ECHA
EUROPEAN CHEMICALS AGENCY

IUCLID 5.4 changes and impact on submission and dissemination of information

Questions and Answers

This document provides advance information
of the upcoming changes due to the IUCLID 5.4 release

Questions and Answers **IUCLID 5.4 changes and impact on submission and dissemination of information**

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1. When will IUCLID 5.4 be released?

The expected release of IUCLID 5.4 is in late May 2012, as was already announced in 2011 on the IUCLID Website: http://iuclid.eu/index.php?fuseaction=home.development#iuclid54

2. What are the changes in IUCLID 5.4 compared to the previous version?

The changes in IUCLID 5.4 are mainly related to the introduction of new fields to report key information, currently in the Chemical Safety Report (CSR), in a more structured manner and facilitate the publication of certain information contained in the Safety Data Sheet (SDS) (see question 7 for further explanation). In general, the main changes are summarised below:

- PBT (Persistent, Bioaccumulative and Toxic chemicals) assessment: IUCLID will be adapted in order to be able to store the outcome of the PBT assessment performed under the REACH Regulation. The template will contain:
    - the PBT / vPvB status of the substance assessed
    - the likely routes of exposure
    - the outcome of the assessment for each criterion (Persistence, Bioaccumulation, Toxicity).
- Modification of IUCLID section 3 (Manufacture, use and exposure): The objective of the modified section 3 of IUCLID 5.4 is to allow the documentation of the information on manufacture and use of a substance and the related exposure and risk assessments in a more structured and harmonised way. The main amendments on this section are related to the reporting of the following information: conditions of use, exposure estimates for humans and the environment, methods and tools used for the assessment.
- Endpoint summaries of IUCLID section 7 (toxicological information) will be enhanced in order to report more information on the hazard assessment (e.g. selection of the key study, assessment factors).

3. Is there going to be a new version of REACH-IT released as well?

After the IUCLID 5.4 release, REACH-IT will be updated in order to be able to process dossiers in the new IUCLID format. The new version of REACH-IT is planned to be released in July 2012.

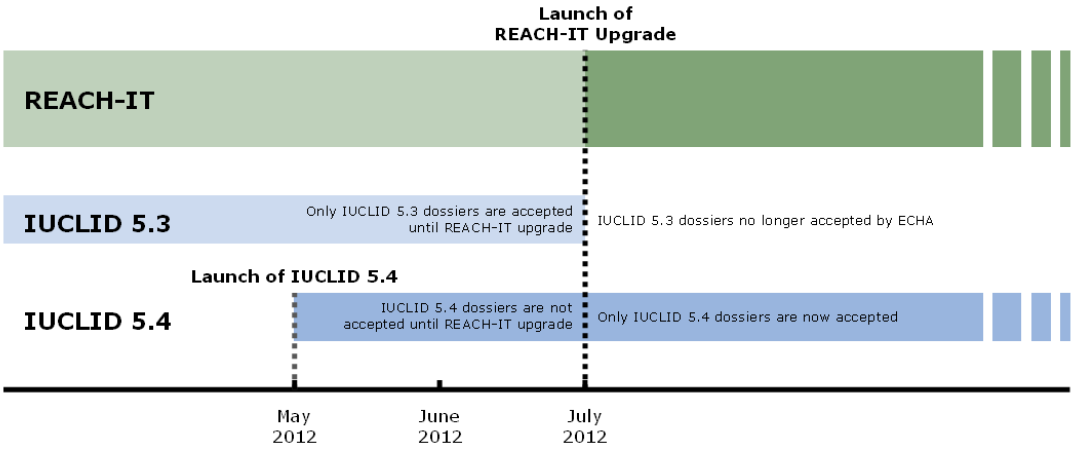
4. When will I be able to submit a IUCLID 5.4 dossier to ECHA?

REACH and CLP dossiers created in the latest IUCLID 5.4 format will be accepted by ECHA only after the new version of REACH-IT has been released. Before that, only IUCLID 5.3 dossiers will be accepted by ECHA.

This applies to all dossiers, initial or updated, submitted to ECHA via REACH-IT (Registration dossiers, PPORD, Inquiry, DU report, SiA notification, CLP notification created in IUCLID, etc.)

or using one of the manual submission systems (e.g. Application for Authorisation, Request for alternative chemical name under CLP Article 24, dossiers submitted by authorities).

