REACH joint registration workflows for Chesar users

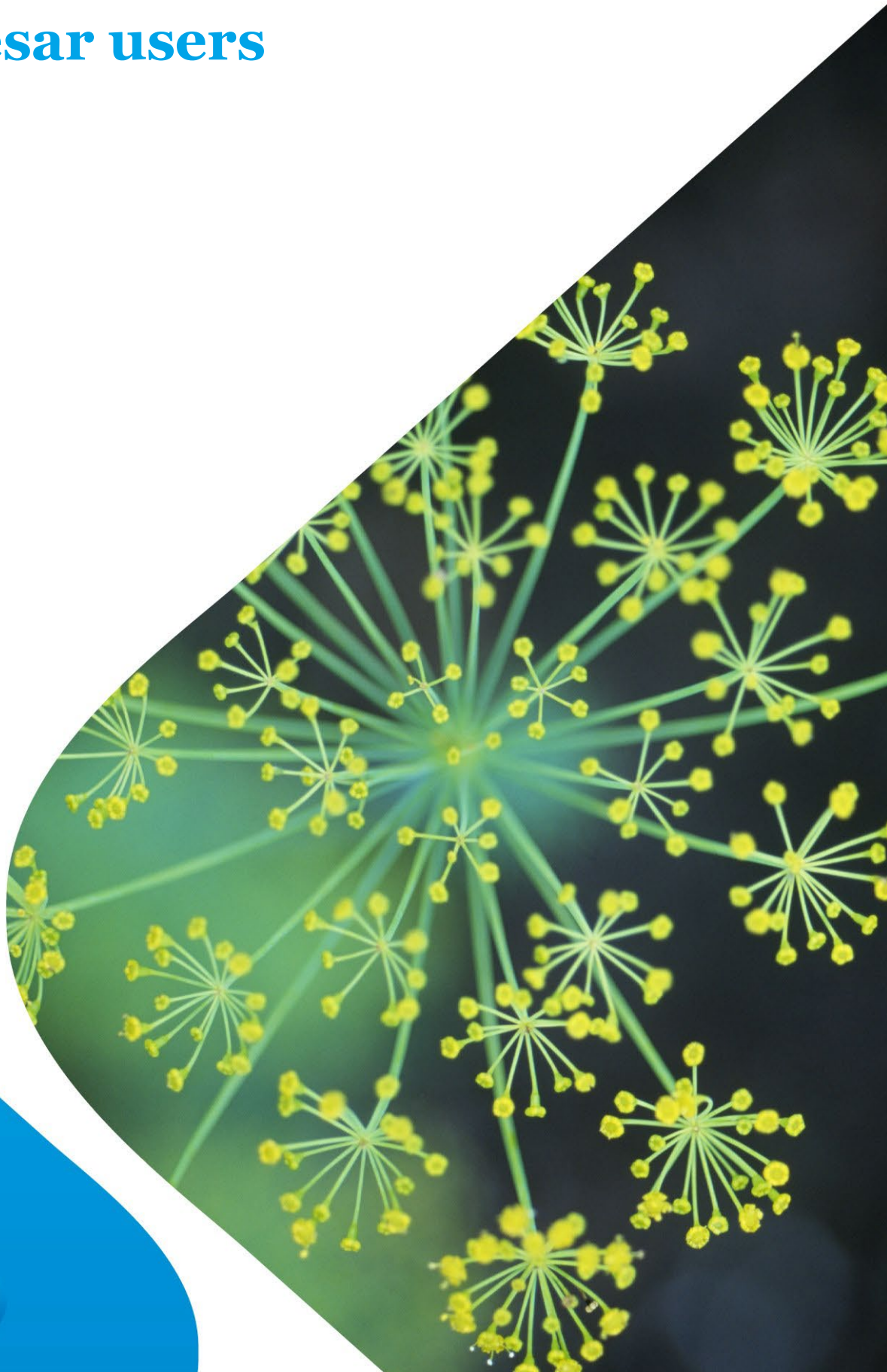

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Table of Contents

1. Introduction

When importing or manufacturing a substance into the European Union (EU) in quantities of 1 tonne or more per year, registrants must identify and manage the risks linked to the substances they manufacture and market in the EU, as described in the REACH Regulation (EC) No 1907/2006. To comply with the regulation, they need to demonstrate how the substance can be safely used as part of the registration of their substance.

When multiple registrants are manufacturing and/or importing the same substance, they have to register the substance jointly within the same joint submission, as described in REACH Article 11. They must agree on one registrant that will take the role of a lead registrant. Each of the registrants (manufacturer, importer or only representative) must submit their own registration dossier.

There is a difference between the information that the lead registrant needs to submit, and the information submitted by other members of the joint submission. Every registrant must submit in their dossier the information on substance's identity and composition, analytical information of substance, information on the manufacture and uses of the substance, and information on exposure for the substance.

The lead registrant must submit information on the classification and labelling of the substance, as well as scientific studies referred in Annexes VII to X to REACH, on behalf of the members of the joint submission.

For all substances manufactured or imported above 10 tonnes, a chemical safety report (CSR) must be included in the registration dossier, unless exempted by REACH Article 14(2). The CSR can be submitted by the lead registrant on behalf of all registrants, or individually by each registrant, depending on the agreement within the joint submission.

