

How to prepare an application for authorisation



Changes to this document

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1.0	First version

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1. Introduction

1.1. Objective

The purpose of this manual is to assist in the preparation of an application for authorisation and its submission to the European Chemicals Agency (ECHA). More particularly it outlines the IUCLID sections and fields to be filled-in in order to prepare an application according to Title VII of REACH.

It should be noted that the aim of this manual is to help the applicants to identify which of the numerous IUCLID fields are of prime importance for a successful submission of an application: all the "mandatory" sections (see chapter 7. How to create a Substance dataset) need to be filled-in to enable ECHA to process the application. The generated IUCLID application for authorisation dossier can then be submitted to ECHA through REACH-IT.

Instructions in this manual cover applications made by one or several persons (legal entities), applying for one or several uses for one or several substances.

For more details on the authorisation process, you can consult:

- the section on "How to apply for authorisation" available at: <http://echa.europa.eu/web/guest/applying-for-authorisation>
- the Q&As available at: <http://echa.europa.eu/web/guest/support/faqs>
- the *Guidance on preparation of an application for authorisation* at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>
- the *Guidance on Socio-Economic Analysis-Authorisation* at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>

This manual assumes that IUCLID has been installed and you have a valid ECHA account. More information about the different functionalities in IUCLID and how to use those functionalities can be found in the help system built-in IUCLID (see chapter 1.5 *Functionalities of IUCLID*). The manual also assumes that you have all relevant information available.

1.2. Overview of the preparation and the submission of a dossier

A IUCLID dossier is non-editable snapshot file of a substance dataset, containing the information to be submitted to ECHA. The steps below indicate the approach for the preparation of an application for authorisation dossier in IUCLID:

- Step 1.** Sign-up in REACH-IT and create the *Legal entity* for the applicant (see Chapter 2)
- Step 2.** Create in IUCLID the *reference substances* related to the Annex XIV substance (see Chapter 6)
- Step 3.** Create in IUCLID the *substance dataset* for the Annex XIV substance (see Chapter 7)
- Step 4.** Enter information in the substance dataset on the Annex XIV substance (see Chapter 7)
- Step 5.** Create an application for authorisation dossier in IUCLID (see Chapter 9)
- Step 6.** Export the application for authorisation dossier from IUCLID (see Chapter 10)

Step 7. Submit the application for authorisation dossier to ECHA via *REACH-IT* (see Chapter 11)

1.3. Information required for an application for authorisation

The following information is required in an application for authorisation dossier:

- identity of the applicant(s), i.e. name, contact details (REACH-IT account, web-form);
- contact person of the applicant(s) (REACH-IT account, web-form);
- identity and composition of the substance(s) as referred to in section 2 of Annex VI to REACH (web-form, IUCLID – sections 1.1, 1.2 and 1.3);
- the use(s) for which the applicant(s) applies for authorisation (web-form, IUCLID – sections 3.5 and 3.10);
- general information on the exposure scenario(s) covering the use(s) for which the applicant(s) applies for authorisation (section 3.5);
- a chemical safety report (CSR) in accordance with Annex I covering the risks to human health and the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV (IUCLID – section 13). Alternatively, reference to a registration dossier which includes such a CSR can be provided (IUCLID – section 1.3);
- Public versions of the exposure scenario(s) (sections 9 and 10 of the CSR) covering the use(s) for which the applicant(s) applies for authorisation (if the version provided in the CSR is deemed confidential) (IUCLID – section 13);
- an analysis of the alternatives, including also a public version (if the complete version provided is deemed confidential) (IUCLID – section 3.10);
- a substitution plan if relevant, including also a public summary (IUCLID – section 3.10);
- a socio-economic analysis if relevant, including also a public version (if the complete version provided is deemed confidential) (IUCLID – section 3.10);
- a summary of risk management measures (RMMs) and operational conditions (OCs) (public document) (IUCLID - section 13)
- a justification for not considering certain risks if relevant (IUCLID – section 3.10);
- reference(s) to other applications or previous authorisations if relevant (IUCLID – sections 1.3 and 3.10);
- application form for a joint application (including mapping of uses) (IUCLID – section 13);
- name and address of the non-EU company represented by an applicant (relevant for Only Representatives) (IUCLID - section 1.7);
- argumentation for substance grouping (access category object through IUCLID – section 0.2).

The following information is not specifically required. You can nevertheless provide it on a voluntary basis in the relevant IUCLID sections (indicated in brackets):

- analytical information for the substance (IUCLID – section 1.4);
- information on the classification and labelling (IUCLID – section 2.1);
- information on mixtures containing the substance (IUCLID –section 3.4);
- endpoints information (IUCLID – section 4 to 7)
- information on the estimated quantities (IUCLID – section 3.2);
- information on use sites (IUCLID – section 3.3);
- information on the uses advised against (IUCLID – section 3.6);
- information on environmental assessment from aggregated sources (IUCLID – section 3.7);

- information on the recipients (IUCLID – section 1.8);
- information on analytical methods (IUCLID – section 8);
- information on the literature search (IUCLID – section 12).

To correctly file an application for authorisation, it is important to firstly understand concepts such as of legal entity, substance, reference substance, substance dataset, and dossier in IUCLID. These concepts, as well as the general functionalities of IUCLID 6 are explained in the first chapters of this manual. If you are already a proficient user of IUCLID and know how to create a legal entity, reference substances and substance dataset, we advise you to go directly to chapter 7 of this manual, where you will find information on how to fill-in your application for authorisation dossier.

1.4. Checks performed by ECHA on the submitted dossiers

All dossiers submitted to ECHA undergo initial technical and administrative checks in order to ensure that they can be handled properly and that the subsequent required regulatory processes can be successfully carried out. Such checks are called business rules (BR).

A dossier can be accepted for processing only if all of the relevant business rules, such as format verification and availability of administrative information are satisfied.

For more information on the business rules check refer to the Annex: *Overview of the business rules checks performed by ECHA on the submitted dossiers*.

Note that passing the business rules provides confirmation only that the dossier can be accepted for processing, not that the dossier is complete.

1.4.1. The Validation assistant

The *Validation assistant* (VA) plugin has been developed to enable you to perform some checks on the dossier before you submit it to ECHA via REACH-IT.

Therefore, before the submission, we strongly advise you to use the *Validation assistant* plugin in two steps:

- To check your dataset (before the dossier is created) to be able to correct any failures reported at this level.
- To check the final dossier and address any issues identified in this step.

Using the plugin in both steps is vital for you to minimise any unnecessary failures and potential rejection of your submission.

For instructions on how to run the *Validation assistant*, refer to the help system of IUCLID.

The validation assistant will only check your dossier for some, but not all the business rules applicable for applications for authorisation.

1.5. The functionalities of IUCLID

The functionalities of IUCLID are described in detail in the help that is built in to the IUCLID application. To view the help, press the F1 key anywhere inside the application. The help system will try to display the most relevant part of the help content. From there it is possible to navigate to the specific help required. For example, if the export wizard of the application is open, pressing F1 should open the help content at a description of the Export


functionality. As an alternative to pressing F1, there are links to help in the application interface, wherever there is a help icon in the form of a question mark.

2. Legal entity

Submissions to ECHA are done by *Legal entities* which have to be defined including contact details prior to submission. The contact details of the company are stored as a *Legal Entity Object (LEO)*. You can create a LEO both in IUCLID and in the *ECHA accounts* available at <http://echa.europa.eu/support/helpdesks/echa-helpdesk/echa-accounts>.

Note that ECHA will use only the contact details of the legal entity that you have registered in the ECHA accounts or in REACH-IT.

You have already created one legal entity when you installed IUCLID. You can add more legal

entities by right clicking on *Legal entity*  on the IUCLID home page. However, ECHA will not enforce the consistency between the IUCLID legal entity and the ECHA accounts legal entity.

Please note that by the default settings the legal entity is not included in the dossier. If you wish to include the legal entity in your dossier, you can change the default settings during the dossier creation in the dossier creation wizard (see chapter *How to create a Dossier*).

If you include a legal entity in the dossier which will be submitted to ECHA it may be beneficial to check if the legal entities in IUCLID and REACH-IT are the same. For further information on how to create a Legal Entity Object (LEO) and how to synchronise it between IUCLID and REACH-IT, refer to the next chapter.

2.1. How to update and synchronise the LEO information

To register your legal entity you should sign-up into the *ECHA accounts* where you can enter and administer your legal entity information.

When you create a LEO a numeric identifier called Universal Unique Identifier (UUID) is generated. Example of a legal entity UUID: *IUC5-a620a92d-32c6-426a-b6ee-fc338cde0932*.

The UUID is different for each LEO, even within the same company in case the company has several LEOs.

You can synchronise the legal entity between IUCLID and REACH-IT by exporting your LEO from ECHA accounts or REACH-IT. Then you can import the file to your local IUCLID installation. It may be beneficial that the UUID is identical between all the applications where the company identity appears (IUCLID, REACH-IT, any web forms submitted to ECHA). Alternatively, if you have not yet created your ECHA account, you may export the LEO from your IUCLID installation and import the file to ECHA accounts when you create an account. Note that a LEO can be imported to ECHA accounts only while you create an account, and not to an existing ECHA account.

To compare the UUIDs between the applications, you can find them inside each application by following the below paths:

- IUCLID: Home page > *Legal entity* > double click your legal entity. The UUID of the company is displayed in the *Information Panel* at the bottom of the IUCLID window.
- ECHA Accounts: Legal Entity tab > General details > Legal Entity UUID

- REACH-IT: Menu > *Company information* > *General information* > *UUID*




For more information on the ECHA account management refer to the ECHA accounts manual available at <http://echa.europa.eu/support/helpdesks/echa-helpdesk/echa-accounts>.

3. Legal entity site

A *Legal entity site* is an entry where you can indicate the site where manufacture or own use of your substance takes place. This information includes the name of the site, the address and other contact details of the site, and the possibility to include the identifiers of the site under other Company/Organisation IT systems. The *Legal entity site* belongs to only one *Legal entity owner*.

Note that it is not possible to create a site without linking it to a legal entity, but it is possible to modify the link between a site and its legal entity owner by selecting another legal entity from your inventory. More than one legal entity site can be associated with the same legal entity.

3.1. Creating a Legal entity site



- Step 1.** To create a new site right-click on *Legal entity site*  on the home page and select *New*.
- Step 2.** Provide a name for the site and assign it to the *Legal entity owner* by clicking on the  button.
- Step 3.** Fill as many fields as possible under the *General information and Contact address*. The minimum data required is the *Country* where the site is located.
- Step 4.** To save the legal entity site information click on  from the main menu.

4. Contact

In the *Contacts inventory* you can insert the contact details of the relevant competent persons, such as person responsible for the safety data sheet (SDS), toxicologist, etc, which can be attached to the IUCLID dossier. This person may be contacted to provide assistance or ask about the information submitted.

Information on the contact person responsible for your submission must be specified and managed in REACH-IT.

4.1. Creating a contact

- Step 1.** To create a *new contact* right-click on the *Contacts*  on the home page and select *New*.
- Step 2.** Complete as many fields as possible under the *General information*.
- Step 3.** To save the contact information click on  from the main menu.

5. Chemical inventories

The *Chemical inventories* contains chemical identifiers, which serve as the basis for defining the *reference substances*. The term *inventory* is used to compile all the different chemical inventories that can be available in IUCLID. Currently, the **EC Inventory** is the only inventory used in IUCLID.

The EC Inventory is a combination of three individual inventories:

- **EINECS** (European Inventory of Existing Commercial Chemical Substances) includes substances that were deemed to be on the European Community market between 1st January 1971 and 18th September 1981.
- **ELINCS** (European List of Notified Chemical Substances) includes substances notified under Directive 67/548/EEC, the Dangerous Substances Directive Notification of New Substances (NONS) and placed on the market after 18th September 1981.
- **NLP-list** (No-Longer Polymers list) includes substances that have been on the European Community market between 18th September 1981 and 31st October 1993, and were considered to be polymers under the reporting rules for EINECS but were no longer considered to be polymers according to the 7th amendment of Dir 67/548/EEC.

The entries in the EC Inventory consist of a chemical name and a number (EC name and EC number), a CAS number¹ (if available), molecular formula (if available) and description (for certain types of substances).

6. Reference substance

A *Reference substance* enables you to store identification information on a given substance or a given constituent of a substance, such as chemical names (EC name, CAS name, IUPAC name, synonyms, etc.), identity codes (EC number, CAS number), molecular and structural information.

The *Reference substance inventory* gives the possibility to use the same information for the same chemical identity avoiding to re-type it and to ensure that the data is centrally managed and updated. The *Reference substance inventory* is directly maintained by you, in your local installation. Each *reference substance* can be linked to an unlimited number of *substance* or *mixture/product* datasets. For updating the information in a *reference substance*, you can open the *Reference substance inventory*, search for the relevant *reference substance* and update it. The modifications will impact every single dataset linked to that *reference substance*.

To extend the number of entries in your inventory, you can search, download and import available reference substances from the IUCLID website to your local installation. These pre-defined reference substances have been prepared to improve data quality and minimise data entry.

6.1. Creating a reference substance

If you do not find a reference substance in the *Reference substance* inventory, you can create a new reference substance.

¹ In the case of substances listed in the EC inventory with an EC number starting with 4, there may be no CAS number published even though a CAS number may exist for that substance. This is because under the notification scheme for new substances which existed under the previous legislation the CAS number could be claimed confidential and therefore was not published.

There are two types of information that can be reported in a *reference substance*:

1. Information **specific** to the *reference substance*: such information exactly corresponds to the substance/constituent(s) covered by that reference substance;
2. Information **related** to the *reference substance*: this information does not accurately correspond to the substance/constituent(s) covered by that reference substance for any of the following reasons:
 - The information is generic as it also covers other substances/constituents;
 - The information only covers some of the constituents of a reference substance for a substance or a group of constituents;
 - The information refers to a similar constituent/substance;
 - The information is not the latest available information to identify the substance/constituent(s)

Related information should be reported under the *Identifiers of related substances* as it may create an ambiguity on the identity of substance or constituent(s) which a reference substance corresponds to.

To create a reference substance:



- Step 1.** Right-click on the *Reference substance* on the home page and select *New*.
- Step 2.** Enter the name of the reference substance.
- Step 3.** If the **reference substance is listed in the EC inventory** you can assign that entry by clicking the *Add* button.
- Step 4.** If your **reference substance is not listed in the EC inventory**, select a justification from the picklist proposed under the *No inventory information available*.
- Step 5.** Complete as far as possible the remaining fields of the reference substance.

The following information, if available and/or applicable, should be submitted for all the known constituents and additives:

- *EC Inventory* information,
- *CAS number* and *CAS name*,
- *IUPAC name*,
- *Description* (Specify any additional information relevant for the description of the reference substance in this field. This is important especially when the reference substance does not correspond to a well-defined chemical substance. Attached files can be added if necessary.),
- *Synonyms*,
- *Identifiers of related substances*,
- *Molecular formula* (if a molecular formula cannot be derived from the reference substance, a justification should be indicated in the *Remarks* field at the bottom of the section);
- *Molecular weight* range,
- *SMILES notation*,
- *InChI*,
- Upload an image file with the *Structural formula*.

