

Data Submission Manual

Part 22 - How to Prepare and Submit an Application for Authorisation using IUCLID 5



Document history

Version	Changes
1.0	First version

Reference: ECHA-11-B-03-EN

Issue date: April 2011

Language: English

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http://echa.europa.eu/help/echahelp_en.asp

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1 INTRODUCTION

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 in chapter 5, the IUCLID 5 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 users' manual is to help the applicants to identify which of the numerous IUCLID 5 fields are of prime importance for a successful submission of an application: all the "mandatory" sections (see chapter 5.2) need to be filled-in to enable ECHA to process the application. The generated IUCLID 5 application for authorisation dossier can then be submitted to ECHA using a specific web-form (see chapter 9 of this manual). Currently applications for authorisation cannot be submitted through REACH-IT. This functionality will become available at a later stage.

-  The sections of this manual marked with the symbol to the left indicate information essential for the processing of the application dossier.

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. Instructions on how to develop applications in IUCLID 5 for several substances (i.e. meeting the definition of a group of substances in paragraph 1.5 of the REACH Annex XI) are provided, but will be further developed in an update of this manual.

The manual assumes that IUCLID 5 has been installed and that you have a user account assigned to the Legal entity created during the installation of IUCLID 5 (for further instructions, see chapter 2). If IUCLID 5 has not yet been installed, please consult the IUCLID 5 website available at: <http://iuclid.echa.europa.eu>

On this website, you can download the software free of charge, and also find more comprehensive guidance about the use of IUCLID 5.

-  This manual is prepared to support dossier creation in IUCLID 5.3 and later versions.

If you have been using previous IUCLID 5 versions, the data must be migrated to upgrade to the new version. For more information please consult the IUCLID 5 website available at:

<http://iuclid.echa.europa.eu>

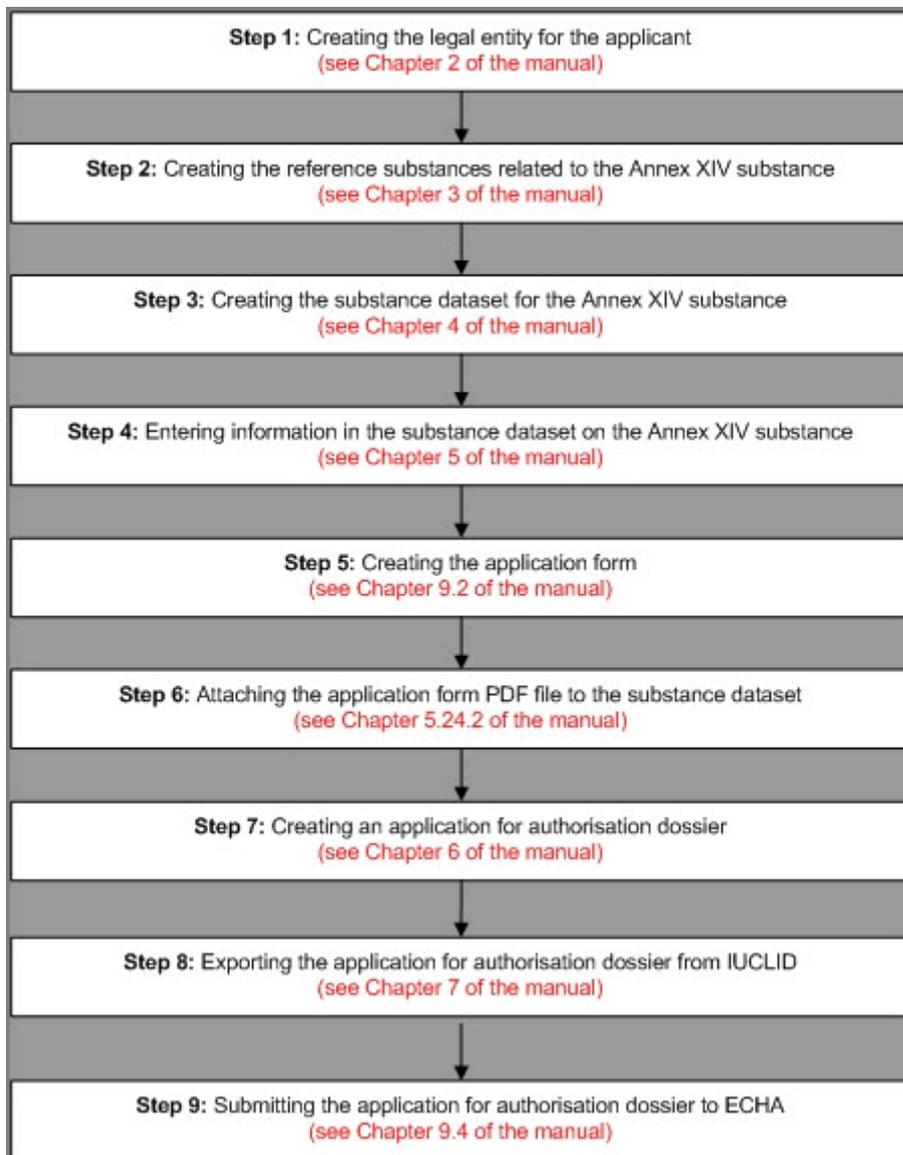
-  For more details on the authorisation process, you can consult:

- the FAQ available at:
http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp;
- the "Guidance on the preparation of an application for authorisation" at:
http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf;
- the "Guidance on the preparation of socio-economic analysis as part of an application for authorisation" at:

http://guidance.echa.europa.eu/docs/guidance_document/sea_authorisation_en.pdf

The figure below provides a stepwise approach for the preparation and the submission of an application for authorisation dossier in IUCLID 5:

Figure 1: Overview of an “application for authorisation” dossier creation in IUCLID 5



 If you are already a proficient user of IUCLID 5 and know how to create a Legal entity, reference substances and substance dataset, we advise you to go directly to chapter 5 of this manual where you will find information on how to fill-in your application for authorisation dossier.

2 LEGAL ENTITIES

-  If you are already a proficient user of IUCLID 5 and have already signed up in REACH-IT you are advised to go directly to chapter 5 of this manual where you will find information on how to create a substance dataset using the Authorisation template.

The “Legal entities” are used in IUCLID 5 to provide contact details on the companies involved in processes under REACH. Similarly, in the case of an application for authorisation, it is necessary to define the Legal entity of the applicant. Legal Entity information is stored in a so-called Legal Entity Object (LEO).

The most important piece of information in a LEO is the unique “company UUID”. This cannot be edited: it is read-only per LEO. REACH-IT uses only the company ID to identify the company in all the data processing it carries out. Therefore it is important that the UUID of the LEO is identical in all contexts the company identity appears in (IUCLID 5, REACH-IT, any web-forms submitted to ECHA).

An official LEO is required both for signing up in REACH-IT and for the installation of the IUCLID 5 application in a local environment. Depending on whether the company has signed up in REACH-IT and/or on the IUCLID 5 webpage, the following possibilities exist for ensuring LEO synchronisation between both applications (see Figure 2):