The European Chemicals Agency (ECHA) has developed IUCLID and Chesar, software applications to support registrants in performing their obligations as described by REACH:

- IUCLID (International Uniform Chemical Information Database) is a application used to record, store, maintain and exchange data on properties of chemical substances. It is the tool to generate registration dossiers under REACH (https://iuclid6.echa.europa.eu/project-iuclid-6).

- Chesar (Chemical safety assessment and reporting tool) is a software application developed to help companies prepare their chemical safety assessments (CSAs) and to report the outcomes into CSRs, required for REACH registration. It can also be used to generate exposure scenarios to be annexed to safety data sheets (SDSs) for downstream users (https://chesar.echa.europa.eu/home). Although Chesar is not a mandatory tool, it is designed and maintained by ECHA to generate CSRs that fulfil the requirements of REACH. As such, it is the tool ECHA recommends for this purpose.

ECHA carries out a technical completeness check (TCC) (https://echa.europa.eu/technical-completeness-check) on each incoming registration as set out in Article 20(2) of REACH. Since March 2021, ECHA's TCC extends to CSRs. From the experience gained with the manual TCC on CSRs, we noted that there have often been inconsistencies in use descriptions between REACH registration dossiers and attached CSRs.

This document aims to address this challenge, by giving practical advice to lead and member registrants that are part of the same joint submission on how to share information when preparing a chemical safety report (CSR) for REACH registration using Chesar.

2. Exchange of data files between lead and member registrants: suggested workflows

When the CSR is needed, it can be provided in different ways, depending on the agreements reached between the members of the joint submission. Three main scenarios are possible, as described here below:

1. The CSR is prepared and submitted by the lead registrant on behalf of all other co-registrants.
2. The CSR is prepared by the lead registrant and submitted individually by every co-registrant (with or without modifications by the co-registrant).
3. The CSR is prepared and submitted individually by every co-registrant.

In every scenario, all uses known to each registrant must be described in their dossier. Each use must be assessed in a CSR, and it must be made clear where this use is assessed: in a CSR submitted jointly, or in their own CSR. This information should be indicated in the "related assessment" field in IUCLID Section 3.5.

Although not strictly related to the preparation of the CSR, all registrants have to generate a safety data sheet (SDS) for their substance. This SDSs should contain, among other information, the physico-chemical, fate and hazard characteristics of the substance as well as the exposure scenarios (ESs).

As a prerequisite to the workflows described in this document, the lead and member registrants should communicate and agree on the composition of the substance. For scenarios 1 and 2, they should also communicate on the identified uses of the substance. The exchange of this information is beyond the scope of this document. Guidance regarding that can be found on ECHA's website (https://echa.europa.eu/regulations/reach/registration/data-sharing).

The technical details on how the information should flow among the co-registrants when Chesar is used, is provided in Chapter 4 of this document.

2.1 The CSR is prepared and submitted by the lead registrant on behalf of all co-registrants

When the lead registrant agrees to prepare and submit a joint CSR on behalf of the members of the joint submission, the CSR must cover all uses known by all registrants within the joint submission.

The member registrants do not need to submit a CSR for those uses. They nevertheless need to report all the uses covered by the CSR which are relevant to them in their own registration dossier. To have a consistent way of documenting the uses between the lead and the member registrants, the lead registrant should provide the use description information (Section 3.5) from their IUCLID dossier to the member registrants so that the members can copy it to their IUCLID database and therefore include it to their registration dossiers.

The detailed workflows for both lead and member registrants are listed here.

2.1.1 Lead registrant workflow

1. Create a IUCLID dataset containing all the necessary information, including hazard and fate properties (https://echa.europa.eu/support/registration/creating-your-registration-dossier/how-to-create-your-registration-dossier-with-iuclid) and import the substance from IUCLID to Chesar.

2. In Chesar, set the related CSR as "Joint", describe the uses and assess them.

3. Export the uses from Chesar to IUCLID (see Chapter 4 for further information on export options). The "related assessment" field in IUCLID Section 3.5 for all these uses will be automatically marked as "use assessed in a joint CSR".

4. In Chesar, generate the full CSR (in box 4). We suggest using the Chesar functionality to automatically create a record in IUCLID Section 13.1, while generating the CSR. This record will contain all necessary information, as described in Chapter 4 of this document.

5. Create an export from the IUCLID dataset containing Section 3.5 (as .i6z file) to be sent to member registrants. Afterwards, if needed, the lead registrant can change the "related assessment" field in IUCLID Section 3.5 to "use assessed in a joint CSR but not lead's own use" in one or more uses.

6. Send the following information to member registrants (so that all the members have the same information):

    a. The IUCLID file containing Section 3.5 as described previously. Note that the lead registrant should also share the information relevant for the core body of the SDS (phys chem, fate, hazard).

    b. The Joint CSR.

    c. The exposure scenarios to be added to the SDS, so that it can be used by the member registrants, as generated by Chesar (in box 5).