The planning for the release of IUCLID 5.4 and REACH-IT and the synchronisation regarding the submission of IUCLID 5.4 dossiers is illustrated in the following figure:



5. Why are the new versions of IUCLID and REACH-IT not released at the same time?

ECHA is publishing IUCLID 5.4 prior to the compatible release of REACH-IT, in order to allow users to prepare for the transition from IUCLID 5.3 to IUCLID 5.4 and adapt any internal procedures based on this application.

Users will be able to test the installation of IUCLID 5.4 beforehand but IUCLID 5.3 must continue to be used for the preparation of dossiers that will be submitted before the switch to the new REACH-IT version (see also question 4).

6. Will I be able to use my existing IUCLID substance datasets that have been created with previous IUCLID 5 versions? How can I migrate them to the new IUCLID 5.4 format?

Similar to previous major IUCLID service releases, a migration step is integrated into the application and backward compatibility will be ensured, meaning that all IUCLID files created with previous versions of IUCLID 5 will be compatible with the latest version. IUCLID users nevertheless need to plan in advance the migration of their own database(s), and organise the recording of potentially additional data. The migration of data to the new format will happen automatically during the first launch of the IUCLID 5.4 application if the update mode is chosen.

7. Are the changes in IUCLID 5.4 going to affect the dissemination of data from registration dossiers?

With the release of IUCLID 5.4, a number of changes will be introduced to the dissemination policy, as was already announced with a press release in May 2011*. The main change is the extension of the interpretation of REACH article 119(2)(d) on the dissemination of

“information, other than that listed in paragraph 1 [of article 119], contained in the safety data sheet” to (amongst others) the registrant’s name, the registration number, and the outcome of the PBT assessment (aka SDS information).

This will affect registrants who will submit an initial registration dossier or an update after the release of the new REACH-IT, as well as registrants who have submitted a registration dossier in the past (earlier registrants). The earlier registrants will be invited to review their previously submitted dossier(s) and add the relevant confidentiality claims where and if needed. A period of time will be stipulated for earlier registrants to resubmit their dossier(s). After this period, the Dissemination pages of registered substances on the ECHA website will be updated to include the SDS information that have not been claimed confidential (full details will follow in due time). Note that all confidentiality claims attract a fee and must be adequately justified in accordance with the published criteria and these claims will be assessed by ECHA.

* http://echa.europa.eu/web/guest/view-article/-/journal_content/77a6455a-c28f-4183-91ca-a854f5c3a176

8. Which are the main new sections/data in IUCLID 5.4 that will be disseminated? Can I claim these data confidential?

The company information of the registrant in relation to the registered substance will be disseminated unless claimed confidential. The fields which will be disseminated are the legal entity name, full address and phone number as indicated in the registrant’s REACH-IT account. For only representatives (ORs), the same information will be disseminated unless claimed confidential, or unless the OR is not the supplier and alternate suppliers are listed in the relevant IUCLID 5.4 section (section 1.7). In the latter case, the legal entity name, full address and phone number of the supplier(s) will be disseminated instead. Please note that ORs must have written approval from the suppliers to be listed in IUCLID section 1.7. ORs will have the opportunity to request confidentiality on their own and the suppliers’ information if deemed necessary.

The registration number will be disseminated in full (13 digits) if not claimed confidential. If the registrant’s legal entity name has been claimed confidential, the last four digits of the registration number will not be disseminated. Moreover, a new confidentiality flag will be available in IUCLID 5.4 to allow registrants to indicate a confidentiality claim on the registration number.

The outcome of the PBT assessment in the new section 2.3 of IUCLID 5.4 will be disseminated, unless claimed confidential.

The corresponding Dissemination plug-in will be updated according to these new rules in order to allow companies to be able to check which fields will be disseminated before submitting.

9. Will I be charged for the confidentiality claims on the SDS information? Will my claims be assessed?

When the new version of REACH-IT is released, confidentiality claims on “information, other than that listed in paragraph 1, contained in the safety data sheet” will be invoiced. This includes claims on the legal entity name (for a manufacturer, importer or only representative), the registration number, the outcome of the PBT assessment, the life cycle description and uses advised against. It should be noted that there is no fee for substances that do not require a safety data sheet in accordance with Article 31 of REACH (and for some items, additionally, there is no fee for registrants not requiring a chemical safety report).