Step 6. To save the reference substance click on  from the main menu.




7. How to create a Substance dataset

This chapter outlines which information you have to provide through different sections of IUCLID, which depends on the type of submission that you wish to do via a IUCLID dossier.

When entering your data you can use the help system of IUCLID which is built inside the application. To view the help, press the F1 key anywhere inside the application and the most relevant information will be displayed in the help window.

To create a IUCLID **dossier**, you first need to create a substance **dataset**. A substance dataset is a repository of administrative and scientific data for a substance. The information in the dataset can be modified: you can add, remove or change information in the dataset. **The dataset is used as basis for the dossier.** The dossier is a snapshot of the dataset at a certain moment; the information in the dossier cannot be modified.

To create a dataset:

- Step 1.** Right-click on the *Substance*  on the IUCLID home page and then select *New*.
- Step 2.** Fill in the field *Substance name*. Especially if your IUCLID installation contains several datasets, ensure to enter a name that you can easily use to distinguish the substance.
- Step 3.** Assign an existing *legal entity* to the dataset by clicking on the  button. A new window opens where you can search for legal entities within your IUCLID installation. Enter the search criteria, select the appropriate legal entity from the list, and assign it to the substance dataset.
- Step 4.** Save the information by clicking the  icon in the main menu.

For more information on how to fill in the fields in this view, see section 1.1 *Identification*.

To complete a dataset:


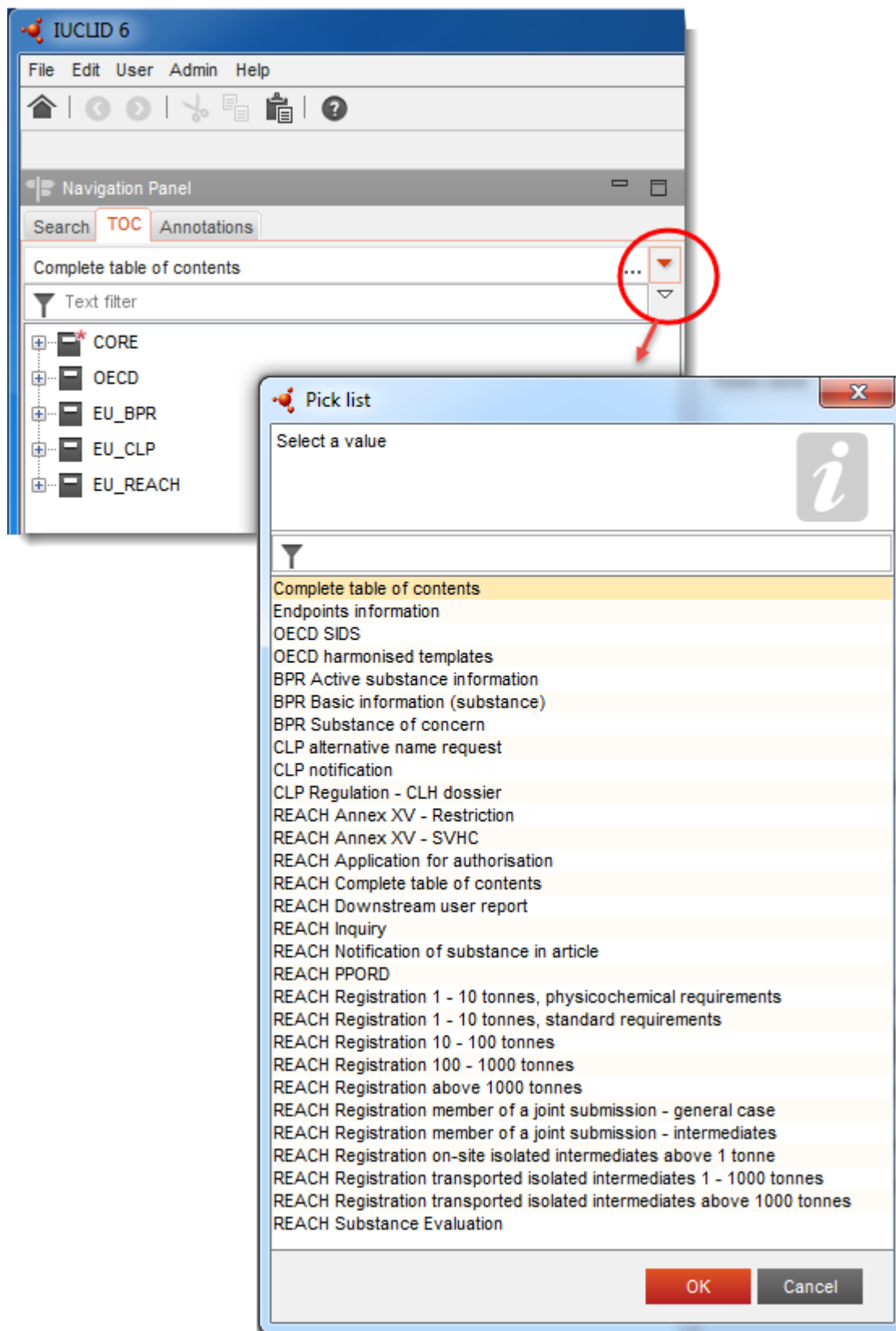
- Step 1.** Once your substance dataset is created it is displayed in the navigation panel on the left part of the screen.
- Step 2.** To open your dataset double-click or right-click and select *Open*.
- Step 3.** When the dataset is open the *Table of contents* (TOC) tab is displayed in the navigation part of the screen.
- Step 4.** To view the table of contents that is relevant for the type of dossier that you are preparing, click on the filled downward arrow () in the TOC tab.
- Step 5.** A list of different submission types appears. Select the specific type of submission from the list.

Figure 1: An example of selecting the template from the picklist



Step 6. The sections relevant for the submission type are now displayed. Sections including mandatory information to complete are marked with the asterisk (*). Note that if you are creating a dataset but do not yet know the exact REACH dossier type that will be prepared, you can select the option *REACH Complete table of contents*. This will display the table of contents containing all sections that are relevant under the REACH Regulation.

Once you have created a dataset for your substance, you can enter data on the substance in this dataset. The following chapters describe what data should be entered into each section of IUCLID for the specific type of submission that this manual refers to. The sections are shown with their name and the numbering used with the relevant IUCLID table of contents view.

When filling in the different parts of a dataset it is important, that:

- when you create many rows in a table, you must fill in the relevant information in each row,
- when *other* is selected in a picklist the adjacent text field marked with 'Other' must be completed,
- when a field is associated with a unit, this must be filled in.

The relevant submission type for an application for authorisation is **REACH Application for authorisation**.

The IUCLID sections that should be completed as a minimum for authorisation applications to be processed are sections 1.1, 1.2, 1.3, 3.5, 3.10, and 13. The details of the information required to complete each of these sections is explained later in this manual (chapter 7).

7.1. Copy/update from a registered substance dataset

A substance dataset already submitted for registration may contain information also relevant for authorisation. Thus, the applicant may take advantage to copy an existing registration substance dataset to a newly created authorisation substance dataset. For instance, IUCLID sections 1.1 Identification, 1.2 Composition, 3.5 Identified uses, and 13 Assessments reports, might benefit to be automatically imported from an existing registration substance dataset.





The applicant may then proceed to the appropriate refinement of information specifically related to authorisation (e.g. it may occur that not all uses identified and described in a registration dataset are relevant for authorisation purposes).

Further instructions on how to create a copy of a substance dataset can be found in the help system of IUCLID.

7.2. Multi-substances dossier - Category approach

Applications may be submitted for one or several substances that meet the definition of a group of substances in section 1.5 of Annex XI of REACH.

The steps that need to be taken in IUCLID for preparing a dossier for several substances are the following:

- Step 1.** For each substance belonging to the group, create a separate substance dataset, in which all required data are to be entered as for any other non-grouped substance, i.e. IUCLID sections 1.1, 1.2, 1.3, 3.5, 3.10, and 13.
- Step 2.** For applications for several substances, section 3.10 allows to indicate which uses apply for which substance in the application. For instance, if a use applies to all substances it shall be listed in sections 3.10 of all substance datasets to be assigned to the category; if a use applies only to one (or some) of the substances, it shall be listed only in section 3.10 of the relevant substance dataset(s). See chapter 7.6.7 of this manual.
- Step 3.** Create a category in IUCLID: Right-click on the *Category*  on the IUCLID home page and then select *New*. Fill in the field *Category name*. Assign an existing *Legal entity* to the dataset by clicking on the  button. Under *Justifications and discussions* fill in the field *Category rationale*.
- Step 4.** Assign to the category the substance datasets you created in steps 1-2 above: Under *Category members* click  *Add...* and then search, select, and click *Assign* for each of the relevant substance datasets. And save the information by clicking the  icon in the main menu.
- Step 5.** When you create a dossier, you can do this from any of the substance datasets you created in step 1 above. While doing this, in the first step of the dossier creation wizard under the *Substance* tab select *EU REACH: REACH Application for authorisation* and under the *Use related categories tab* select *Yes*. Then the dossier will incorporate all the substance datasets assigned to the category. In case the substance belongs to several categories, choose instead *Select category(ies)* and select the appropriate category from the list. Then continue the dossier creation process as described in chapter 7 of this manual.

For more detailed instructions on how to create a dossier based on a REACH category approach, please refer to the help system of IUCLID.

When deciding whether or not to submit an application for a group of substances, a key consideration is maintaining clarity and transparency in the application. For further guidelines on the grouping of substances, please refer to the *Guidance on the preparation of an application for authorisation*, Annex 1 *Considerations for grouping of substances* at:

<http://echa.europa.eu/guidance-documents/guidance-on-reach> and to the ECHA website at <http://echa.europa.eu/web/guest/applying-for-authorisation>.

Due to the possible complexity and technical issues of such group of substances submissions, ECHA recommends that you group substances only in the most favourable cases where all substances of the group have the same uses. In more complex cases, it may be preferable to submit separate applications for each substance of the group.

7.3. Multi-applicants dataset – Joint application

An application for authorisation can be submitted by one applicant or a group of applicants (i.e. joint application). When deciding whether or not to submit an application for a group of applicants, a key consideration is maintaining clarity and transparency through the whole application. For further guidelines on joint applications please refer to the *Guidance on the preparation of an application for authorisation* at <http://echa.europa.eu/guidance-documents/guidance-on-reach> and to the ECHA website at <http://echa.europa.eu/web/guest/applying-for-authorisation>.

Due to the possible complexity and technical issues of joint applications, ECHA strongly recommends that you develop and submit a joint application only when all co-applicants of the group have found an acceptable way to share all information provided in the application. In complex cases, it may be preferable for each co-applicant to submit their own application separately.

ECHA will treat a joint application as a whole and has no possibility to make any special arrangements to accommodate confidentiality issues between joint applicants. Therefore, during processing and opinion making for an application, confidential information is likely to be referred to within the group of joint applicants; note, for instance, that copies of ECHA's communications in REACH-IT are sent to all applicants of a joint application.

The dossier including a substance dataset of a joint application shall be submitted to ECHA by one legal entity herein called "submitting applicant". Chapter 8 of this manual further describes what type of information the submitting applicant shall provide in addition to the substance dataset. Important information to be provided is the list of applicants and the mapping of the "uses applied for". Such a mapping is aimed at properly identifying which applicant applies for which use(s) and for which substance(s). For providing this information, a specific form needs to be attached in section 13 of the IUCLID dossier. This form ("application form for a joint application") is generated by using the relevant web-form, and needs to be sent also to the co-applicants, for them to confirm their participation in the joint application. (see chapter 8 for further details).

7.4. Section 1 General information

In section 1, *General information*, enter some of the information requested on substance identity and identity of the applicant(s). Sections 1.4, 1.5, and 1.8 are optional. Section 1.7 is mandatory only if some of the applicants is an Only Representative.

When filling in section 1, keep in mind that

- i. The identity of the substance shall be consistent with / covered by the one described in the corresponding Annex XIV entry available at: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>
- ii. The *Public name* field is normally not relevant, as the Annex XIV entry corresponding to the substance applied for cannot be considered confidential.
- iii. It is not possible to appoint a *Third party representative* for an application for authorisation.
- iv. For a joint application, the roles of each applicant in the supply chain (*Manufacturer, Importer, Downstream user, Only Representative*) must be indicated when creating the application form (see chapter 8).

7.4.1. Section 1.1 Identification


Section 1.1 contains the identification of the substance, role in the supply chain and the type of (reference) substance.

To complete this section, follow the steps:

Step 1. In the *Substance name* field type a name for the substance which you are preparing the dossier for.

Step 2. If you have any confidentiality concerns about the substance name, you need to fill in the *Public name field*. In this field you have to indicate a generic name suitable for publication, which appropriately describes the substance.

More information on how to derive a *public name* for a substance for use under the REACH Regulation, you can find at <http://echa.europa.eu/manuals>.

Step 3. Assign a *Legal entity* to your substance dataset by clicking on the  button (see chapter *Legal entity*).

Step 4. For REACH registration, Inquiry and PPORD dossiers you can indicate a *Third party representative*.

Information on the *Third party representative* for your submission must be specified and managed in REACH-IT prior to the submission. For more information on *Third party representatives*, please refer to the *Guidance on data sharing* available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>

Role in the supply chain:

Step 5. Select at least one checkbox in this section according to your role in the supply chain with regards to this substance.

Identification of substance:

Step 6. Click the  button to assign a *reference substance* to your substance dataset.

Step 7. A query dialog appears. Search for your reference substance. Click *Assign*.

If you cannot find your reference substance because it has not been created yet, click *New* and create it (see chapter *Reference substance*).

The information to be reported in your reference substance depends on the substance type:

- **Mono-constituent substances:**

A **mono-constituent substance** is a **well-defined substance** for which one constituent is present at a concentration of at least 80 % (w/w). This constituent is the main constituent of the substance. The substance is named according to the chemical name of that main constituent.

If your substance is a **mono-constituent** substance, assign the *reference substance*² corresponding to the main constituent in section 1.1.

- **Multi-constituent substances:**

A **multi-constituent substance** is a **well-defined** substance for which more than one constituent is present at a concentration between 10 % and 80 % (w/w). These

² Note that for the reference substance: *Molecular formula*, *Molecular weight range* and *Structural formula* must be provided. In addition, the *SMILES notation* should also be provided if available.

constituents are the main constituents of the substance. A multi-constituent substance is normally named as a *reaction mass* of the main constituents.³

If your substance is a **multi-constituent** substance, assign the *reference substance*⁴ corresponding to the reaction mass of the main constituents of your substance in section 1.1.

- **UVCB substances:**

UVCB substances (i.e. substances of Unknown or Variable composition, Complex reaction products or Biological materials) are substances that cannot be sufficiently identified by their chemical composition.