7. The lead registrant can decide to exclude their own specific uses (e.g. manufacturing) from the joint CSR. In this case, the lead registrant should submit another CSR (i.e. an own CSR) containing their own uses and related assessment in addition to the joint CSR, and follow these additional steps:

    a. Create and prepare another CSA in Chesar box 1 CSA management while making sure that **this** CSA is **not** flagged as joint.

    b. Export the uses from Chesar to IUCLID (this should lead to having both joint uses and own uses in IUCLID Section 3.5).

    c. Generate the CSR ("Generate full CSR" in Chesar box 4), flag "create a new record in IUCLID Section 13.1, prefill it with the relevant information and attach the CSR" and fill in part A information.

8. Proceed with the finalisation of registration dossier.

2.1.2 Member registrant workflow

1. Member registrants should prepare their own IUCLID dataset to be able to submit their own dossier. In case they have not started when receiving the lead registrant's IUCLID file export, they can import the .i6z file from the lead registrant to their IUCLID database. They will then have to complete this IUCLID dataset with their own information.

    If the member registrant already has a IUCLID dataset of the substance to be registered, the member should copy the data (Section 3.5) from the lead registrant's substance dataset to their own original dataset and proceed with the original dataset.

2. Create a new record in Section 13.1 in which they will indicate only part A of the CSR.

3. Proceed with the finalisation of the registration dossier and flag "chemical safety report" in "Information provided by the lead on behalf of the member(s)" when creating the dossier in IUCLID.
4. Use the information received from the lead registrant for generating their SDS.

2.2 The CSR is prepared by the lead registrant and submitted individually by every co-registrant

This scenario is relevant when in the joint submission there is no agreement on jointly submitting the CSR, but the lead registrant is nevertheless willing to prepare (a basis for) it (without taking the responsibility to submit it on behalf of all the members of the joint submission).

In this case, Sections 3-8 of the CSR are expected to be only submitted by the lead registrant, unless the member registrants opt out for some information. Therefore, the member registrants only need to provide information on Sections 1 (substance identity), 2 (manufacture and use) as well as the two exposure ones 9 and 10 on their CSRs.

If the member registrant agrees with the CSR prepared by the lead registrant, the workflow described in the previous scenario can be followed, with the only exception that member registrants attach the CSR to their IUCLID Section 13.1. and do not flag the "chemical safety report" as part of the "Information provided by the lead on behalf of the member(s)", when creating the dossier in IUCLID.

If instead, the member registrants need to apply some changes to the CSR, the following workflow may be followed.

In this scenario, the lead registrant could send an .i6z-file containing the Chesar input information[1] (including endpoint summaries for PBT assessment, physical and chemical properties, environmental fate, and toxicological information), as well as a chr3-file containing the related Chesar CSA export. By following this workflow, the member registrants will be able to start from a common basis and adapt the CSR according to their needs. The benefit of following this workflow is that each co-registrant will keep the possibility to align the uses in Chesar and IUCLID, if an update is needed.

Note that as a pre-requisite, the lead registrant should be willing to share their relevant IUCLID endpoint summaries to be imported in Chesar as the starting point for the assessment, to ensure data consistency between all the registrants.

2.2.1 Lead registrant workflow

1. Prepare the CSA in Chesar, that should **not** be flagged as joint in the CSA management tab in box 1.
2. Once the CSA is finalised, create a Chesar CSA export (chr3-file) (see Chapter 4 for more detailed information on this file).
3. Create an export from IUCLID containing the Chesar input information from the substance dataset (.i6z-file) (see Chapter 4 for more detailed information on this file). Note that the lead registrant should also share the information relevant for the core body of the SDS (phys chem, fate, hazard).

[1] The "Chesar input information" is a specific working context available in IUCLID, that displays only the sections containing the key information needed to proceed with the chemical safety assessment (CSA) in Chesar.

4. Send both previously exported files (in i6z and chr3 formats) to member registrants.
5. Export the uses from Chesar to IUCLID (see Chapter 4 for further information on export options). The "related assessment" field in IUCLID Section 3.5 for all these uses will be automatically marked as "use assessed in an own CSR".
6. In Chesar, generate the full CSR (in box 4). We suggest using the Chesar functionality to automatically create a record in IUCLID Section 13.1, while generating the CSR. This record will contain all necessary information, as described in Chapter 4.6 of this document.
7. Proceed with the finalisation of the registration dossier.

2.2.2 Member registrant workflow

1. Import the .i6z-file containing the Chesar input information from the lead registrant to their own IUCLID 6 database.[2]
2. Import the substance dataset in Chesar.
3. Import the Chesar CSA provided by the lead registrant in the CSA tab of the substance in Chesar. Make sure the CSA is **not** flagged as joint in CSA management in box 1. Adapt[3] the CSA, if necessary.
4. Export the uses from Chesar to IUCLID (as described in Chapter 4).
5. Generate the full CSR from Chesar box 4, flag "create a new record in IUCLID Section 13.1, prefill it with the relevant information and attach the CSR" and fill in part A information. Member registrants should also indicate in the "Further information on the attached export file/remarks" the note that Sections 3-8 of the CSR are provided by the lead registrant.
6. Chooses "Type of CSR" to be "Own CSR initially prepared jointly within the consortium" in IUCLID Section 13.1.
7. Proceed with the finalisation of the registration dossier.
8. Use the information received from the lead registrant as well as the exposure scenarios generated in box 5 of Chesar, for generating your own SDS.

