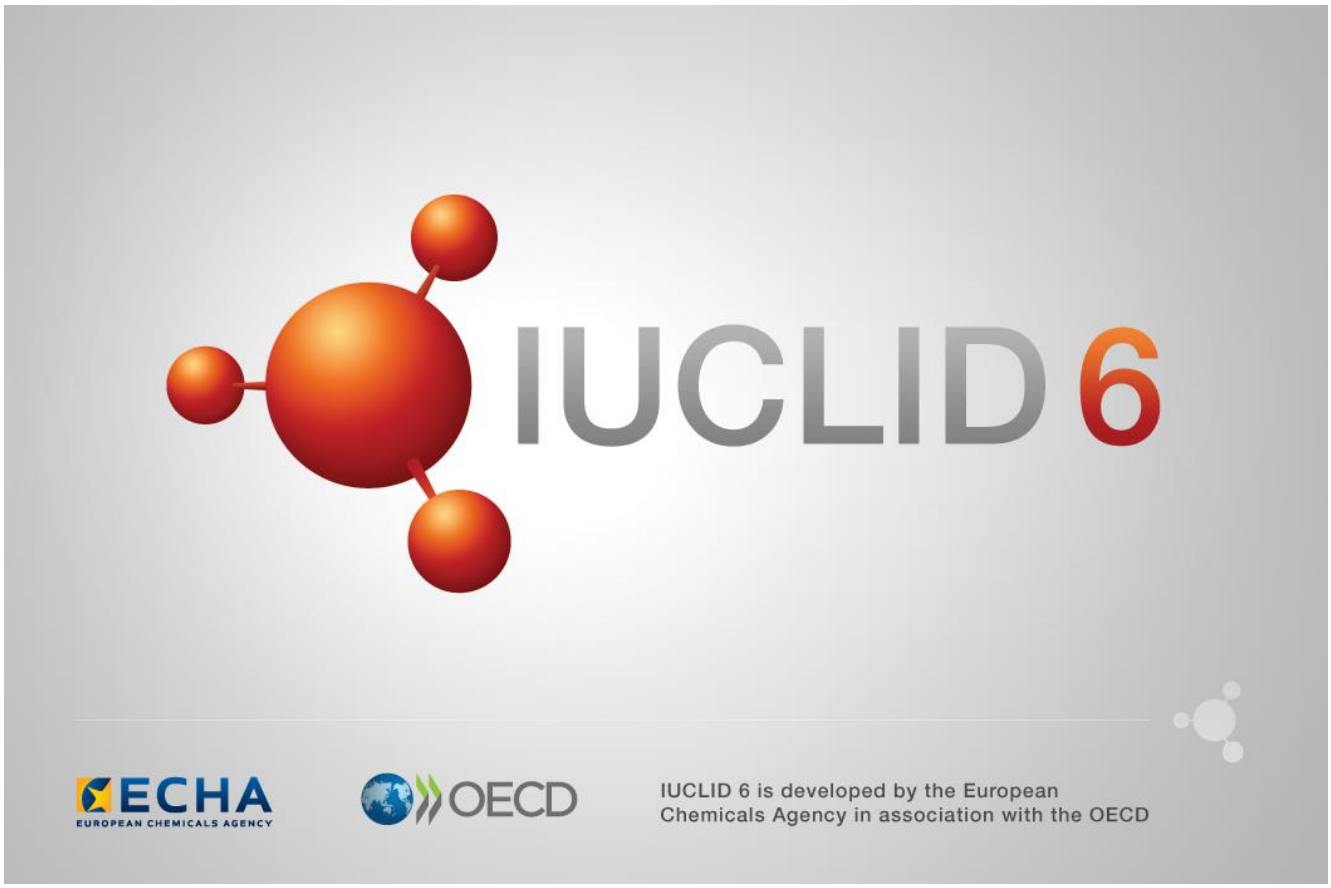
IUCLID 6

# Webinar *'IUCLID 6.5 for biocides users'* Questions and Answers

IUCLID 6.5

24/11/2020



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# 1. INTRODUCTION

The webinar 'IUCLID 6.5 for biocides users' took place on 24th of November 2020. The recording is available on the webinar page https://www.echa.europa.eu/-/iuclid-6-5-for-biocides-users. The webinar presented the IUCLID 6.5 published on 28th of October 2020 in the context of biocides.

The webinar covered following topics:

- Biocides submissions: biocidal product dataset, substance dataset, creation and navigation of a dossier Biocides submissions: biocidal product dataset, substance dataset, creation and navigation in a dossier
- Preparing a dossier for Technical Equivalence
- Format changes most relevant for Biocides users
- Annotations, attachments and print
- Report generator
- Plans for 2021

The question and answer session has been organized in Slido. The content of this session is reported in this document.

# 2. QUESTIONS & ANSWERS

## 2.1. IUCLID Functionalities

**Q1**: How can you copy and paste multiple sections at the same time? Instead of one at a time?

**A1**: You can use the 'Copy data from ...' feature to copy one or more documents into your Biocidal dataset. You can copy from another dataset/dossier or template. You can take a look at the Functionalities of IUCLID in the web user interface manual for how to do this. Please be aware that currently, this feature is only available to Full Access users. This configuration will be changed with the next public release of IUCLID so that a user with Write permissions on the data can use the feature as well.

**Q2**: If we have a substance but we use different grades or different sources for different biocidal products, how should we manage that? Can we create two substances with same name?

**A2**: In IUCLID, you can create a substance or mixture with the same name. Just be aware that you will be warned that you are creating an entity with the same name, and that you will need to confirm that you wish to continue with the creation of the substance or mixture.