If your substance is a **UVCB** substance, assign a *reference substance*⁵ corresponding to the UVCB substance in section 1.1.

Type of substance:

Step 8. Select the appropriate *Type of substance* from the picklist. For submissions under REACH, you can only select between mono-constituent substance, multi-constituent substance and UVCB (the options *polymer* and *other:* are not relevant).

We also recommend you to read the *Guidance for identification and naming of substances under REACH and CLP* available at <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

Step 9. Select the *Origin*, e.g. organic or inorganic, from the picklist.

Step 10. If relevant, you can include additional identifiers for your substance under *Other identifiers*. Such identifiers may include Trade names of the substance, identifiers by which the substance was previously known but have later been replaced/refined, or identifiers which are used to identify the substance under other regulatory schemes. Chemical (scientific) synonyms should not be listed here, but should be indicated in the reference substance information.

Step 11. You can add information of the contact person(s) for this substance from the previously defined contacts (see chapter *Contact*).

Step 12. To save the information click  from the main menu.

Annex XIV can contain entries for which it might not be straightforward how to fill in IUCLID section 1.1, e.g. entries specifying more than one EC numbers. Specific (case-by-case) instructions regarding such entries can be found at the *Questions & Answers* section of ECHA's website, available at: <http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/authorisation> (see sub-section *Applications for Authorisation - Technical instructions for specific Annex XIV entries*)

³ Certain multi-constituent substances corresponding to reaction masses of isomers may sometimes be more conveniently named using a chemical name where the isomeric form is not specified rather than as a "reaction mass".

⁴ Note that the *Molecular formula*, *Molecular weight range* and *Structural formula* of the reference substance must be provided or a justification for not providing this information must be given in the *Remarks* field. In addition, the *SMILES notation* should also be provided if available.

⁵ Note that the *Molecular formula*, *Molecular weight range* and *Structural formula* of the reference substance must be provided or a justification for not providing this information must be given in the *Remarks* field. In addition, the *SMILES notation* should also be provided if available.

7.4.2. Section 1.2 Composition

Section 1.2 is used for describing the identity of your substance at a compositional level. In this section, you will report the identity and concentration of the constituents of the composition, including any impurities and additives. The state and form of your composition(s) is reported in this section.

You are advised to ensure that the information included in IUCLID section 1.1 and section 1.2 is sufficient to clearly report your substance identity and is consistent between both sections. In particular, this information reported may not be so generic that it would describe more than one substance.

Each substance dataset must contain at least one composition record which refers to the composition manufactured, imported or used by the registrant/notifier/applicant. Depending on the type of substance and dossier to be prepared, it may be necessary to report more than one composition. This is in particular the case where compositional differences affect the hazard profile and classification of the substance.

Each composition is reported as a record in IUCLID. To create a new record:

- Step 1.** Right-click on the *1.2. Composition* in the *TOC* from the navigation panel on the left part of the screen.
- Step 2.** From the picklist select *New record*.
- Step 3.** A new record to report a new composition is created.

Next, fill in the information on your substance composition.

General information:

- Step 1.** Provide a descriptive *Name* for the composition. This is especially relevant if you report multiple compositions.
- Step 2.** The default selection in the *Type of composition* field is *legal entity composition of the substance*. This refers to a composition manufactured, imported or used by the registrant/notifier/applicant. Each dataset should contain at least one composition of this type. Only modify this value where you intend to report a composition with a different purpose. For more information on what composition types that can be reported for that submission please refer to the specific instructions for the submission type that you are preparing.
- Step 3.** Indicate the physical *State/form* of the composition by selecting the appropriate value in the picklist. Where the substance covers different physical states or forms, a separate composition should be created for each of them.
- Step 4.** You can give more detailed information on the composition under the *Description of composition*. This is particularly important when several compositions are reported in order to clarify the differences between the compositions. Providing further considerations on how the composition has been defined is also advisable when the composition covers wide concentration ranges or polymorphs or isomers. For substances that cannot be described with well-defined and quantified constituents (e.g. UVCB substances), further information to identify the composition is provided in this field, including the identity of the starting materials and a description of the production process used to manufacture the substance.
- Step 5.** You can provide supporting attachments under the *Attached description*.

Step 6. In the *Justification for deviations* field, provide where relevant, the justification for deviating from the rules for reporting the composition of substances as specified in the legal text and indicated in the *Guidance for identification and naming of substances under REACH and CLP* available at <http://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.



Degree of purity:


Step 7. Provide the degree of purity of the composition, together with the unit of measurement. For instance, a substance with a purity of between 95-98% (w/w) will be given as shown below. Note: The degree of purity should correspond to the overall concentration of the (main) constituents in the composition.

Figure 2: Degree of purity



Constituents:

Step 8. Include the *constituents* for the composition by clicking the  button. Each composition must have, as a minimum, one constituent. The number of constituents to be reported will depend on the type of substance. To add more constituents, click the , and then the new repeatable blocks will appear.

Step 9. Assign a *reference substance* to the newly created constituent by clicking the  button. Search for the appropriate reference substance and add it by selecting it and clicking *Assign*; alternatively, create a new reference substance to specify the constituent (see *Reference substance*). Ensure that the reference substance contains a chemical name in the IUPAC name field, and the appropriate EC and CAS identifiers, as available.

Step 10. Indicate the *Typical concentration* and the *Concentration range* (minimum and maximum values, and unit of measurement) for every constituent.

Figure 3: Constituent

The screenshot shows a software window titled 'Constituents' with a sub-header 'Styrene / Styrene / 100-42-5 / 202-851-5, ca. 98 % (w/w), >= 96 - <= 99.5 % (w/w)'. The interface includes a 'Reference substance' field containing 'Styrene / Styrene / 100-42-5 / 202-851-5'. Below this is a table with the following data:

Inventory	Inventory number	Inventory name
EC Inventory	202-851-5	styrene
CAS number	CAS name	
100-42-5	Benzene, ethenyl-	
IUPAC name		
Styrene		

Below the table, there are input fields for 'Typical concentration' (set to 'ca. 98 % (w/w)') and 'Concentration range' (set to '>= 96 <= 99.5 % (w/w)').

Impurities and additives:

Step 11. To complete the information regarding *Impurities* and *Additives* follow the same procedure.

Step 12. Where the impurity or additive is considered relevant for classification and labelling of the substance, the relevant box must be ticked.

Step 13. The function of each *additive* has to be provided by making a selection in the picklist *Function*. Only selections beginning with the word *stabiliser* are applicable under REACH and CLP.

To report **unknown impurities**, create a generic reference substance (see *Reference substance*) and insert in the *IUPAC name* field the phrase *unknown impurities*. In the *Remarks* field of the impurity block, specify the nature, number and relative amounts of the impurities as far as possible. Also provide the *Typical concentration* (with unit of measurement) and *Concentration range* (with unit of measurement) for the *unknown impurities*.

Figure 4: Unknown impurities

Impurities ^

Unknown impurities / Unknown impurities, ca. 0.05 % (w/w), $\geq 0.04 - \leq 0.08$ % (w/w)

Reference substance
Unknown impurities / Unknown impurities

Inventory	Inventory number	Inventory name
...

CAS number	CAS name
...	...

IUPAC name
Unknown impurities

Typical concentration
ca. 0.05 % (w/w)

Concentration range
 ≥ 0.04 ≤ 0.08 % (w/w)

Remarks
3 unknown organic impurities for which the individual concentration does not exceed 0.03% according to the HPLC analysis (see section 1.4). Based on the fragmentation pattern in the HPLC-MS analysis (see also section 1.4), the structure of these impurities might include one chlorine and two bromine atoms

Figure 5: Additive

The screenshot shows the 'Additives' window with the following details:

- Reference substance:** 4-tert-butylbenzene-1,2-diol / 4-tert-butylbenzene-1,2-diol / 98-29-3 / 202-653-9
- Inventory table:**

Inventory	Inventory number	Inventory name
EC Inventory	202-653-9	4-tert-butylpyrocatechol
CAS number	CAS name	
98-29-3	1,2-Benzenediol,4-(1,1-dimethylethyl)-	
IUPAC name		4-tert-butylbenzene-1,2-diol
- Typical concentration:** ca. 0.01 % (w/w)
- Concentration range:** >= 0.005 - <= 0.02 % (w/w)
- Function:** stabiliser: inhibitor
- Details of function in composition:** This stabiliser is added to styrene in order to prevent its polymerisation

When reporting information on the composition, where there is any deviation from the rules for identifying a mono-constituent, multi-constituent or UVCB substance, you will need to provide explanations for the deviations in the field *Justification for deviations*. Such deviations include, for example, reporting a mono-constituent composition that includes a main constituent with a concentration of less than 80 %.

The composition to be reported depends on the substance type:

Mono-constituent substances:

For mono-constituent substances, you have to complete the following information:

- Report only the main constituent under the *Constituents* in section 1.2. Assign the same reference substance for this constituent as in section 1.1.
- Report individually any impurities under the *Impurities* in section 1.2.
- Report any additive necessary to stabilise your composition under the *Additives in* section 1.2. Specify the stabilising function of the additive from the picklist *Function*.
- Report the concentration range (both minimum and maximum values) and the typical concentration for the main constituent, any impurity and any additive.

Note: The typical concentration and concentration range values reported for the main constituent of a mono-constituent substance should normally not be less than 80% (w/w).⁶

- Report a degree of purity for your composition corresponding to the concentration range of the main constituent.


Multi-constituent substances:

For **multi-constituent** substances, you have to complete the following information:

- Report the main constituents under the *Constituents* in section 1.2.
Note: The main constituents should be the same for all compositions reported.
- Report any other constituent below 10% under *Impurities* in section 1.2.
- Report any additive necessary to stabilise your composition under *Additives* in section 1.2. Specify the stabilising function of the additive from the picklist *Function*.
- Report the concentration range (both minimum and maximum values) and the typical concentration for the main constituents, any impurity and any additive.
Note: The typical concentration and concentration range values of each main constituent should normally be ≥ 10 and $< 80\%$.⁷
- Report a degree of purity for the composition corresponding to the overall concentration range of the main constituents.

UVCB substances:

For **UVCB** substances, you have to complete the following information:

- Report the description of the manufacturing process, as well as other information relevant for the substance identification, in the field *Description of the composition*.
Note: To facilitate the reporting of the manufacturing process, suggestions as to what to enter are provided in a free text template for the field *Description of composition*. To open the free text template, click on the icon that shows the letter A with an arrow at the bottom right, . A pop-up window appears. Click *Option 2: composition of a UVCB substance*. To copy the text from the template to the field, click on the button labelled *Insert*. The text should then be edited so that it contains only the relevant data.
- Report the appropriate individual constituents or groups of constituents under *Constituents*.
Note: To provide information on the constituents or groups of constituents in your substance, you must not reuse, in section 1.2, the reference substance already assigned for your substance in section 1.1.

⁶ Any deviation from the "80% rule" should not be applied, unless a valid justification is provided. This justification should be provided in the *Justification for deviations* field for each composition where such a deviation is applied.

⁷ Any deviation from the "80% rule" should not be applied, unless a valid justification is provided. This justification should be provided in the *Justification for deviations* field for each composition where such a deviation is applied.

- Do not report any constituent under the *Impurities* header of the composition (impurities are not considered relevant for UVCBs).
- Report any additive necessary to stabilise your composition under the *Additives* header. Specify the stabilising function of the additive.
- Report the concentration values of the individual constituents, groups of constituents and any additive as a concentration range (both minimum and maximum values) and typical concentration.
- Report the appropriate degree of purity for your UVCB substance (the degree of purity should normally be 100% for UVCBs which do not include any additive, as the concept of *impurity* is not considered relevant for these substances).

Reporting the characterisation of nanomaterials:


This sub-section is filled in when *solid: nanomaterial* has been selected in the *State/form* picklist for that composition. It includes fields to report key characteristics of compositions that are nanoforms.


Step 14. Select the *Shape* of the nanoform from the available options in the picklist.

Step 15. Provide size ranges for the three *Dimensions* *x*, *y*, *z* and the unit of measurement (e.g. nm). Provide the *Percentile* (e.g. D50) of the size distributions to which the size ranges refer to. Additional information on shape of the nanoform can be provided in the *Remarks* field.

Step 16. Provide the ranges of specific surface areas of the nanoform, together with the unit.

Step 17. Under *Surface treatment applied*, indicate whether surface treatment was applied, and the type of treatment as relevant.

Step 18. Where surface treatment was applied, provide information on the treatment. Click on the  button to create a surface treatment block and indicate a name for the surface treatment.

Step 19. Next, in the table *Surface treatment* report the identity of the surface treatment agents layer-by-layer. Click on the *Add* button to create a new row for each layer. This action will open a dialogue window, where you indicate the layer number, and link a reference substance that describes the surface treatment agent applied by clicking the  button.

Step 20. Indicate the nature of the *External layer* by selecting one of the options available in the picklist. Provide the % (w/w) *Total fraction of core particle* that is representative of this nanoform. This value refers to the weight fraction of the core particle relative to the total weight of the surface-treated particle. Any supporting information, such as illustrations of the particle structure can be attached.

Note that several surface treatment blocks can be created within the same composition. This refers to the situation where several nanoforms with similar surface treatment exist, but where the dossier submitter has determined that this does not impact the chemical identity or the hazard profile of this composition.

When the nanoforms of the substance vary significantly in shape, specific surface area or surface treatment applied, then separate composition records are created to reflect these differences.

Step 21. To save the information click  from the main menu.

For applications for authorisation, applicants are advised to carefully check before the submission of the dossier that the information provided in IUCLID section 1.1 and IUCLID section 1.2 is sufficient to clearly identify the substance wished to be covered by the authorisation. In particular, this information should normally not be so generic resulting in potentially describing more than one substance or leading to a substance identity outside the frame of the Annex XIV entry. The substance identification in the application for authorisation dossier should follow the *Guidance for identification and naming of substances under REACH* (<http://echa.europa.eu/guidance-documents/guidance-on-reach>). Any deviation from the guidance should be properly documented in the dossier.

It is possible to specify more than one composition for a substance. For instance, a Manufacturer/Importer may manufacture/import more than one compositions of an Annex XIV substance, or the compositions may differ from one applicant of a joint application to another applicant: discrepancies can occur in terms of degree of purity, or in terms of nature and quantities of impurities/additives. In case of minor divergence you might be able to report only one composition by setting appropriate concentration ranges for the constituents, impurities and additives. However, in cases where more significant differences in composition need to be reported, additional repeatable composition blocks can be added

As stated above, Annex XIV can contain entries for which it might not be straightforward how to fill in IUCLID sections 1.1 and 1.2, e.g. entries specifying more than one EC numbers. Specific (case-by-case) instructions regarding such entries can be found at the *Questions & Answers* section of ECHA's website, available at: <http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/authorisation> (see sub-section *Applications for Authorisation - Technical instructions for specific Annex XIV entries*)

7.4.3. Section 1.3 Identifiers


Section 1.3 of IUCLID is relevant for initial applications, requested updates, subsequent applications, and review reports. For further information on the above application types please see also chapter 9.2. *Specific submissions*.