2.2.3 Complex cases (the substance has multiple assessment entities)

Currently, Chesar does not support this workflow for substances containing assessment entities (AEs). AEs are a way of assessing substances that have multiple different compositions/forms with different hazard and/or fate properties.

More information on AEs in:
https://echa.europa.eu/documents/10162/1804633/manual_regis_and_ppord_en.pdf/891754cb-a6b6-4bb6-8538-52ccde74070e Annex 5.

[2] If the member registrant already has a IUCLID dataset of the substance, the member should copy the data (Chesar input information covering the relevant IUCLID endpoint summary in Sections 2.3, 4, 5, 6 and 7) from the lead registrant's substance dataset to their own original dataset and proceed with working with the original dataset.

[3] The information pertaining the qualitative assessment (i.e. justification of minimisation of release) are lost when importing the CSA file and need to be re-defined.

In Chesar, when assessing a substance in which AEs are defined, the assessor must create assessment entity groups (AEGs) in Chesar box 1 ("assessment entities and groups). These AEGs are lost when creating a CSA export in Chesar. The AEGs are maintained only when the assessed substance is exported as a whole (export from "substance management" in box 1).

If the lead registrant decides to share the Chesar substance file with all member registrants, the lead registrant needs to be aware that the member registrants will not be able to synchronise this Chesar substance with their corresponding IUCLID ones.

To have an own Chesar CSA, the following rather complex workaround can be performed: the member registrants should import their own substance dataset from IUCLID to Chesar, create their assessment entity group as suggested in the lead registrant CSR, import the Chesar CSA shared by the lead registrant, assign the assessment entity groups to each contributing scenario and regenerate the assessment using the information from the lead registrant CSR.

2.3 The CSR is prepared and submitted individually by every registrant

In this scenario, the member registrants do not share the information on the uses with the lead registrants. Each co-registrant must rely on the hazard and fate data shared by the lead registrant. As in the previous scenarios, Sections 3-8 of the CSR are expected to be only submitted by the lead registrant, unless the members opt out for some information. Therefore, the members only need to provide information on Sections 1 (substance identity), 2 (manufacture and use) as well as the two exposure ones 9 and 10 in their CSRs.

2.3.1 Lead registrant workflow

1. Prepare an own CSR in Chesar.
2. Create an export from IUCLID containing as a minimum the *Chesar input information* from the substance dataset (.i6z) (see Chapter 4 for more detailed information on this file). Note that the lead registrant should also share the information relevant for the core body of the SDS (phys chem, fate, hazard).
3. Send that .i6z file to member registrants.
4. Export the uses from Chesar to IUCLID (see Chapter 4 for further information on export options). The "related assessment" field in IUCLID Section 3.5 for all these uses will be automatically marked as "use assessed in an own CSR".
5. In Chesar, generate the full CSR (in box 4). We suggest using the Chesar functionality to automatically create a record in IUCLID Section 13.1, while generating the CSR. This record will contain all necessary information, as described in Chapter 4.6 of this document
6. Proceed with the finalisation of registration dossier

2.3.2 Member registrant workflow

1. Import the .i6z file from the lead registrant to their own IUCLID database[4] and import the dataset to Chesar.

[4] If the member registrant already has a IUCLID dataset of the substance, the member should copy the data (Sections 2.3, 4, 5, 6 and 7) from the lead's substance dataset to their own original dataset and proceed with working with the original dataset (for more information see Chapter 4.4).

2. Make sure the CSA is not flagged as joint in CSA management in box 1 in Chesar and complete the CSA with Chesar.
3. Export the uses from Chesar to IUCLID (see Chapter 4 for further information on export options).
4. Generate the CSR: "generate full CSR" in Chesar box 4, flag "create a new record in IUCLID Section 13.1 (as described in Chapter 4.6 of this document). The member registrant should also indicate in the "Further information on the attached export file / remarks" the note that the Sections 3-8 of the CSR are provided by the lead registrant.
5. Proceed with the finalisation of the registration dossier.
6. Use the information received from the lead registrant as well as the exposure scenarios generated in box 5 of Chesar, for generating your own SDS.

3. Supporting material

The following selection of supporting material may be helpful when preparing the (joint) CSR in accordance with REACH.

Useful links

- Webinars on CSR:
  - Getting your chemical safety assessment done: https://www.youtube.com/watch?v=o9MjoemTF0Q&feature=youtu.be
  - Completeness checks of chemical safety reports - practical advice: https://www.youtube.com/watch?v=b8ggw5_6sJk

- Joint submission web pages
  - Creating a new joint submission: https://echa.europa.eu/creating-a-new-joint-submission1
  - Data sharing: https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations

- Chesar 3
  - Chesar manuals and FAQ: https://chesar.echa.europa.eu/support

- IUCLID video tutorials:
  - IUCLID webinars: https://iuclid6.echa.europa.eu/webinars