The fee foreseen in the Fee regulation* will be invoiced once per registration, regardless of the number of confidentiality claims on some or all of the specific items of SDS information. Nevertheless, each item needs to be claimed in the dossier and the reason for confidentiality separately justified. Confidentiality claims that are invoiced will be assessed.

The justification for the confidentiality claims needs to include (1) a declaration that the information is not in the public domain or general knowledge in the industry, (2) a demonstration of a commercial interest worthy of protection for non-disclosure of the information, and (3) a demonstration that disclosure of the information would cause potential harm to the commercial interest of the registrant or a third party.

Confidentiality claims that are not invoiced, because the substance does not require a safety data sheet, are not assessed.

The Fee Calculation plug-in will also be updated accordingly and will allow companies to calculate the amount of the fees related to the confidentiality claims before submission.

* Fee regulation: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:107:0006:0025:en:PDF

10. Will the new version of IUCLID/REACH-IT have an impact on the existing Business Rules (BR) check?

IUCLID 5.4 offers the possibility to claim confidential the information contained in the SDS (e.g. registration number, legal entity, PBT assessment, uses). These claims will be charged and invoiced (see question 9). As before, BR will check that chargeable claims are supported by a justification. A new BR will be introduced to check that the outcome of the PBT assessment is provided, to allow for proper processing and invoicing in REACH-IT.

In addition, a new BR will ensure that the IUPAC name of the substance is provided in the IUCLID section 1.1.

11. Will the new version of IUCLID/REACH-IT have an impact on the existing Technical Completeness Check (TCC) requirements?

No, the existing TCC rules are not impacted at the moment. This means that a dossier which was considered as technically complete with IUCLID 5.3 will also be considered as complete with the new version of IUCLID 5.4.

Although the new fields related to the CSR information will not be subject to TCC until 2014, the registrants are encouraged to fill them in already in the best feasible manner. This way they will avoid updating their dossier at a later stage when the new format is made mandatory or new registrations or dossier updates.

12. Is there any other impact on the registration dossiers submission process due to the IUCLID/REACH-IT update?

The key facts that need to be kept in mind are:

- The new REACH-IT release will only accept IUCLID 5.4 dossiers

- A few BR checks are added mainly to allow proper processing and invoicing of confidentiality claims on the information contained in the safety data sheet

- The TCC requirements remain the same

13. Where can I find more detailed instructions and assistance on IUCLID 5.4 dossier creation and submission?

The manuals on how to create, check and submit IUCLID 5.4 dossiers using REACH-IT (i.e. Data Submission Manuals and REACH-IT Industry User Manuals) will be updated and published together with the new REACH-IT release.

Similarly, ECHA has developed a series of IUCLID plug-ins to help registrants preparing their dossiers (i.e. Technical Completeness Check, Fee Calculation, Dissemination and CSR plug-ins). Plug-ins currently available for IUCLID 5.3 will be updated for IUCLID 5.4 and will be made available at the same time as the release of the new version of REACH-IT.

14. Will Chesar be compatible with IUCLID 5.4?

Chesar 2.0 which will be compatible with the new IUCLID format is under development. A fundamental difference is that it will be a stand alone application and not a IUCLID plug-in anymore (full details will follow in due time).

Chesar 2.0 will need the IUCLID 5.4 substance dataset as a basis for carrying out the chemical safety assessment. A template will be developed in IUCLID 5.4 to easily identify which data are necessary or useful for running Chesar. These are mainly the endpoint summaries for a number of physico-chemical and fate properties, as well as the PBT status and the hazard conclusions for the environment and human health (endpoint summaries 6 and 7, which have both been revised in IUCLID 5.4).

In order to generate the full CSR, the CSR plug-in will be extended to combine both the information from IUCLID to populate sections 1 to 8 and from Chesar to populate sections 9 and 10. The CSR plug-in will also continue to work even if Chesar is not used.

Chesar 2.0 with the basic functionalities is intended to be released in summer 2012. Note that the current version of Chesar (v. 1.2), which can be installed on IUCLID 5.3, will not be compatible with IUCLID 5.4.

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