A series of identifiers may need to be added in this section:

- i. **REACH Annex XIV substance entry number:** for all types of applications (this number can be found from the Authorisation List available at ECHA's website at: <http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>.);
- ii. **REACH Registration number:** in order for ECHA to access a referenced "CSR" submitted as part of the registration according to Article 62(4)(d). Please note that if a CSR covering all uses applied for is included in the IUCLID dossier when applying for an authorisation, no registration number should be provided here;
- iii. **REACH Authorisation number:** for subsequent applications which refer to a granted authorisation according to Article 63(2);
- iv. **REACH Authorisation number:** for reviews of authorisation which refer to a granted authorisation according to Article 61(1);

Note that for subsequent applications which refer to a submitted application according to Article 63(1) and for updates requested by the Committees according to Article 64(3) the (last) submission number has to be placed in the dossier header when creating the application for authorisation dossier (see also chapter 10).

To enter your data, you must first create a new record by right-clicking on the section name and selecting a *new fixed record*.

- Step 1.** Press *Add* button to add a new identifier to the *Regulatory programme identifiers* table.
- Step 2.** Depending on the type of submission, select the appropriate identifier from the *Regulatory programme* picklist.
- Step 3.** Enter the relevant number in the *ID* field.
- Step 4.** Click on *OK* and the added regulatory programme identifiers will appear in the table.
- Step 5.** If you need to provide more than one programme identifier, create a new row by repeating the previous steps.
- Step 6.** To save the information click  from the main menu.

The table below gives an overview of where to report in IUCLID the different identifiers for each type of submission.

Table 1: Identifiers to be reported in the dossier

Type of application	Annex XIV entry number	Registration number (CSR)	Annotation number	Last submission number	Authorisation number
Initial application	Section 1.3 Regulatory programme identifiers	Section 1.3 Regulatory programme identifiers			
Requested update (Article 64(3))	Section 1.3 Regulatory programme identifiers	Section 1.3 Regulatory programme identifiers	Dossier header / creation wizard	Dossier header / creation wizard	
Subsequent application (Article 63(1))	Section 1.3 Regulatory programme identifiers	Section 1.3 Regulatory programme identifiers		Dossier header / creation wizard	
Subsequent application (Article 63(2))	Section 1.3 Regulatory programme identifiers	Section 1.3 Regulatory programme identifiers			Section 1.3 Regulatory programme identifiers
Review report	Section 1.3 Regulatory programme identifiers	Section 1.3 Regulatory programme identifiers			Section 1.3 Regulatory programme identifiers

7.4.4. (Optional) Section 1.4 Analytical information

Section 1.4 is for the inclusion of analytical information such as spectra or chromatograms to enable the identity of your substance to be verified, including the compositions specified in the dossier. It is also the place to include the descriptions of the methods used to generate this information.

In this section you can create several records to include analytical information you consider sufficient to verify the identity of your substance. To create a new record:

- Step 1.** Right-click on *1.4 Analytical information* in the *TOC* from the navigation panel on the left part of the screen.

Step 2. From the picklist select *New record*.

Step 3. A new record to report the analytical information is created.

To complete this section, follow the steps:

Methods and results of analysis:

Use the table *Analytical determination* to provide analytical information used to verify the identity of the substance.

Step 1. Click on the *Add* button and then the pop-up window appears.

Step 2. Fill in the information on the analytical methods and results.

For each analytical determination: enter the purpose for which the analysis was carried out, select the *Analysis type* (e.g. spectral, chromatographic), *Type of information provided*, and any *Remark* you consider relevant. For each method, you should attach the file containing the method and the result of the analysis. If you cannot provide results for the indicated analysis type, select the reason from the picklist *Rationale for no results* and fill in the explanation in the *Justification* field. Note that several analysis types can be reported for one determination.

You can choose to enter *identification* or *quantification* as purpose of an analysis. Both identification and quantification analyses are expected to be submitted to verify the composition of a substance.

Identification refers to any analysis carried out to establish the identity of the constituents, including their chemical functionalities, present in the composition of a substance. Examples of analyses used for identification are spectroscopic analyses such as UV, IR, NMR, MS or XRD.

Quantification refers to any analysis carried out to establish the concentration of the constituents in the composition. Examples of analyses used for quantification are chromatographic analyses, elemental analyses, titration.

Some analyses may be carried out both for identification and quantification purposes.

Figure 6: Analytical determination

Purpose of analysis	Analysis type	Type of information ...	Attached methods/r...	Rationale for no res...	Justification	Remarks
quantification	chromatography – HPLC, chromatography –	methods and results	Analytical report_chromatographic analyses.pdf /			
identification	other: HPLC-MS, UV/Vis, NMR, IR	methods and results	Analytical report spectroscopic analyses.pdf / 1.245			

Step 3. Indicate whether your substance is optically active by selecting the appropriate value from the picklist.

Step 4. Provide information on the optical activity, whenever applicable in the *Remarks* field.

Figure 7: Optical activity

Optical activity

yes

Remarks

The specific rotation has in this case been recorded on a diluted sample (c 2.0, CHCl₃)
Specific rotation: [α] = -30.0° (20°C, 589 nm)

Related composition(s):

Step 5. You can link the reported analytical information to the relevant *Composition* from *section 1.2* by clicking the *Add* button. This is especially relevant when you have reported several compositions in *section 1.2*.


For joint applications for authorisation, in case you want to describe analytical methods / results which are specific to some of the applicants you can create further records under this IUCLID section.


7.4.5. (Optional) Section 1.5 Joint submission

In this section you may wish to indicate, for your own administrative purposes, the name and some further details of the applicants in the corresponding fields. To enter your data, you must first create a new record.

Note that the legal entity information in the REACH-IT accounts of the applicants (as well as legal entity names listed in the application form (see chapter 8), to be attached in section 13 of the IUCLID dossier) has precedence over any information provided in IUCLID section 1.5. If these data are inconsistent with each other, ECHA will consider the REACH-IT data as valid.

The submitting applicant creates the joint application in his local IUCLID installation and may request from the co-applicants their legal entity information so that data consistency may be ensured between IUCLID installations. Each co-applicant may export his own legal entity object (LEO – see chapter 2 of this manual) and send the export file (LEOX) electronically to the submitting applicant.

Submitting applicant: Indicate the name of the submitting applicant in the field *Lead*. Click the  button to select the legal entity of the submitting applicant and establish the link. It is strongly recommended not to use the *New* button to create locally the legal entity information. This would result in the legal entities being differently identified in the various IUCLID installations and would compromise data exchange.

Co-applicants: After having imported each co-applicant's LEOX, the submitting applicant can indicate all the co-applicants of the Joint application. Click the  button to select the co-applicant and establish the link. The same recommendations as those provided for assigning the Lead apply.


7.4.6. Section 1.7 Suppliers

For a company applying as an Only representative, information about the company outside the EU which is represented must be provided in section 1.7.

In case of a joint application, the co-applicants need to provide the respective information to the submitting applicant, who will include it in section 1.7 of the IUCLID dossier.

- Step 1.** Right-click on *1.7 Suppliers* in the *TOC* from the navigation panel on the left part of the screen.
- Step 2.** From the picklist select *New record*.
- Step 3.** A new record to report the represented company is created.

To complete this section, follow the steps:

- Step 1.** At the *Name* field under *Manufacturer, Importer, Formulator* assign the legal entity of the represented company to the dataset, by clicking on the  button. A new window opens where you can search for existing legal entities within your IUCLID installation or create a new legal entity by clicking *New*. Under *General information* fill in the field *Legal Entity name* with the exact name of the represented company. Under *Contact information* fill in as minimum the *Address, Town or Region/State,* and *Country* where the represented company is located. Click *Save* to store the information provided on the Legal Entity and *Assign* to assign it to the section.
- Step 2.** In case this is a joint application, under *Remarks* indicate the name of the applicant (Only Representative) concerned by this record.
- Step 3.** You are advised to attach clear documentation of the appointment as the only representative (e.g. a copy of the appointment letter which was sent to importers) in the field *Assignment from non EU manufacturer*. If you want, you can also indicate the list of the importers' names covered by your application in the field *Other importers*.

In case this is a joint application and there are further applicants who apply as Only Representatives, repeat the above steps by creating a new record for indicating the company.

- Step 4.** To save the information click  from the main menu.

7.4.7. (Optional) Section 1.8 Recipients

This optional section can be used to indicate a downstream user, a distributor or a customer being supplied with the Annex XIV substance. These definitions never include consumers. To enter your data, you must first create a new record.

7.5. Section 2 C&L and PBT assessment

Section 2 is optional.

7.5.1. (Optional) Section 2.1 GHS

This optional section can be used to provide the Classification and Labelling information of the substance for which authorisation is sought. To enter your data, you must first create a new record.

As the application is assessed on the basis of the intrinsic properties given in Annex XIV, the Classification and Labelling information should at least reflect these properties.

It is recommended to consult Annex I of the CLP Regulation for the classification criteria and the Introductory Guidance on CLP at <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp> for more detailed instructions on the application of the Classification and Labelling rules.

Harmonised classification has to be respected and you should not modify any of the harmonised hazard classes/differentiations. If the substance has a harmonised classification for some hazard classes/differentiations you may classify for other hazards according to available and reliable data. Additional hazards (e.g. phys-chem hazards: flammability, explosivity) can also be specified here.

For joint applications: different C&L can be addressed by inserting several C&L records, provided that they reflect as a minimum the C&L mentioned in Annex XIV and that they remain consistent with the information available in the assessment reports.

7.6. Section 3 Manufacture use and exposure

Sections 3.1, 3.2, 3.3, 3.4, 3.6, and 3.7 are optional.

7.6.1. (Optional) Section 3.2 Estimated quantities


This optional section can be used to provide the estimated manufactured/imported quantity in tonnes per calendar year or multi-yearly average. You can also provide in the *Remarks* field estimated tonnages per use and per year. To enter your data, you must first create a new record.

The estimated quantity given for each "use applied for" (a use for which the application is intended and an authorisation is sought) should be consistent with the amount(s) provided in the exposure scenario(s) covering that use, as documented in the chemical safety report.

Public tonnage information per "use applied for" is recommended to be included as part of the brief wording of the broad information on use, in section 3.5 (see chapter 7.6.4 below). That information will be published in the context of ECHA's public consultation on alternatives.

7.6.2. (Optional) Section 3.3 Sites

In this section you can specify the information on your substance manufacture and use sites.

To report the data you can create several records and each of them must have one of the existing Legal entity sites linked to it by the chain button .

The related uses taking place at each the site can then be linked by the *Add* button where previously created uses can be selected and assign to the site.

For applications for authorisation, this section might be relevant in the cases where the conditions of use of Annex XIV substance are site-specific and/or where:

- i. the applicant provides a justification in IUCLID section 3.10 for not considering risks arising from emissions of the Annex XIV substance from an installation for which a permit was granted in accordance with the IPPC Directive;

- ii. the applicant provides a justification in IUCLID section 3.10 for not considering risks arising from emissions of the Annex XIV substance from a point of source governed by the requirements of the Water Framework Directive.

7.6.3. (Optional) Section 3.4 Information on mixtures

This optional section can be used to provide information on the mixtures in which the Annex XIV substance is contained for the uses applied for, if applicable. Information to be provided in this section includes the name and type of mixture as well as the typical concentration range of the substance in the mixture. To enter your data, you must first create a new record.

7.6.4. Section 3.5 Use and exposure information

This section enables applicants to provide information on the uses they apply for an authorisation. In particular, section 3.5 of IUCLID offers a multi-level structured system enabling applicants to categorise the type of use of the Annex XIV substance by using standard descriptors and free text information. "Identified uses" created in IUCLID section 3.5 will serve to populate the links with the "uses applied for" (in IUCLID section 3.10).

Before filling out this IUCLID section, it is recommended to read the ECHA *Guidance on Information Requirements and Chemical Safety Assessment - Use description* (R.12) at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

and the document with further advice on *How to develop the description of uses in the context of Authorisation* at:

<http://echa.europa.eu/applying-for-authorisation/start-preparing-your-application>

7.6.4.1. Information on uses

Uses of the Annex XIV substance can be reported each as a record in different subsections corresponding to different life cycle stages⁸: 3.5.2 *Formulation or re-packing*, 3.5.3 *Uses at industrial sites*, 3.5.4 *Widespread uses by professional workers*, 3.5.5 *Consumer uses*, and 3.5.6 *Service life*⁹.

Each record must be complete and also consistent with the information contained in the related exposure scenario.

To create a new use:

Step 1. Right-click on the relevant life cycle stage where you want to add a new use.

Step 2. Select *New record* and indicate an intuitive name for the record so that you can easily recognise it later.

Next, fill in the information on your use.

- For a complete record in the subsection **3.5.2 Formulation or re-packing** at least the fields *Use name*, *Process Category (PROC)* under *Contributing activity / technique for workers*, *Technical function of the substance during formulation*, *Related assessment*, and *Remarks* must be filled in.

⁸ The Manufacture stage can be described here even though it would not be considered as a "use applied for"

⁹ If the article service life stage (i.e. the use of the article containing the Annex XIV substance) is not considered as a use of the Annex XIV substance it must nevertheless be covered in the development of the exposure scenarios

- For a complete record in the subsection **3.5.3 Uses at industrial sites** at least the fields *Use name*, *Process Category (PROC)* under *Contributing activity / technique for workers*, *Technical function of the substance during use*, *Related assessment*, and *Remarks* must be filled in. In addition, the fields *Environmental release category (ERC)* under *Contributing activity / technique for the environment* and *Subsequent service life relevant for this use* should be provided, but if unavailable, the field *Sector of end use* must be filled in.
- For a complete record in the subsection **3.5.4 Widespread uses by professional workers** at least the fields *Use name*, *Process Category (PROC)* under *Contributing activity / technique for workers*, *Technical function of the substance during use*, *Related assessment*, and *Remarks* must be filled in. In addition, the fields *Environmental release category (ERC)* under *Contributing activity / technique for the environment* and *Subsequent service life relevant for this use* should be provided, but if unavailable, the field *Sector of end use* must be filled in.
- For a complete record in the subsection **3.5.5 Consumer Uses** at least the fields *Use name*, *Technical function of the substance during use*, *Related assessment*, and *Remarks* must be filled in.
- For a complete record in the subsection **3.5.6 Service Life** at least the fields *Service life name*, *Technical function of the substance during use*, *Related assessment*, and *Remarks* must be filled in.

When completing this IUCLID section, please note that if *other:* is selected in any of the IUCLID section 3.5 picklists then the adjacent free text field must be filled in.

In the following sub-chapters, the content to be provided in one record is detailed.

7.6.4.2. Use identifiers, descriptors, and function

An identified use is to be described by:

- a number;
- a name;
- a brief description of use process;
- tonnage of substance;
- a selection of use descriptors;
- a selection of substance function(s);
- information on whether the use leads to the inclusion of the substance into an article and a possibility to link to the relevant subsequent service life;
- a reference to (an) exposure scenario(s) relevant for that use.