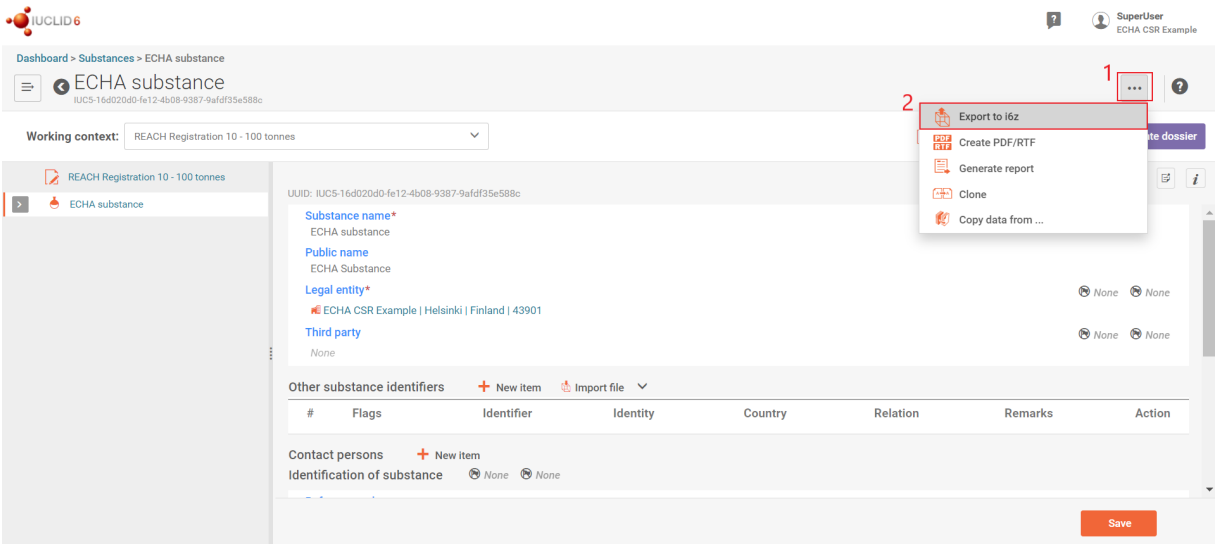
- Additional material that may be useful to consult
  - How to prepare registration and PPORD dossiers: https://echa.europa.eu/manuals
  - Technical completeness check: https://echa.europa.eu/technical-completeness-check
  - IUCLID 6, Completeness Check and regulatory processing: https://iuclid6.echa.europa.eu/documents/1387205/2774520/IUCLID6_Training_EN.pdf/bb5485a2-5953-479d-63f1-ef632249bf12
  - Guidance document on information requirements and Chemical safety assessment: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

4. IUCLID and Chesar step-by-step description

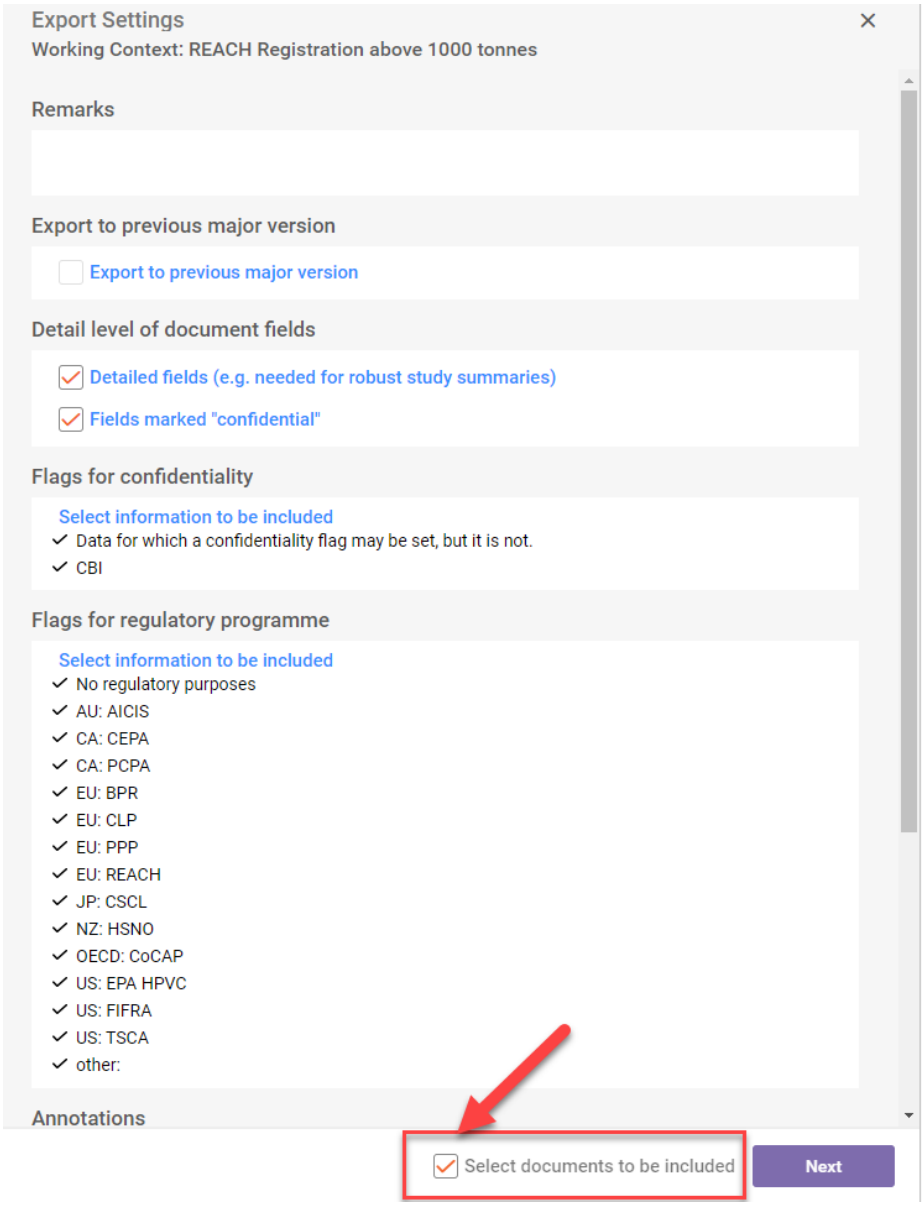
4.1 Creating an export from a IUCLID dataset containing only Section 3.5

These steps are useful when the lead and/or the member registrants need to share the information on use available in IUCLID.