It might be good to name the substances according to the grades as well in order to more easily differentiate them. The substance name is only for your own use as the key substance identifier are stored in the reference substance linked to the substance document and in the composition document.

**Q3**: When doing a read across is it necessary to enter the study twice like we have to for REACH? For REACH the study has to be entered once for the substance assessed in the study/paper and a second time for the substance to be registered.

**A3**: As with REACH, to do an analogue read across in the context of Biocides', you would use the source-target approach (see section 8.6.3 in the REACH-PPORD manual: https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf). In this approach, you would create a source endpoint and establish a cross-reference link to a target endpoint. In the reason/purpose for the cross reference, you would add in the source endpoint which you are reading across from, that this is a 'read-across source'.

## 2.2. Validation rules

**Q4**: Does R4BP portal submission check verify IUCLID validation assistant result, as it is the case for REACH?

**A4**: Currently, the validation assistant rules available in IUCLID are not integrated as part of an automated validation check in R4BP 3. However, as we further review additional validation rules for the various Biocides' working contexts', we will consider integrating these as part of the submission

check in R4BP 3. This will help users to know quickly after submitting, what rules have initially passed or failed.

**Q5**: Is there a European deadline to submit IUCLID 6.4 dossiers (without validation assistant check) or does acceptance depends on competent authority?

**A5**: Validation assistant check has not changed in version 6.5 in context of biocides. There are the same two rules related to the composition as in 6.4. We explore the possibility to provide more rules in the future, starting with the validation for the Technical Equivalence, probably next year. Then, indeed, a Competent Authority could decide about potential updates because, for BPR dossiers, the verification is done at the level of the Member States.

## 2.3. Dossier submitted in older IUCLID 6 version

**Q6**: If our already submitted product family dossier according to old IUCLID 6 structure needs to be updated, will we have to change it according to the new structure in IUCLID 6.5? Or can we keep the old dossier prepared in IUCLID 6 (e.g. without the meta families)

**A6**: The summaries compositions for the meta SPC have been already available in the older versions of IUCLID 6. You do not need to update your dossier due to the recently implemented changes. The links inserted in the older versions of IUCLID 6 have been preserved.

**Q7**: If we upgrade to IUCLID 6.5 what will happen with already entered mixtures/ongoing applications for biocidal product families? Are they compatible with the updated version?

**A7**: All data will be migrated to the new version. Two versions 6.4 and 6.5 are compatible.

**Q8**: Will authorities refuse dossiers made with previous IUCLID versions? Do we need to upgrade to 6.5?

**A8**: R4BP 3 accepts dossiers prepared in the IUCLID 6.4. Only for the Technical Equivalence dossier, version 6.5 shall be used. Authorities will access the submitted dossier in the IUCLID database hosted by ECHA, migrated to version 6.5. However, a Competent Authority can ask for the update in the upgraded version if it would facilitate the evaluation.

**Q9**: Will biocidal product dossiers that have to be resubmitted also fail format check in R4BP3 if they are not prepared in IUCLID6.5 format?

**A9**: R4BP 3 accepts biocidal product dossiers prepared in the IUCLID 6.4. Only for the Technical Equivalence dossier, version 6.5 shall be used.

## 2.4. Reports

**Q10**: Do I have to put the working context on Summary of product characteristics to be able to generate an SPC? If I do this and open the file in the SPC editor, I don't see anything?

**A10**: Draft SPC XMLs are generated from IUCLID dossier / dataset information via a specific report template ("Summary of product characteristics (SPC) report [XML]"). In order to generate such SPC XMLs, there is no need to select the Summary of product characteristics working context in IUCLID.

**Q11**: Is it possible to generate from IUCLID a draft SPC even in the case of biocidal product families?

**A11**: The report template of IUCLID that is used to generate draft SPC XMLs ("Summary of product characteristics (SPC) report [XML]") assumes that the IUCLID dossier contains information about a single product. As such no SPC XML can be generated for biocidal product families.

**Q12**: When do you expect the possibility to generate parts of the PAR with IUCLID?

**A12**: With the new modular approach to reporting, together with the interest in creating large assessment reports from Mixtures in the context of Pesticides' data, we do plan to create a report that can be used as a basis for building a PAR. The generated report will be in RTF format (opened in Word). We hope that next year we will progress on this and provide an initial draft to the Biocides' user community to test and provide feedback on.

## 2.5. Confidentiality claims

**Q13**: When is the request for confidentiality needed? At the time of handing in the dossier or can it be requested up until the time the substance is authorised?

**A13**: Request for confidentiality has to be claimed during the preparation of a dataset (using confidentiality flags), so this information is included in the dossier. Later on, the change of this request would require an updated dossier submission.

**Q14**: Where do we put a request for confidentiality, i.e. at the beginning of the dossier or for each point and what will be available publicly after authorisation of the active substance?

**A14**: You need to put a request for confidentiality for each point. Please find more information on what information can be claimed as confidential in the Biocides Submission Manual: Process of confidentiality requests for biocides applications. This manual will be updated soon. Currently, the biocides information is disseminated based on the data provided in the public version of the assessment report, which is submitted by the Member States. The SPC is also published, this cannot be claimed as confidential.

## 2.6. Miscellaneous

**Q15**: Is it necessary to attach the PDF of each published paper from journals to the IUCLID dossier?
**A15**: The evaluation of a BPR dossier is done at the level of the Member States, therefore unfortunately we are not in the position to answer this question.