Use number: It is recommended that a unique number is entered by the applicant for each row.

Use name: The name of the identified use identifies the activity carried out within that use, and must be consistent (if not identical) with the exposure scenario title as described in *Remarks*.

Further description of use: Applicants are requested to propose for each "use applied for" a non-confidential broad description, named hereafter as "brief wording".

Pursuant to Article 64(2) of REACH ECHA is required to make available on its website broad information on uses applied for, and open a public consultation inviting interested parties to submit information on alternative substances or technologies. This broad information on uses of the Annex XIV substance should be meaningful enough to enable interested parties to submit relevant and useful information on possible alternatives.

In the fields *Further description of use* applicants have the opportunity to propose a public description ("brief wording") for each "use applied for". This "brief wording", which is dedicated to the public consultation, is recommended to contain the following set of public information:

- i. Name of the "use applied for"¹⁰
- ii. Key elements on the conditions and constraints under which the substance is used and the function is delivered (e.g. process conditions, quality criteria for the end-product etc)
- iii. Annual average tonnage
- iv. Review period requested
- v. List of descriptors (codes for ERC, PROC, PC, SU, AC and picklist values for the function)

Based on i) the proposed "brief wording" submitted by the applicant and ii) the information contained in the application, ECHA will establish an initial version of this "brief wording" and will invite the applicant to provide comments within a specified deadline. On the basis of the applicant's comments ECHA will establish and communicate to the applicant the final "brief wording" of the broad information on uses.

After the fee for an application for authorisation has been received, ECHA will publish on its website for the purpose of the public consultation: the final version of the "brief wording", the public version of the exposure scenarios (sections 9 and 10 of the CSR), the Summary table of representative RMMs and OCs, the public version of the Analysis of Alternatives, the public summary of the substitution plan (where relevant), and the public version of the Socio Economic Analysis.

Contributing activity / technique for the environment - Environmental release category (ERC): a new repeatable block should be added under this title, and an ERC descriptor should be selected which describes the broad conditions of the use from the environmental perspective.

Contributing activity / technique for workers - Process category (PROC): a new repeatable block should be added for each Contributing activity / technique within the use. The name and PROCs respective to each activity / technique must be indicated. Alternatively, a single repeatable block can be added under this title, and all the PROC descriptors must be selected which describe the application techniques or process types involved in the specific use, defined from the occupational perspective. However, in the CSR the workers exposure must always be assessed per Contributing scenario.

Product category used (PC): the chemical product category describes in which types of chemical products (= substances as such or in mixture) the substance is finally contained when it is supplied to end-uses.

Sector of end use (SU): this descriptor describes in which sector of the economy the substance is used. This includes mixing or re-packing of substances at formulator's level as well as industrial, professional and consumer end-uses.

Technical function of the substance during use: In addition to the use descriptors, applicants should also indicate for each use the function(s) of the Annex XIV substance in the picklist *Technical function of substance during use*. If the function of the Annex XIV substance is not available in the picklist, you should select *Other* and type the appropriate information in the adjacent text field.

Substance supplied to that use in the form of: select as appropriate by clicking one or the two checkboxes specifying that the substance is supplied *as such* or *in a mixture* for that use.

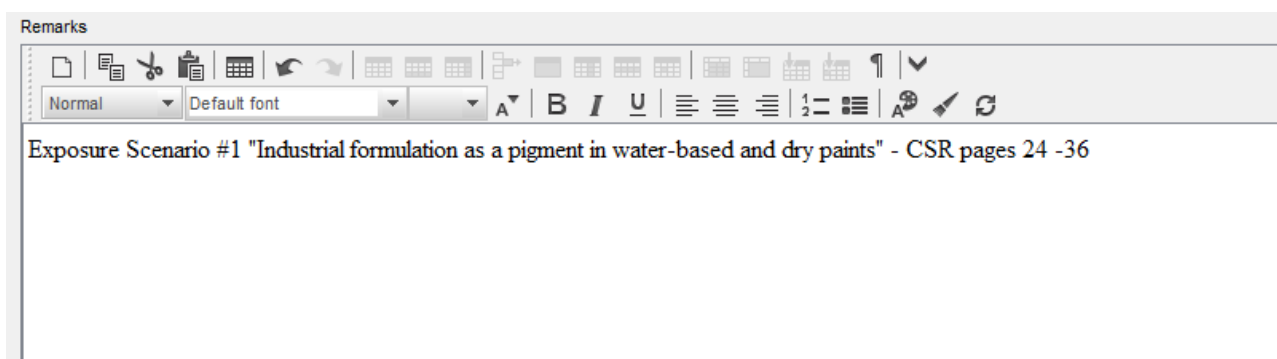
¹⁰ This can be the same as the "Use name" in section 3.10, if it is considered as public. In that case, it doesn't need to be repeated in this field. A simple reference to the name of the use applied for can be made instead.

Tonnage of this substance for this use (tonnes/year): this information could be reported here and shall be consistent with information documented in the related exposure scenario and the brief wording proposal.

The use-descriptor system is based on five separate descriptor lists which in combination with each other form a brief description of use, also to be used as an exposure scenario title.

Related assessment and Remarks: These mandatory fields enable the applicant to create links between “uses applied for” and exposure scenarios. At the *Remarks* field it is important to make a reference to the respective for the use exposure scenario number and name (short title) which is present in the CSR provided by the applicant. The name of the exposure scenario (short title) should be consistent (if not identical) to the name of the use.

Figure 8: Providing a reference to the exposure scenario for a use applied for



The image shows a screenshot of a software interface for entering remarks. At the top, there is a toolbar with various icons for editing text and tables. Below the toolbar, there is a text input field with the following text: "Exposure Scenario #1 \"Industrial formulation as a pigment in water-based and dry paints\" - CSR pages 24 -36". The text is in a standard font and is centered within the field.

Each use in IUCLID section 3.5 which is applied for (i.e. that is also listed in IUCLID section 3.10) shall refer to an exposure scenario, at the *Remarks* field (see Figure 8). The reference shall allow ECHA to retrieve the exposure scenario covering this use in the related Chemical Safety Report and in the public version of the exposure scenario (if provided).

The tabs *Contributing scenarios for the environment (related to workers activities)*, *Contributing scenario for the workers*, and *Use takes place under rigorously contained conditions* are optional and thus don't need to be filled in. Such information is expected to be included in the CSR provided in section 13.

7.6.5. (Optional) Section 3.6 Uses advised against

This optional section enables the applicant to provide information on use(s) advised against as specified in the REACH regulation (section 3.7 of Annex VI).

The hierarchical structure of IUCLID section 3.6 is similar to the structure of IUCLID section 3.5 (*Use and exposure information*). Moreover, the standard descriptor system to be used here is strictly the same as the one already described for the identification of uses in IUCLID section 3.5. Please refer to all indications described in chapters 7.6.4.1 and 7.6.4.2 of this manual to fill in the required information.

If no uses advised against have been identified then you should not enter any information in section 3.6 *Uses advised against*.

If you have identified use(s) advised against (e.g. uses already covered by a restriction set out in Annex XVII of REACH), then you can add a record for each use advised against and fill in the information required. It is recommended to fill in as a minimum the field *Use name*.

7.6.6. (Optional) Section 3.7 Environmental assessment from aggregated sources

This section is optional and thus don't need to be filled in. Such information can be included in the CSR provided in section 13.

7.6.7. Section 3.10 Application for authorisation of uses

This section should contain specific information related to the application for an authorisation of use.

This section enables the applicant to apply for multiple uses for authorisation. To enter your data, you must create a *New record* for each use applied for.

Each record shall contain the following assessment reports:

- i. an analysis of alternatives;
- ii. a substitution plan (where relevant);
- iii. a socio-economic analysis (where relevant - recommended to include also for adequate control route applications); and
- iv. a justification for not considering certain risks (where relevant).

The analysis of alternatives and the socio-economic analysis can also be prepared in one document, instead of two separate documents.

If you have developed generic assessment reports which cover all "uses applied for", ECHA recommends that you attach them only in the first record (i.e. for Use#1). For the following records (i.e. Use#2, Use#3 etc...) you can therefore only refer to the appropriate parts (chapters, pages...) of the documents attached in the first main record.

In the following sub-chapters, the content to be provided in each record is detailed.

7.6.7.1. Request for authorisation (for one use: Use#1)

In the field *Use concerned by the request* fill in the name and number of the use applied for.

In case of an application for more than one uses, use a sequential number for each use, starting from 1. In case of a joint application, it is important that the use number given in the *Use concerned by the request* field matches the one given for this use in the application web-form.


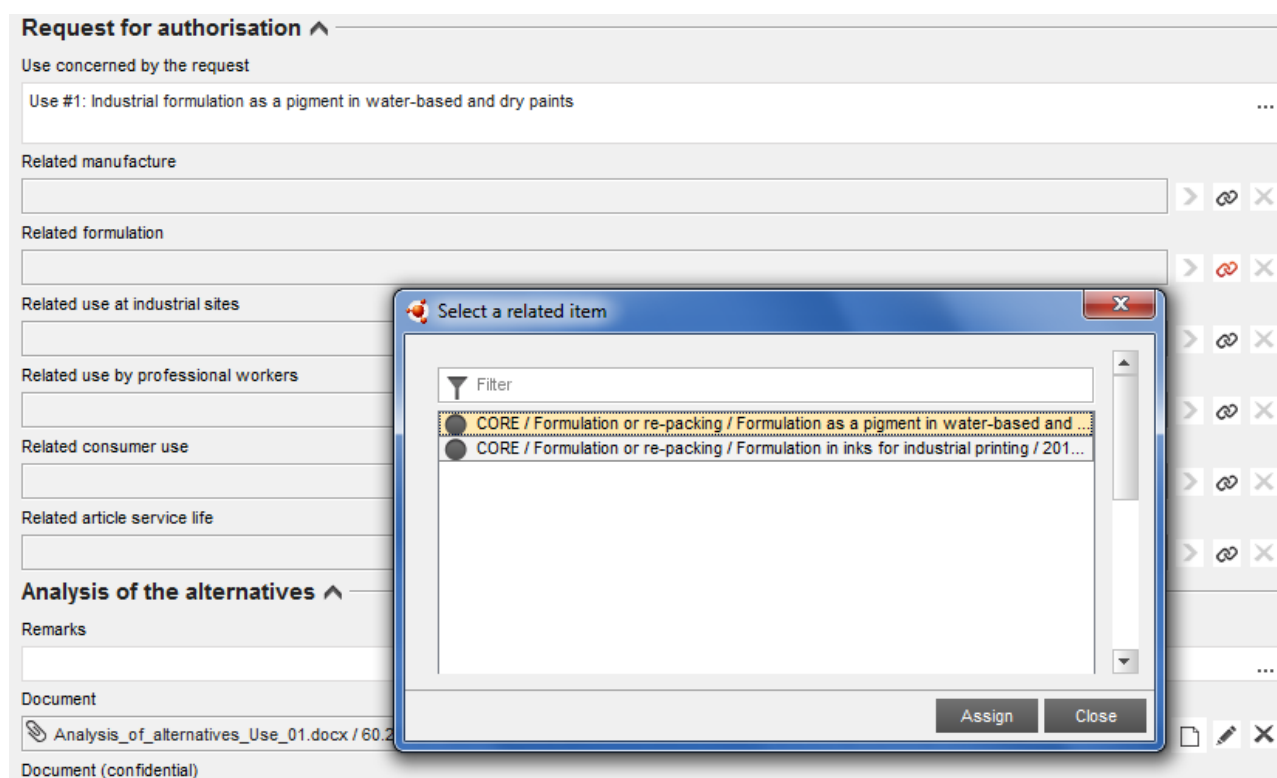
Click on the  button to link the "use applied for" to an "identified use" which has already been described in the IUCLID section 3.5. This will in particular enable a mandatory link (preferably one to one) between the "use applied for authorisation" and an exposure scenario in an accessible Chemical Safety Report (reference to the exposure scenario is provided in section 3.5).

Figure 9: Description of the "Use concerned by the request" and link to IUCLID section 3.5



The text in the field *Use concerned by the request* in IUCLID section 3.10 is considered by ECHA to be the name (and number) of a "use applied for", i.e. a use for which the application is intended and an authorisation is sought.

As for the consistency between IUCLID section 3.10 and the linked identified use in section 3.5, although it is also recommended that the use numbers and names given in these sections match, this is not mandatory. However, the name in section 3.10 has precedence over the name in section 3.5.

7.6.7.2. Analysis of the alternatives


The analysis of alternatives shall be included in the application for authorisation dossier.

The analysis of alternatives shall be provided following the format available on the ECHA website (<http://echa.europa.eu/web/guest/applying-for-authorisation>) and the *Guidance on the preparation of an application for authorisation* at:

<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

It is also possible to prepare a combined analysis of alternatives and socio-economic analysis in one document. In this case, use the corresponding format indicated at ECHA website and attach the document at the field *Analysis of the alternatives*.

In case the analysis of alternatives contains confidential information, you shall prepare two versions.

- **Document field:** Add a public version of the analysis of alternatives documentation by clicking the  button. Specify the path and the name of the file to be inserted and click


OK to insert the file. This is the version to be published by ECHA during the public consultation on alternatives.

- *Document (confidential)* field: In this field add the confidential version, if relevant.
- *Remarks* field: If necessary, provide any additional comment here.

7.6.7.3. Socio-economic analysis


Where relevant, the application may include a Socio-Economic Analysis (SEA) conducted in accordance with the format available on the ECHA website (<http://echa.europa.eu/web/guest/applying-for-authorisation>) and the *Guidance on the preparation of socio-economic analysis as part of an application for authorisation* at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

It is also possible to prepare a combined analysis of alternatives and socio-economic analysis in one document. In this case, use the corresponding format indicated at ECHA website and attach the document at the field "analysis of alternatives".

- *Document* field: Add a public version of the socio-economic analysis documentation by clicking the  button. Specify the path and the name of the file to be inserted and click OK to insert the file. This is the version to be published by ECHA during the public consultation on alternatives.
- *Document (confidential)* field: In this field add the confidential version, if relevant.
- *Remarks* field: If necessary, provide any additional comment here.


7.6.7.4. Substitution plan

Where relevant, the application may include a substitution plan following the format available on the ECHA website (<http://echa.europa.eu/web/guest/applying-for-authorisation>) and the *Guidance on the preparation of an application for authorisation* at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

- *Document* field: Add a public version of the substitution plan documentation by clicking the  button. Specify the path and the name of the file to be inserted and click OK to insert the file. This is the version to be published by ECHA during the public consultation on alternatives.
- *Document (confidential)* field: In this field add the confidential version, if relevant.
- *Remarks* field: If necessary, provide any additional comment here.