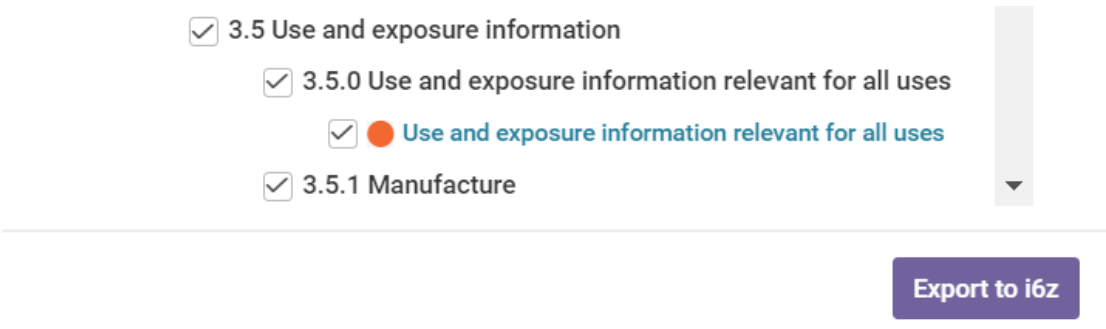
1. Click "…" in the upper right corner of the IUCLID user interface.
2. Choose "Export to i6z" and click "Next".



3. Filter the information you want to export by ticking "Select documents to be included" at the bottom of the pane that appears.



4. Click next.
5. In the list of endpoints suggested to be exported, unflag everything except 3.5 Use and exposure information.

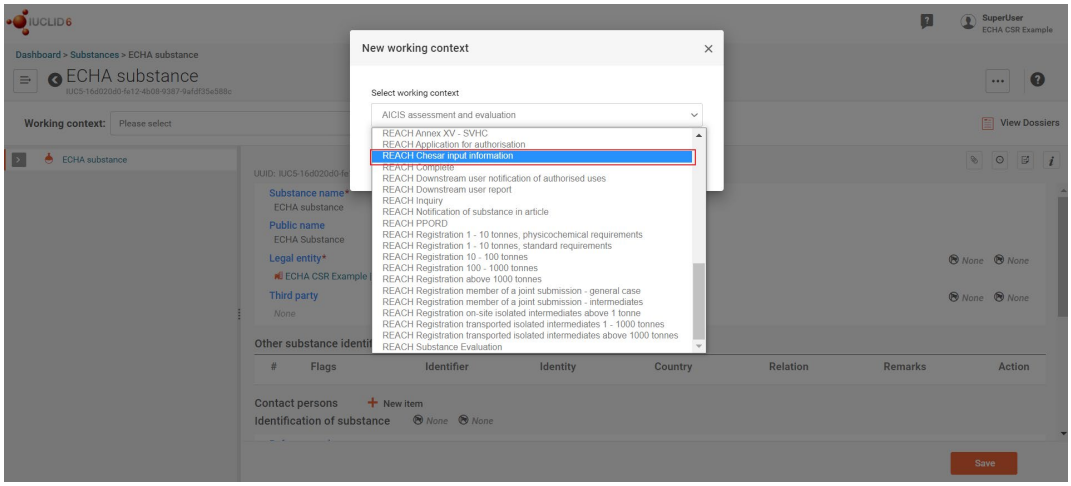


6. Click "Export to i6z" in the bottom right corner.

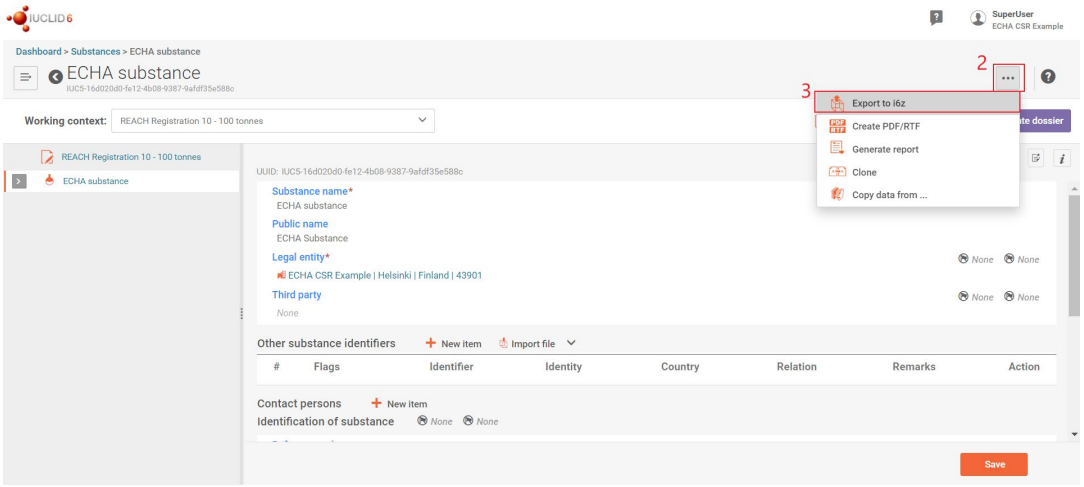
4.2 Creating an export from IUCLID containing the Chesar input information from the substance dataset