7.6.7.5. Justification for not considering risks to human health and environment

- *Remarks* field: Enter the justification for not considering risks to human health and the environment arising either from emissions of a substance or discharges of a substance according to Article 62(5)(b)(i) and (ii), or


- *Document* field: Add a public version of the socio-economic analysis documentation by clicking the  button. Specify the path and the name of the file to be inserted and click *OK* to insert the file. This is the version to be published by ECHA during the public consultation on alternatives.


7.6.7.6. Reference to other applications or previous authorisations (for subsequent applications)

An application for authorisation may refer to previous applications for authorisation for the same substance(s) and use(s). This is mentioned in the REACH Regulation as “subsequent application”. The following two situations are possible:

- i. if you have the permission from a previous applicant who has applied for an authorisation for the same substance and use(s), you can refer to the appropriate parts of the previous application submitted and which is still under process;
- ii. if you have the permission from the holder of a previously granted authorisation who has applied for the same substance and use(s), you can refer to the appropriate parts of the previous application submitted.

For more information please refer to the “Guidance on the preparation of an application for authorisation” at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>

Click the  *Add...* button to open the repeatable block. An empty block is now ready to be filled in. Describe the reference to previous authorisations or other applications for which you have a written permission. If more than one reference needs to be specified, add a new block for each one.

- *Written permission* checkbox: Select the checkbox and attach a copy of the relevant document(s) by clicking the  button.
- *Remarks* field: Provide any additional comment on the previous authorisation. Note that for subsequent applications, reference numbers from other applications or granted authorisations (submission numbers and/or authorisation numbers) must be reported in section 1.3 of IUCLID or in the dossier header (see chapter 7.4.3 of this manual).

Applicants are strongly recommended to provide clear justifications on the reasons why they refer to a previous application, and to demonstrate the relevance and the purpose that the referral plays in their application.

When referring to different parts of other applications particular attention should be paid to the identification of the uses (i.e. numbering and description). For example Use#1 of the subsequent applicant may differ from Use#1 of the initial applicant. The same applies to any references to the *Exposure scenarios* in the CSR of the previous applicant. See also chapter 9.2 *Specific submissions* of this manual.

7.6.7.7. Request for authorisation for additional uses (Use#n)

Once the first record has been filled in for Use#1, the same approach can be taken for Use#2 in the second record and accordingly any additional uses.

If your assessment reports (analysis of alternatives, or socio-economic analysis or substitution plan) are specific to the use described in the block, you can attach them as instructed for Use#1 in the first record.

However, if the scope of the assessment report covers several uses, do not duplicate the same document in the next blocks, but rather refer to certain parts of the reports already attached in the first record.

Note that a new record must be created for each different "use applied for".

Multi-substance applications: For applications for several substances, section 3.10 allows to indicate which uses apply for which substance in the application. For instance, if a use applies to all substances it shall be listed in sections 3.10 of all substance datasets to be assigned to the category; if a use applies only to one (or some) of the substances, it shall be listed only in section 3.10 of the relevant substance dataset(s). See also chapter 7.2 of this manual.

Joint applications: Create a new main repeatable block for each different "use applied for". The mapping of uses per applicant (and per substance if relevant) has to be made online, in the web-form (see chapter 8 of this manual), and the generated .PDF (application form for a joint application) should be attached to the section 13 of the IUCLID dossier.

7.6.7.8. Brief wording on uses

Applicants are requested to propose for each "use applied for" a non-confidential broad description, named "brief wording". The "brief wording" should be provided in section 3.5 of the IUCLID dossier (see chapter 7.6.4.2 of this manual).

7.7. (Optional) Sections 4 to 7 - Endpoint sections

Although information related to IUCLID sections 4–7 is not mandatory for an application for authorisation, applicants may wish to provide them in their dossier either as a copy of an existing registration dataset of the Annex XIV substance or as a specific set of information (see chapter 7.1 of this manual).

Further instructions on how create a substance dataset and how to fill out IUCLID sections 4 to 7 can be found in the manual *How to prepare registration and PPORD dossiers*

7.8. (Optional) Section 8 Analytical methods

IUCLID section 8 can be used for summarising analytical methods for determining a given substance in various matrices. Depending on the requirements of the relevant legislation, methods for the following matrices may have to be recorded: soil, sediment, suspended particulates, air, water (including drinking water), animal and human body fluids and tissues, plants, plant products, food and feedingstuffs, formulated product, other.

Further instructions on how to fill out IUCLID section 8 can be found in the manual *How to prepare registration and PPORD dossiers*.

7.9. (Optional) Section 11 Guidance on safe use

Applicants may provide guidance on safe use in this optional IUCLID section by filling out the following fields:

- i. First aid measures;
- ii. Fire-fighting measures;
- iii. Accidental release measures;
- iv. Handling and storage;
- v. Transport information;


- vi. Exposure controls / personal protection;
- vii. Stability and reactivity;
- viii. Disposal consideration.

Further instructions on how to fill out IUCLID section 11 can be found in the manual *How to prepare registration and PPORD dossiers*.

7.10. (Optional) Section 12 Literature search

This optional IUCLID section can be used to record any literature search(es) carried out. Specify the date of the literature search in field *Date* (only format yyyy-MM-dd allowed, e.g. 2011-03-20).

In the field *Remarks*, describe the databases searched and the main search profile. Indicate the major search results, e.g. state for which endpoints no information could be retrieved.

It is also possible to attach the document with the literature search profile in tab *Attachments* in the *Information Panel* at the bottom of the IUCLID screen (right-click into the left panel and then click the  button).

7.11. Section 13 Assessment reports

IUCLID section 13 is a section in which different assessment reports can be attached covering information not documented in other IUCLID sections.

All applications must contain at least two records in IUCLID section 13: one including the Chemical Safety Report (CSR) and one including the summary of risk management measures (RMMs) and operational conditions (OCs). Joint applications must also contain the application form generated by the web-form (see chapter 8).

During the public consultation on alternatives, ECHA will publish the exposure scenarios covering your “uses applied for” as documented in the CSR (chapters 9 and 10 of the CSR), as well as the summary table of representative RMMs and OCs. Should you consider this information confidential, please attach in this section in addition to the CSR, public versions of the exposure scenarios covering your “uses applied for” (e.g. such as those annexed to an e-SDS) and of the summary of representative RMMs and OCs, preferably in the form of editable text documents.

7.11.1. Chemical Safety Report


A Chemical Safety Report (CSR) must be provided in IUCLID section 13.

In case the CSR contains confidential information or it is provided in a protected format, you shall prepare two versions, in two separate records in section 13:

- i. a complete / confidential version containing all relevant sections of the CSR;
- ii. and a public version containing only Part A sections 2 and 3 (i.e. declarations that RMMs are implemented and communicated) and Part B sections 9 and 10 (i.e. Exposure Assessment and Risk Characterisation)

Part A section 1 of the CSR is recommended to be provided as a separate document (see chapter 7.11.2 below)

Attach the CSR(s) in IUCLID section 13 as described below.

- Step 1.** Right-click section 13 *Assessment Reports* in *TOC* and select *New record*.
- Step 2.** In the *Document / report* field click the  button. You can subsequently attach the document, preferably in an editable text format.
- Step 3.** From the pick-list under *Type of report* select *REACH Chemical safety report (CSR)*.
- Step 4.** Alternatively, the application can refer to a CSR already provided as a part of a registration dossier. In this case, IUCLID section 13 needs to be filled out as indicated above, but instead of attaching a CSR in the *Document* field, a reference to the registration dossier should be provided in the *Further information on the attached file* field. Also note that when referring to a CSR from a registration dossier, the corresponding registration number must be provided in section 1.3 of IUCLID (see chapter 7.4.3).
- Step 5.** If the CSR is not attached, the registration number provided in IUCLID section 1.3 must belong to the submitting applicant or to one of the co-applicants of the group. If this is not the case a valid permission of the CSR's owner must be attached in IUCLID section 13.
- Step 6.** Applicants may consider to provide a refined version of the CSR that has been submitted as part of a REACH registration dossier. They can either update the CSR in their registration dossier and refer to it in their authorisation dossier, or they can attach the refined version in the authorisation dossier. In the latter case it is recommended that applicants ensure consistency between the two versions.

If you need to provide a further version of CSR (i.e. public / confidential), then repeat the above steps.

7.11.2. Summary of risk management measures (RMMs) and operational conditions (OCs)

A summary of risk management measures (RMMs) and operational conditions (OCs) must be attached in IUCLID section 13.

This succinct summary table of representative RMMs and OCs shall be provided following the format available on the ECHA website (<http://echa.europa.eu/web/guest/applying-for-authorisation>) and it replaces Part A section 1 of the CSR.

Follow similar steps as in chapter 7.11.1 to attach this document in a new record in section 13. From the pick-list under *Type of report* this time select *REACH application for authorisation: summary of representative RMMs and OCs*.

7.11.3. Application form for a joint application

The application form for joint applications must be attached in IUCLID section 13. The application form is generated by Web-form 1 (see chapter 8 of this manual for more detailed information).

7.11.4. Other supporting documentation

Any additional reports which provide information which cannot be documented in the other IUCLID sections should be included in new records in section 13. Such reports could for

example comprise any modeling reports, calculation sheets, or mapping of changes performed (the latter may be relevant for updates in response to ECHA's Committees requests to bring the application in conformity) (see chapter 13.1).

8. Application form for a joint application

If you are submitting a single application, skip this step and proceed to chapter 9.

8.1. Generating the application form

If you are not the submitting applicant of a joint application, skip this step and proceed to chapter 8.2

To create the application form that needs to be attached in IUCLID section 13 for joint applications (see chapter 7.11), go to the webpage *How to apply for authorisation* (located at: <http://echa.europa.eu/web/guest/applying-for-authorisation>), click on *Submit your application*, and then click on the link to the Web form 1 (Generate your application form) (Web-form 1: https://comments.echa.europa.eu/comments_cms/AuthorisationApplication_Create.aspx).

This form must be created by the submitting applicant of the joint application.

To fill in the Web-form 1 (Figure 10 and Figure 11), follow the steps below:

Step 1. Indicate the number of substances included in your application for authorisation.

In accordance with Article 62(3) of REACH, applications may be made for one or several substances that meet the definition of a group of substances in section 1.5 of Annex XI of REACH. If the application is for several substances, an argumentation for substance grouping must be appended in the Category Rationale field of the IUCLID application file.

Step 2. Click on the drop down menu(s) under the total number of substances and select from the Annex XIV entries the substances that you wish to include in your application. Keep in mind that the substance or substances selected shall be consistent with the substance information in the IUCLID dossier.

Step 3. Indicate the number of "uses applied for" included in the application.

Step 4. For each "use applied for", enter the use name in the free text field below the total number of uses.

The numbering and the names of the uses should be identical with the ones in section 3.10 of the IUCLID dossier under the *Use concerned by the request field*.

Step 5. Indicate which (if not all) uses apply to which substances in the application, by selecting the appropriate use-substance combinations. Note that each substance and each use listed in the form should be selected at least in one substance-use combination.

Step 6. Indicate the number of applicants by choosing the correct value from the drop-down menu (Figure 11).

Figure 10: Web-form 1 - Creation of the application form

Application form for a joint application for authorisation

Fields marked with an asterisk (*) are mandatory.

Substance(s) applied for

Please note that in accordance with Article 62(3) of REACH Regulation, applications may be made for one or several substances that meet the definition of a group of substances in section 1.5 of Annex XI of REACH. If the application is for several substances, an argumentation for substance grouping must be appended in the Category Rationale field of the IUCLID 5 application file.

* Total number of substances

* Substance 1

Use(s) applied for

Please enter, for each use applied for, the use description (in the fields "Use 1", "Use 2" etc.).

The numbering and the descriptions of uses should be identical with the ones in section 3.10 of the IUCLID application for authorisation dossier under the "Use concerned by the request" field.

* Total number of uses

* Use 1

Step 7. For the submitting applicant and the co-applicants the following information shall be entered in the section "Applicant(s)":

- i. legal entity name and legal entity UUID as specified in REACH-IT;
- ii. the Role(s) in the supply chain;
- iii. the use(s) along with the respective substance(s) that the authorisation is being applied for ("mapping of uses"). The submitting applicant should collect this information from each co-applicant. Note that each substance and each use listed in the form should be selected at least in one substance–use combination by at least one applicant.

The legal entity name and the legal entity UUID indicated in the application form must be identical with the corresponding data in each applicant's REACH-IT account. The company name and UUID can be found under the *Company information* section in REACH-IT. In the case of a joint application, the co-applicants need to provide this information to the submitting applicant and ensure that the data is identical with their data in REACH-IT.

Step 8. Enter a valid email address. For joint applications, this should be the email address of the submitting applicant. The email address indicated in the web-form will be used to communicate important information related to the submission of the application, e.g. the application form in .PDF format, and the submission code or the token.

Step 9. Select the preferable option (either via email or via download) for receiving the PDF version of the application form, which will need to be attached to your IUCLID substance dataset.

Figure 11: Applicants information (Web-form 1)

Applicant(s)

* Total number of applicants

* Applicant legal entity name as indicated in the REACH-IT account * Applicant UUID as indicated in the REACH-IT account * Role(s) in the supply chain press "Ctrl" for multi-selection * Uses and substances applied for

Applicant 1 (submitting)

Company name of submitting applicant Use 1 for Substance 1
 Use 2 for Substance 1

Applicant 2

Company name of applicant 2 Use 1 for Substance 1
 Use 2 for Substance 1

Applicant 3

Company name of applicant 3 Use 1 for Substance 1
 Use 2 for Substance 1

* Email of submitting applicant
 Please ensure that the email address is correct, as ECHA will communicate important information related to your submission, e.g. the application form in .PDF format, and the submission code or the token.

* Confirm email

I would like to receive the application form file (.PDF format) at the above email address (an email will be automatically sent after clicking on the "Create application form" button). I understand and accept that the email (and its attachments) sent by ECHA will not be encrypted and may therefore be liable to be compromised. ECHA does not, to the extent permitted by law, accept any liability for any external compromise of security and/or confidentiality in relation to transmissions sent by email.

I wish to download myself the application form file (a new screen to allow the download of the application form in PDF format will appear after clicking on the "Create application form" button)

- Step 10.** Before creating the form, the submitting applicant needs to type the text visible in the user identification box (CAPTCHA) in the field above the *Create Application* button.
- Step 11.** Click the *Create application form* button.
- Step 12.** The information provided during creation of the application form will be included in a .PDF file (from now on mentioned as "application form") that is automatically generated when the web-form is submitted.
- Step 13.** If the *receipt via email* option was selected, then an email will automatically be sent. If the *download* option was selected above, then a new screen will appear allowing the applicant to download the generated files.
- Step 14.** If the *download* option is selected, it is important that the applicant saves (by downloading from the screen which will appear after clicking *Create application form*) the two files generated by the web-form and retains them.
- Step 15.** The submitting applicant will receive an email (or will be requested to download the files) including the application form and further instructions. ECHA will make preliminary checks to ensure the consistency of the information provided in Web-form 1. In case of any inconsistencies, the applicant will receive a notification to the email address provided in the web-form. If all the data in the created application form are valid, the applicant will receive a security token related to this joint

application to the email address provided in the web-form. After verifying that all information in the application form is correct, the submitting applicant shall then provide the application form and the security token to the co-applicants. To proceed with the application, go to chapter 8.2: Confirming participation in a joint application. If the application form includes incorrect information, the submitting applicant needs to create a new application form.

Note that the creation of the application form does not constitute a submission of an application for authorisation.

Step 16. As described in the following chapter (8.2), the co-applicants need to confirm their participation to the joint application by uploading a copy of the application form along with further information. Then, the application form needs to be attached in IUCLID section 13 (see chapter 7.11). Finally the IUCLID dossier of the application for authorisation needs to be submitted as described in chapter 11 *How to submit dossier*).

8.2. Confirming participation in a joint application

If you are the submitting applicant of a joint application, skip this step and proceed to chapter 8.3.

After the submitting applicant has completed the creation of the application form, the co-applicants need to receive the application form in .PDF format and the security token for the joint application from the submitting applicant.

The information included in the application form shall be carefully verified by all co-applicants. Check in particular that the following information that you have provided to the submitting applicant is correctly displayed in the form:

- i. the legal entity name and the legal entity UUID of your company (note that only the first and last characters will appear in the application form) are included in the form and they are consistent with the data in your REACH-IT account. This information can be found in REACH-IT under the section *Company information*;
- ii. the role(s) of your legal entity for the purpose of the application for authorisation is(are) correct;
- iii. the mapping of the use(s) and substance(s) "applied for" is correct and corresponds to your legal entity's intentions.

If the information in the application form is not correct, you shall notify the submitting applicant who needs to create a new application form. In that case, ignore the application form and token sent to you and wait for the corrected application form and the new token to be communicated again to you (and to all the co-applicants) by the submitting applicant. After you have verified the new .PDF file you can proceed by confirming your participation in the joint application.

You should not confirm your participation in the joint application unless you have carefully verified all the information included in the application form.

Ensure also that the company size, contact information, and the company address indicated in your REACH-IT account, under the section *Company information*, are up to date. Note that ECHA will use this information when communicating with the applicants, and

furthermore ECHA will use the company size of each applicant to determine the fee for your application.

To confirm your participation in the joint application, go to the webpage for “How to apply for authorisation” (located at: <http://echa.europa.eu/web/guest/applying-for-authorisation>), click on *Submit your application* and then click on the link to the Web form 2 (Confirm your participation) (Web-form 2: https://comments.echa.europa.eu/comments_cms/AuthorisationApplication_ConfirmParticipation.aspx) and follow the steps below (Figure 12).

- Step 1.** Enter the token provided by the submitting applicant in section *Token and Application form*.
- Step 2.** Upload the application form (.PDF) that you received from the submitting applicant. For uploading the file, click on *Browse* to open a dialogue box which allows you to select the application form file.
- Step 3.** Under *Applicant info* enter the legal entity UUID and the legal entity name of your company as they appear in your REACH-IT account. Ensure that this information matches also the data in the application form (in particular for the UUID, you will have to provide the complete number, although only part of the number is revealed in the PDF file).

Figure 12: Web-form 2: Confirm your participation in a joint application

Confirm participation in joint application for authorisation

Fields marked with an asterisk () are mandatory.*

Token and Application form

* Token provided by the submitting applicant

* Application form provided by the submitting applicant
After verification of its content, please upload the PDF file of the application form which has been provided to you by the submitting applicant.

Applicant info

* Company UUID
as indicated in the REACH-IT account

* REACH IT account user name

* Legal entity name
as indicated in the REACH-IT account

* Email

* Confirm email

* Declaration I declare that I am an authorised representative of the applicant legal entity for the purpose of submitting the joint application for authorisation and I am authorised to transmit and to receive documents on behalf of this applicant

- Step 4.** Enter your REACH-IT account user name. This username needs to belong to an existing user with submission rights; therefore it shall be a user with either a “Company Manager” or “Company Normal” role (not “Company Reader”).

- Step 5.** It is important that the company size, contact information, and the company address indicated in your REACH-IT account, under the section *Company information*, are correct. ECHA will use the company size to determine the fee for your application. The Commission will use the company address at the end of the process to send to the applicant the final decision on the application for authorisation.
- Step 6.** Enter a valid email address. A preliminary confirmation of your participation in the joint application will be sent to this email address.
- Step 7.** Before submitting the form, type the text visible in user identification box (CAPTCHA) in the field above the *Join application* button.
- Step 8.** Click the *Join application* button to confirm your participation in the joint application.
- Step 9.** You will then receive an email with a preliminary confirmation of your participation in the joint application. ECHA will make preliminary checks to ensure the consistency of the information provided in Web-form 2. In case of any inconsistencies (for instance if the provided REACH-IT account does not exist), at the following days you will receive a notification about the error by email to the email address you provided in the specific web-form.

Note that at this stage ECHA will not send any notification in case your confirmation of participation was successful. After it has been verified that all co-applicants have successfully confirmed their participation in the joint application ECHA will inform the submitting applicant that the creation of the joint application is complete.

The confirmation of participation in a joint application does not constitute the submission of an application for authorisation. Only after all co-applicants of the joint application have confirmed their participation, the submitting applicant has uploaded the IUCLID dossier and the dossier has passed the Business Rules check, the application is considered successfully submitted.

The next instance that co-applicants will be contacted by ECHA is some time after the submitted IUCLID dossier has passed the Business Rules check, in order to inform them regarding the main steps and timelines in the processing of their application (see chapter 11.1). Therefore, at this stage co-applicants are advised to be in contact with the submitting applicant for getting informed about the status of the submission process.

8.3. Receiving the joint application confirmation from ECHA

After ECHA has verified that all co-applicants have successfully confirmed their participation in the joint application (see chapter 8.2), the submitting applicant will receive by ECHA via email a confirmation that the creation of the joint application is complete.


Attach the application form to section 13 of the IUCLID substance dataset as indicated in chapter 7.11.3 and proceed with creating the IUCLID dossier for the application for authorisation.

9. How to create a Dossier


Once you have included all relevant information in your substance dataset, the next step is to create a dossier.

Before creating a dossier you are advised to check the completeness of your substance dataset by running the *Validation assistant*. For more information on how to run the Validation assistant refer to the help system of IUCLID.

This may also be a good time to verify if the quality of the dataset can be improved before creating a dossier, please check the webpage *How to improve your dossier* on the ECHA website: <http://echa.europa.eu/support/how-to-improve-your-dossier>

- Step 1.** To create a dossier open the list of available substance datasets by clicking on the *Substance*  on the IUCLID home page.
- Step 2.** All available substances (within the limits of the search results managed in the user's preferences) are displayed in the navigation panel on the left part of the screen. If a substance does not appear in the list you can search for it using the search panel. If the list is very long, you can also filter by typing (part of) the name of the substance in the filter field.
- Step 3.** Select the substance for which you want to create a dossier.
- Step 4.** Right-click on the substance in the query results list. From the pop-up menu select *Create dossier*.
- Step 5.** After selecting the *Create dossier* option the dossier creation wizard is displayed. Follow the steps in the dossier creation wizard.

Only two steps are displayed in the dossier creation wizard as the default option: *Select submission type* (1) and *Complete the dossier header* (5). If you wish to change the default settings to have more options you can select the checkbox *Use advanced settings*.

- Step 1. Select the submission type.** Choosing the correct dossier template by selecting the submission type is essential for a successful submission. Before exporting your dossier you have to make sure that the selected template corresponds with the intended submission.
When the checkbox *Use advanced settings* is selected follow the steps 2-4, if the default settings are kept (recommended approach), go to step 5 directly.
- Step 2.** Define the confidentiality level by selecting the data protection flags. If you have included any confidentiality or regulatory programme flags in your substance dataset, please make sure that the relevant information is included in your dossier by selecting the appropriate flags in this step. If you are unsure it is recommended to select the defaults option 'all fields - including confidential test material'. ECHA will assess the confidentiality of the information and the justifications provided. You can find more information on the publication of part of the dossier on the ECHA website at <http://echa.europa.eu/manuals>.
- Step 3.** Select whether the annotations should be included in the dossier.
- Step 4.** Verify and select which documents and entities will be included in your dossier. To this end, select in the Entities list the substance entity which will be preceded by . The documents and entities connected to the substance will be listed in the References to window; documents to be included are already checked. Certain documents, such as section 1.1, will always be included in a dossier, and cannot be excluded in this step. Likewise, depending on the submission type, some documents will not appear in the list and cannot be included as they are not relevant for the selected submission type. If you are unsure of the information to be included, you can select Next and rely on the default settings for that submission type.
- Step 5. Complete the dossier header** by entering additional administrative information.

Information contained in the dossier header is crucial for business rules checking when you submit your dossier. Missing or incorrect information can result in that your submission cannot be accepted for further processing and will be automatically removed from the system. In this case you need to create a new dossier with corrected information and submit it again. For more information refer to the Annex: *Overview of the business rules checks performed by ECHA on the submitted dossiers*.

The following subchapters describe how to fill in the administrative information in the dossier header.

Note that the instructions here do not cover completely applications for specific types of dossiers such as applications for more than one substances or subsequent applications as defined in Article 63 of REACH. For such applications, before a dossier is created please check the additional specific instructions provided in the respective chapter of this manual (for applications for several substances please see chapter 7.2; for subsequent applications, updates and review reports please see chapter 13.3).


9.1. Name of the dossier

In the field *Dossier name (given by the user)*, enter an appropriate name which enables you to easily identify the dossier when searching or exporting it from IUCLID. It may be useful to refer to the substance name and the dossier version, in case several were created.

9.2. Specific submissions

See chapter 13 for specific submissions (i.e. updates, subsequent applications and review reports).

10. How to export a Dossier

To start the export process, first search for the Dossier  in the navigation panel of the IUCLID application. When the Dossier is shown in the list of search results, right-click on its entry, and then *select* Export from the menu.

For details on the export wizard, see the help that is built in to the IUCLID application.

11. Submit Dossier

To submit your dossier to ECHA you must sign-up in REACH-IT with the legal entity details of the submitting entity, and follow the instructions provided there for your specific type of submission.

You can access REACH-IT from ECHA website: <http://www.echa.europa.eu/> or go directly to the REACH-IT website: <https://reach-it.echa.europa.eu/>.

The dossier including a substance dataset of a joint application shall be submitted to ECHA by one legal entity herein called "submitting applicant".

ECHA has established preferred submission windows for submitting applications for authorisation (see submission dates at: <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/afa>). This relates mainly to the need for synchronisation with the scheduled meetings of ECHA's Risk Assessment and Socio-Economic Analysis Committees, and intends to ensure the workability and efficiency of the opinion-making process of the Committees. Uploading your application within these windows can ensure the minimum processing time for your application by ECHA and its Committees. Uploading during the first days of these windows can in fact reduce the risk of missing a specific period's deadline due to failing the business rules check, which could result in a delay up to three months before the invoice can be issued.

It is important that the company size, contact information, and the company address indicated in your REACH-IT account, under the section *Company information*, are correct. ECHA will use the company size to determine the fee for your application. The Commission will use the company address at the end of the process to send to the applicant the final decision on the application for authorisation.

After having uploaded the dossier, the applicant is required to monitor their REACH-IT message box to follow the progress of their application. In case the dossier cannot be accepted for processing, ECHA will communicate the reason to the applicant by a REACH-IT internal message, and the applicant is asked to submit a new application.

For further information on the use of REACH-IT message box, please consult the help system of REACH-IT.

11.1. Receiving your submission number

After the application (IUCLID dossier) has been uploaded, REACH-IT will automatically issue a preliminary submission number for the application. After this the application is processed by REACH-IT in a series of steps.

In case any of these preliminary checks (virus check, file format validation, XML format check, business rule check) fails, the applicant is asked to modify their substance dataset, create a new dossier and upload it in REACH-IT. REACH-IT will issue a new preliminary submission number for the application.

When the business rule check passes, the applicant is informed, via REACH-IT internal message, of the submission status of their application, and the preliminary submission number will be considered as a submission number.

After the Business Rules check has been passed, and before the invoice is sent, ECHA will

- a. inform the applicant(s) regarding the main steps and timelines in the processing of their application
- b. review the proposed "brief wording" on uses that will be published as part of the broad information on uses on ECHA's website for the purpose of public consultation [Art. 64(2)] (see also chapter 7.6.4.2).
- c. ECHA will establish an initial version of the "brief wording" and will invite the applicant to provide comments within a specified deadline. On the basis of the applicant's comments ECHA will establish and communicate to the applicant the final "brief wording" of the broad information on uses.

The notice(s) on the "brief wording" of the broad information on uses and the invoice are sent to the applicant via REACH-IT annotations. In case of a joint application, the notice(s) on the "brief wording" of the broad information on uses and a single invoice are sent to the submitting

applicant. Invoice information and a copy of the notice on the “brief wording” are provided to the co-applicants.

After successful payment of the invoice, a message will be sent to the applicant via REACH-IT, acknowledging the “date of receipt” of the application and the application for authorisation reference number. In case of a joint application, the message will be sent to the submitting applicant as a REACH-IT annotation and a copy will be provided to the co-applicants.

12. Next steps: the opinion and decision making procedure

Once the date of receipt has been set, the application file will be handed-over to ECHA’s Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC), who will immediately start performing their tasks in the framework of the opinion-making process. In parallel, a public consultation will be launched by ECHA on its website to collect information from third parties on possible alternatives.

ECHA’s Committees may request the applicant to submit (within a specified time period) additional information to bring the application into conformity; the Committee for Socio-Economic Analysis may also require the applicant to submit additional information on possible alternative substances or technologies. Such requests will be communicated to the applicant via REACH-IT. In the case of a joint application, requests and other communication (e.g. draft and final opinions) from ECHA’s Committees will be sent to the submitting applicant and copies will be provided to the co-applicants via REACH-IT.

Any communication by ECHA requesting additional information will specify whether the applicant (submitting applicant, in case of joint application) needs to update the IUCLID dossier (see chapter 13.1 on “Requested update”) and submit it as described in chapter **Error! Reference source not found.**, or he should provide the information via a dedicated web-form instead (update of the IUCLID dossier is basically foreseen for cases of requests to bring an application into conformity).

After the draft opinion is finalised it will be sent to the applicant(s) via REACH-IT. The applicant (submitting applicant, in case of joint application) shall notify ECHA of his intention to comment the draft opinion within one month of receipt of the draft opinion. The comments shall be sent to ECHA via a dedicated web-form (link to be provided in ECHA’s communication) within two months of the receipt of the draft opinion. In case of a joint application, comments to the draft opinion shall be sent by the submitting applicant.

The final opinions of ECHA’s Committees will be sent to the Commission, the Member States and the applicant(s).

The final decision from the Commission will be sent to applicant(s) via registered post. The Commission will use the address(es) specified as general contact in the applicants’ REACH-IT account. The letter will be addressed to the contact(s) (First name and Last name) of the REACH IT account(s). Authorisation numbers will be included in the decision letter for all the substances and uses the authorisation was granted.