These steps support lead registrants to generate a IUCLID export file containing only the information needed to enable member registrants to run the assessment in Chesar (as described in Chapter 2.2.1.

1. Choose working context: "REACH Chesar input information".



2. Click "…" in the upper right corner of the IUCLID user interface.
3. Choose "Export to i6z".



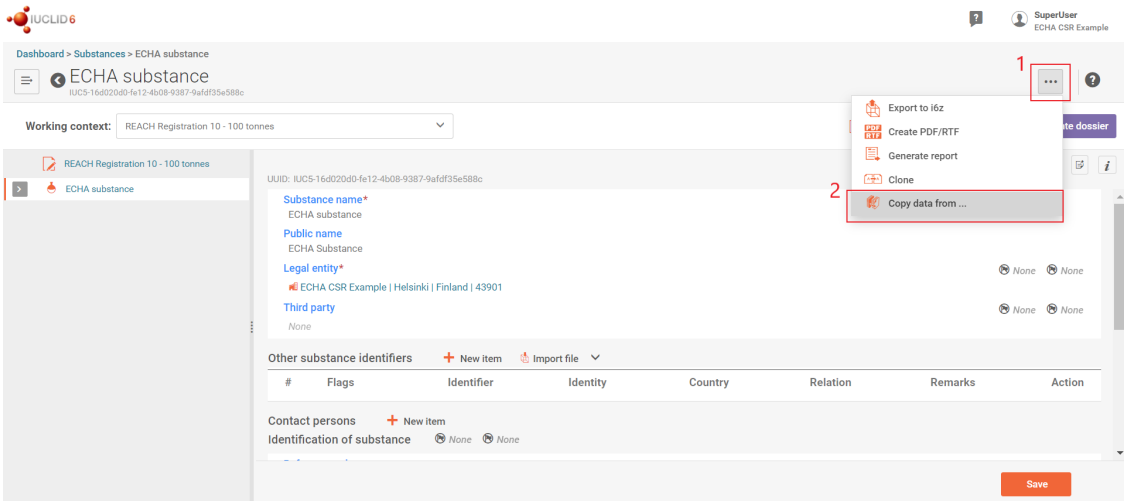
4. Click "Export to i6z" after choosing the desired settings.

4.3 Copying data between IUCLID datasets, e.g., from a lead to a member registrant IUCLID dataset

These steps are to be used when the lead registrant is sharing the dataset with the Chesar input information, and the member registrant already has their own dataset for the substance that needs to be registered.

1. Import the dataset into your own IUCLID instance. This will create a new substance.
2. Pick the substance dataset you wish to copy data to.
3. Click "…" in the upper right corner of the IUCLID user interface.

4. Choose "copy data from…".

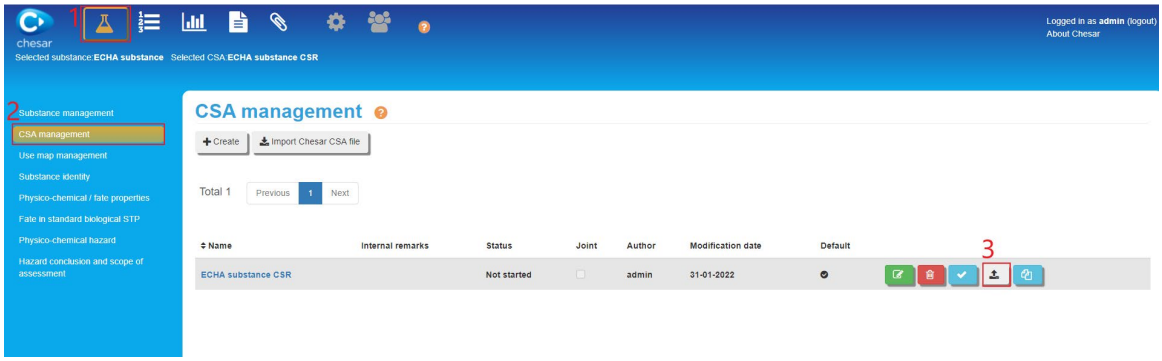


5. Choose the substance dataset where you wish to copy the data from.
6. Flag the data you want to copy (for example: "use and exposure information").
7. Make sure that only the desired data is flagged.
8. Click "copy" from the bottom right corner.