13. Specific submissions

This section provides instructions on how to submit:

1. updates as requested by the Committees in the context of Article 64(3);
2. subsequent applications as defined by Article 63;
3. review reports in the context of Article 61.

If for any of the above purposes you need to submit further updated (or reviewed) information on your application for authorisation dossier, you do not need to re-type again all your substance data. Instead you can update the information in your substance dataset.

To edit the substance dataset, select it from the navigation panel and fill in or update the relevant data. When the dataset is ready you can create a dossier (see section 9. How to create a Dossier).

When creating your dossier, specify the type of specific submission in step 6 of the dossier creation wizard (dossier header).

To export and submit the dossier, please refer to chapters 10 and **Error! Reference source not found.** of this manual.

13.1. Requested update (to bring the application in conformity)

In case of an update made on request of the Committees as per Article 64(3), and in particular in the specific situation where this is a request to bring the application in conformity, you may be requested to resubmit to ECHA the updated version of your initial IUCLID dossier and attach in IUCLID section 13 a document indicating where exactly you have made the updates (e.g. IUCLID sections and/or sub-sections, attachments and/or their related parts etc).

When creating your updated dossier the checkboxes *The submission is an update* and consecutively *Further to a request/decision from regulatory body* must be selected. The last submission number and the annotation number in the request letter must be entered in their respective adjacent fields.

13.2. Spontaneous update

This type of update is not allowed and will not be processed by ECHA.

Please ensure that the checkbox *Spontaneous update* is not selected.

13.3. Subsequent application

In case of subsequent applications made in accordance with Article 63(1) and (2) please submit to ECHA your initial IUCLID dossier as instructed in chapters 10 to **Error! Reference source not found.** of this manual.

IUCLID sections 1.1, 1.2, and 1.3 cannot be covered by a reference to parts of a previous application. You need to complete them as instructed in chapters 7.4.1, 7.4.2, and 7.4.3 of this manual.

All "uses applied for" in a subsequent application must be listed in the IUCLID section 3.10:

- a. to ensure the clarity and the workability of a subsequent application it is strongly recommended that the applicant submits a subsequent application only if he/she refers to the same combination of use(s) and substance(s) already submitted in a previous application.
- b. uses that refer to other applications must keep the same description (e.g. name and descriptors) and if possible the same numbering. It is also strongly recommended that i) you attach in the IUCLID section 3.10 as described in chapter 7.6.7, the (updated) assessment reports that you are referring to, and ii) you provide clear justifications on the reasons why you refer to a previous application, and demonstrate the relevance and the purpose, of that reference, for your application. These justifications can be made in

the corresponding "Remarks" field of the main repeatable block of IUCLID section 3.10. Please see chapter 7.11.1 when referring to a CSR which is not part of your application.

- c. Attached (updated) assessment reports for uses referring to other applications will be the actual versions to be considered by ECHA for opinion forming; i.e. they have precedence over the assessment reports in the application referring to.
- d. For solely referred (not attached) assessment reports ECHA will retrieve the versions which correspond to the "last submission number" of the application referring to, as indicated by the applicant. Any potential further updates of the previous application (the application referring to) submitted by the previous applicant will not be considered for opinion forming¹¹.
- e. uses that do not refer to other applications must be documented in IUCLID section 3.10 as instructed in part 7.6.7 of this manual. They must also be linked to an accessible CSR via the reference to the exposure scenarios in IUCLID section 3.5. (see chapter 7.6.4.2);

Written and valid permissions from the previous applicant(s) must be attached under the block *Reference to other applications or previous authorisations* in IUCLID section 3.10.

It is important that you clearly indicate the parts of the other applications that you refer to. This information should be attached as a document in IUCLID section 13.

Furthermore, IUCLID section 13 must contain the application form as generated by the Web-form 1 (see chapter 7.11.3 and chapter 8 of this manual).

When creating your dossier: ensure that in the dossier header *The submission is a subsequent application* is selected. If you submit an application under Article 63(1), please write the last submission number of the application you are referring to in the *Last submission number* free text field.

13.4. Review report

In case of a review report, please resubmit to ECHA your reviewed/updated IUCLID dossier.

- i. IUCLID section 13 can be used to attach a document indicating exactly the parts that you have updated;
- ii. IUCLID section 1.3 must be filled in with the previous authorisation number. See chapter 7.4.3;
- iii. When creating the dossier, in the dossier header the checkbox *The submission is a review report* must be selected. No last submission number needs to be indicated in the *Last submission number* free text field.

¹¹ All updates receive a new submission number, which will therefore be different from the last submission number indicated

Annex 1. Overview of the business rules checks performed by ECHA on the submitted dossiers

Business rules are a set of dossier format and administrative pre-requisites that must be fulfilled before ECHA can establish that the dossier can be handled properly and that the required regulatory processes can be successfully carried out. Business rules do not assess the completeness of the data provided or conformity of an application. If the dossier submission fails at the business rule level, the dossier will be automatically removed from the system, and a new submission is required before any regulatory processes can be initiated.

This document will guide you through the basic requirements of creating the substance dataset and the IUCLID dossier header. In addition, it is recommended to use the IUCLID Validation Assistant plugin on the substance dataset and also on the final dossier before exporting it from IUCLID. Right-click on your substance dataset or on the dossier in the IUCLID navigation panel and select *Validate*. This plugin will check only some of the business rules. For instance some of the business rules depend on the submission context (e.g., validity of reference number, duplicate submissions, etc.), and therefore the plugin cannot simulate all the business rules checked by the Agency.

Business Rules applicable for Application for Authorisation		
Location (IUCLID/REACH-IT)	Rule description	Relevance
IUCLID substance dataset	An application for authorisation dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset.	Application for Authorisation
IUCLID substance dataset	If you wish to include a category in the dossier, you need to create the dossier from a substance dataset that has been assigned to the category.	Application for Authorisation
IUCLID – all sections	An application for authorisation must be submitted in one of the official EU languages.	Application for Authorisation
IUCLID section 1.1 – Identification	Select a role in the supply chain in IUCLID section 1.1.	Application for Authorisation
IUCLID section 1.1 - Identification	The ‘Only representative’ as a role in the supply chain cannot be marked together with ‘Manufacturer’ or ‘Importer’. Separate legal entities are required for each non-EU manufacturer represented.	Application for Authorisation
IUCLID section 1.1 – Identification	A reference substance must exist in section 1.1.	All dossier types
IUCLID section 1.1 – Identification; section 1.2 – Composition	Each reference substance in section 1.1 and 1.2 must contain a substance identifier. An acceptable substance identifier is: - EC/List number - CAS number - IUPAC name	Application for Authorisation

	<p>Any EC/List number defined in section 1.1 and 1.2 of IUCLID must exist in the REACH-IT EC inventory.</p> <p>If you use a reference substance to report unknown constituents/impurities, they must be “identified” by inserting “Unknown constituent/impurity” in the IUPAC name field.</p>	
IUCLID section 1.1 – Identification	In IUCLID section 1.1 you must select a 'Type of substance'. If you select 'other:', the adjacent text field must be filled in.	Application for Authorisation
IUCLID section 1.2 – Composition	<p>At least one composition must be defined in section 1.2. The following requirements are also to be fulfilled:</p> <p>All created compositions must contain at least one constituent.</p> <p>All constituents must be linked to a reference substance.</p>	All dossier types
IUCLID section 1.2 – Composition	<p>All compositions created in section 1.2 must have the composition type indicated. At least one of the compositions in section 1.2 must reflect the composition of the substance supplied for the uses applied for. This composition must be marked as the “Legal entity composition of the substance”.</p> <p>If the composition type “other” is selected from the list, the relevant information must be provided in the adjacent free text field.</p>	Application for Authorisation
IUCLID section 1.1 – Identification; section 1.2 – Composition	If the substance is defined as mono-constituent, the first ‘legal entity composition of the substance’ in section 1.2 has to have a matching substance identity when compared with the reference substance in section 1.1.	All dossier types
IUCLID section 1.1 - Identification; section 1.2 – Composition	If the substance is defined as a multi-constituent substance, the reference substance in section 1.1 cannot be identical to any of the constituents defined in the first composition of type ‘legal entity composition of the substance’ in section 1.2.	All dossier types
IUCLID section 1.2 – Composition	All constituents of a multi-constituent or of a UVCB substance must identify distinct reference substances.	All dossier types
IUCLID section 1.2 – Composition	You must provide the full 'Concentration range' (lower and upper value together with a unit) for each constituent of a ‘legal entity composition of the substance’ in IUCLID section 1.2. If you are reporting a constituent at exactly 0% or 100%, provide this value, together with the unit, in the field 'Typical concentration' and leave the 'Concentration range' fields empty.	Application for Authorisation
IUCLID section 1.3 – Identifiers	If you wish to submit a review report of an application for authorisation then ensure that you indicate the correct authorisation number in section 1.3 of the dossier. The authorisation number must correspond to the same substance and same uses or part of the uses (or uses of more limited scope than the ones in the first application).	Application for Authorisation

IUCLID section 1.3 - Identifiers	Indicate a REACH Annex XIV entry number in section 1.3 of your IUCLID dossier. This must be consistent with the substance identity described in sections 1.1 and 1.2. If you are applying jointly, please also verify that the entry numbers in your application form and the IUCLID section 1.3 match.	Application for Authorisation
IUCLID section 1.3 – Identifiers; dossier header	If you are submitting an application for authorisation of the type 'Subsequent application' then your dossier is expected to refer to a previous application for authorisation, either by indicating a valid submission number in the dossier header's field 'Last submission number' or a valid authorisation number in section 1.3 under 'Regulatory programme identifiers'.	Application for Authorisation
IUCLID section 1.3 - Identifiers	If you wish to provide REACH registration number related to your application in IUCLID section 1.3, the number has to be a valid registration number.	Application for Authorisation
IUCLID section 3.5 – Use and exposure information	In IUCLID section 3.5 there must be a use (record) corresponding to each 'Use concerned by the request' in IUCLID section 3.10. Each of these uses in IUCLID section 3.5 must indicate a clear reference to an exposure scenario (number, title, or pages in CSR) under the “Remarks” field.	Application for Authorisation
IUCLID section 3.10 - Application for authorisation of uses	At least one record must be included in IUCLID section 3.10. Each record must contain a use description in the field 'Use concerned by the request' and must be linked to a use (record) in IUCLID section 3.5.	Application for Authorisation
IUCLID section 3.10 - Application for authorisation of uses	Attach document(s) in IUCLID section 3.10 under the 'Analysis of the alternatives' header covering each use applied for. If necessary, provide any additional comment in the “Remarks” field.	Application for Authorisation
IUCLID dossier template	The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT.	All dossier types
IUCLID section 3.10 - Application for authorisation of uses	If you are submitting an application for authorisation of the type 'Subsequent application' then your dossier is expected to include an attachment (permission to refer) in section 3.10 under 'Reference to other applications or previous authorisations'.	Application for Authorisation
IUCLID section 13 – Assessment reports	If your dossier is for a joint application for authorisation then please include a joint application form in the section 13 of your IUCLID dossier.	Application for Authorisation
IUCLID section 13 – Assessment reports	The application form in IUCLID section 13 must be identical with the application form of the complete joint application.	Application for Authorisation
IUCLID section 13 – Assessment	The application form attached in the IUCLID section 13 must be for a complete joint application. ECHA will inform the submitting applicant when all the co-applicants have	Application for Authorisation

reports	confirmed their participation and the joint application is complete. In case the joint application cannot be completed, please proceed to create a new joint application form .	
IUCLID section 13 – Assessment reports	The names of the uses applied for in the joint application form must match the names of the 'Use concerned by the request' in IUCLID section 3.10.	Application for Authorisation
IUCLID dossier header	If you have been requested to submit an update dossier then the reason for updating must be "Further to a request/decision from regulatory body". Tick the appropriate tickbox in the dossier header when creating your dossier and provide the relevant information in the adjacent fields.	Application for Authorisation
IUCLID dossier header	If you have been requested to send an update, the last submission number and the communication number in the dossier header have to be correct.	All dossier types
REACH-IT	You are expected to submit the dossier for your joint application using the same REACH-IT account as you have indicated while creating the joint application form.	Application for Authorisation
REACH-IT	Parallel submissions are not allowed for the same annotation number. You cannot submit a dossier quoting the same annotation number while another dossier is still being processed.	Application for Authorisation
REACH-IT	Parallel submissions are not allowed for the same applicant, substance, and use. You cannot submit a dossier while another dossier for the same applicant, substance, and use is being processed.	Application for Authorisation
REACH-IT	No submissions can be made from the account of a legal entity, which at the time of submission undergoes the legal entity change (merge) process.	Application for Authorisation
REACH-IT	The same IUCLID dossier cannot be submitted more than once.	Application for Authorisation

Before you complete your IUCLID dossier, make also sure that you have provided the following information.

Identification of the uses:

Table 2 Checklist: minimum information needed to identify “uses applied for”

√ / X	Minimum Information
	Consistent numbering of the uses (to be used in a consistent way in all parts of the IUCLID dossier, assessment reports and the application form for a joint application).
	Clear and consistent name for each use.
	Clear and consistent description of each use (based on the use descriptor system).
	Information about the technical function of the substance.
	For each use, a reference to (a) relevant exposure scenario(s).
	The application form (in case of joint application - see chapter 8)
	For each “use applied for” a non-confidential broad description (“brief wording”) that can be published on ECHA website for public consultation.

Assessment reports:

Table 3 Checklist: minimum assessment reports needed

√ / X	Minimum Information
	Chemical Safety Report if not provided yet as a part of a REACH registration.
	REACH Registration number in case a Chemical Safety Report was already submitted as part of a registration.
	For each use for which you apply for an authorisation: → an analysis of the alternatives; → a substitution plan (where relevant); → a socio-economic analysis (where relevant - recommended to include also for adequate control route applications). → a succinct summary table of representative RMM and OC

It is recommended that the assessment reports are .PDF documents.

Legal entities and mapping:

Table 4 Checklist: Legal entities and mapping

√ / X	Minimum Information
	REACH-IT legal entity name of all applicants (for joint applications as generated by Web-form 1 – see chapter 8).

√ / X	Minimum Information
	REACH-IT legal entity UUID of all applicants (for joint applications as generated by Web-form 1 – see chapter 8).
	Role in the supply chain for each applicant (for joint applications as generated by Web-form 1 – see chapter 8).
	A mapping of uses per applicant and per substance (for joint applications as generated by Web-form 1 – see chapter 8).
	In case of an Only Representative, name and address of the company represented.

Contact information:**Table 5 Checklist: contact information**

√ / X	Minimum Information
	First and last name of the contact person (to be provided in REACH-IT).
	Phone number of the contact person (to be provided in REACH-IT).
	Email address of the contact person (to be provided in REACH-IT and in the web-forms).
	Complete address of the contact person (to be provided in REACH-IT).

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