4.4 Creating a CSA export in Chesar

These steps support the lead registrant to share the initial assessment, to be sent to the member registrants, for them to adapt to their own uses, as indicated in Chapter 2.2.1

1. Go to box 1 in Chesar.
2. Choose "CSA management".
3. Click the export icon next to the CSA you want to export.



4.5 Exporting uses from Chesar to IUCLID

Consistency of use descriptions between IUCLID and the CSR is required by REACH and manually verified during the technical completeness check (TCC). Exporting uses from IUCLID to Chesar is not supported by the current version of these tools. Therefore, it is recommended to first describe the uses in Chesar, then finish the CSA and afterwards export the uses from Chesar to IUCLID.

This ensures consistency between the CSR and the registration dossier. If the registrant also has uses that do not need to be assessed (e.g. uses as intermediate in strictly controlled conditions registered under Articles 17 or 18 of REACH), these uses should be added in IUCLID after the other uses have been exported from Chesar to IUCLID. When reporting such uses in IUCLID, the "related assessment" field in IUCLID Section 3.5 should be changed to "use not assessed".

When exporting uses from Chesar to IUCLID (in box 4), a pop-up window gives three choices regarding "options of removal of Uses in IUCLID":

4.5.1 Update uses that have a corresponding use in Chesar and keep all other existing uses

"Corresponding uses" refers to uses previously exported from Chesar to IUCLID. If there is a pre-existing use in IUCLID that is not previously exported from Chesar, with the same use description as a use being exported from Chesar to IUCLID, a duplicate will be created.

By selecting this option:

- All previously exported uses from Chesar will be updated in IUCLID Section 3.5.
- Any new use reported in Chesar will be transferred to IUCLID Section 3.5.
- Any previously existing use in IUCLID will be maintained regardless of the option selected in the "related assessment" field.

This option should be selected carefully as it may create inconsistency in your IUCLID Section 3.5 (for example if you deleted some uses in Chesar).

4.5.2 Remove all uses from IUCLID identified as "use assessed in an own [joint] CSR" in the field "Related assessment" and which have not been previously exported from Chesar

This option should be selected when you have updated your Chesar uses for a specific CSA (already exported in IUCLID) and you also have some other additional uses in IUCLID Section 3.5 (for example, uses that do not need to be assessed, or both joint and own uses).

By selecting this option:

- All Chesar uses will be transferred (or updated if there is already existing information) to IUCLID Section 3.5.
- Any previously existing use in IUCLID for which the "related assessment" field is set differently from your CSA will be maintained (i.e. if you are exporting uses belonging to an "own" CSA, then all IUCLID uses flagged as "joint" or "use not to be assessed" or without any selection in the "related assessment field" will be maintained in IUCLID. We strongly encourage users to always select a picklist entry in this field to prevent inconsistency in the life cycle).

If the CSA created in Chesar has the flag "joint", then Chesar will reformulate the second option as "Remove all uses from IUCLID identified as 'use assessed in a joint CSR'" in the field "Related assessment" and which have not been previously exported from Chesar" (i.e. if you are exporting uses belonging to a "joint" CSA, then all IUCLID uses flagged as "own" or "use not to be assessed" or without any selection in the "related assessment field" will be maintained in IUCLID).

This option may be useful when updating the CSA/CSR. It is particularly important if there are

uses that have different type of "related assessment" values (for example joint and own uses but also possibly uses not assessed).

4.5.3 Remove all existing uses

This option should be selected when you want to ensure that the uses listed in Chesar are exactly the same ones reported in IUCLID Section 3.5 and in Section 2 of the CSR.

By selecting this option:

- All uses reported in Chesar will be transferred (or updated if there is already an existing use previously exported from Chesar to IUCLID) to IUCLID Section 3.5.
- Any previously existing use in IUCLID (that was not exported from Chesar) will be removed regardless of the option selected in the "related assessment" field.

This option may be useful when exporting uses from Chesar to IUCLID for the first to "clean" IUCLID Section 3.5. Nevertheless, take care not to delete uses that for example are not expected to be assessed.

It is worth noting, when updating uses that have already been previously exported from Chesar to IUCLID by exporting the uses again, if the name of the use has been changed in Chesar, the use name in the IUCLID Section 3.5 document changes, but the name in the IUCLID tree view does not automatically change. That name should be manually changed to avoid confusion.

4.6 Generate a full CSR from Chesar

A full CSR consists of:

- Part A in which a summary of the risk management measures is indicated. Note that this section is obligatory in all CSRs.
- Part B Sections 1-8 (information coming from IUCLID).
- Part B Sections 9-10 (information coming from Chesar).

To generate a full CSR from Chesar, IUCLID needs to be running and connected to it, and the uses should have already been exported to IUCLID.

From Chesar, you can directly create a complete record in Section 13.1 of IUCLID.
In that record, the following IUCLID fields will be pre-filled as follows:

- Type of CSR: Own CSR (own uses) or Joint CSR (joint uses) depending on the selection indicated in your Chesar CSA.
- CSR contains: Part A, Part B Sections 1 to 8 and Part B Sections 9 and 10.
- Chemical safety assessment/report tool used: Chesar.
- Chemical safety report (CSR): the complete CSR is attached in PDF or RTF format (depending on the selection indicated by the assessor in the Chesar dialogue).

Moreover, Chesar can also attach the Chesar export file (in .chr3 file format).

When Chesar generates the full CSR, a PDF or RTF copy of it will be also downloaded on your computer, so that you can check its content, save it and share it with the member registrants.

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