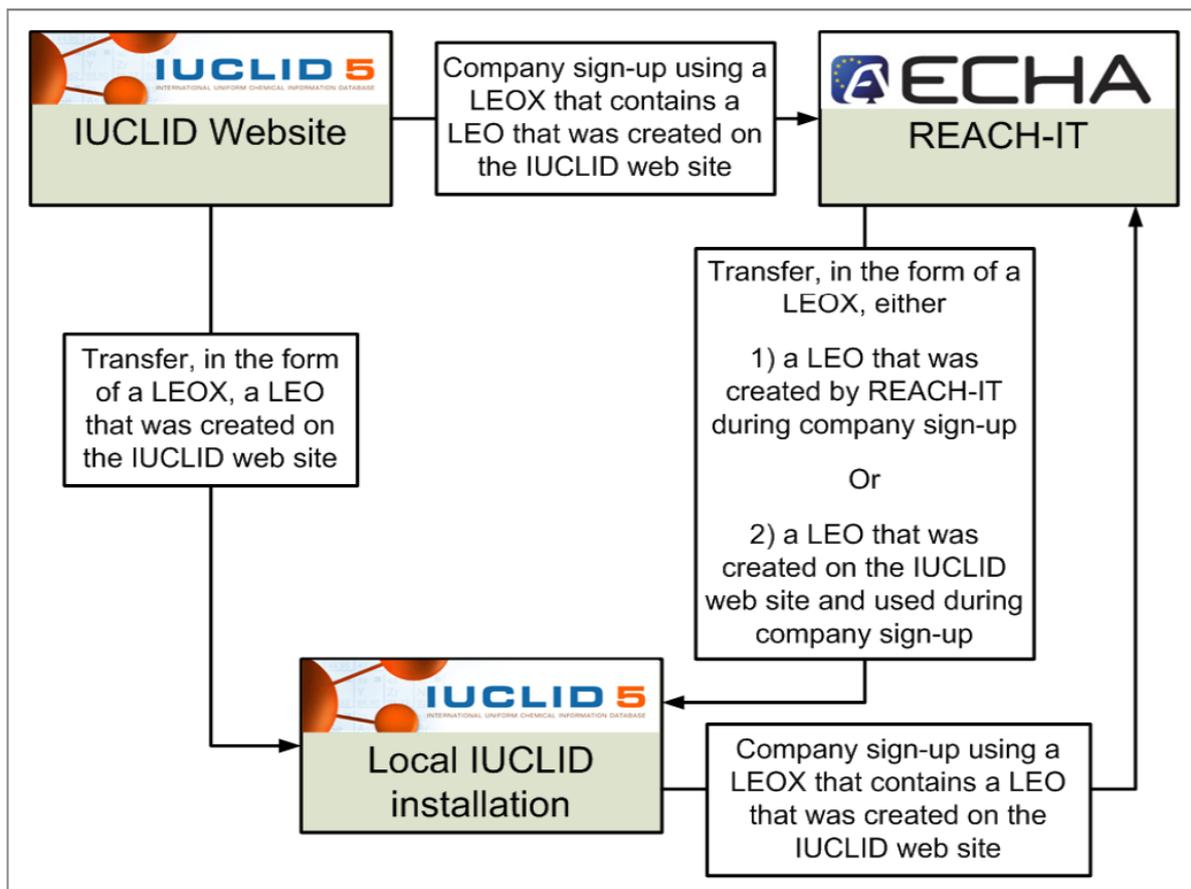
- If your company has not yet signed up in REACH-IT or on the IUCLID 5 website, the advisable way to create a LEO is on the IUCLID 5 website. The creation of an official LEO takes place during the installation and downloading of IUCLID 5 (for more details on how to download and install IUCLID 5 refer to <http://iuclid.echa.europa.eu>). The generated LEO XML file (LEOX) can then be imported into your local IUCLID 5 installation as well as into REACH-IT, ensuring the synchronisation of the information (Company name, contact information, UUID).
- If your company already has an active account in REACH-IT but has yet to install IUCLID 5, it is advisable to export the LEO XML file (LEOX) from REACH-IT into your local IUCLID 5 installation. This is done by going to the <Company> tab in the main menu of REACH-IT and selecting <Export>. The LEOX file will be saved on your local computer from where you can import it into IUCLID 5.
- If your company already has installed IUCLID 5 and created an official LEO on the IUCLID 5 website, but has yet to sign up in REACH-IT, it is advisable to import the existing LEOX file into REACH-IT during the sign-up process. This is done during step 2 of the signing-up process “Company information”, where the user is asked to upload an already existing LEOX.

If your company has a REACH-IT account and a IUCLID 5 installation, but you are unsure of whether the UUIDs between the two applications match, proceed as follows:

- Go to the REACH-IT main menu, and select <View> under the <Company>. The second row under “Company information” displays the company UUID in REACH-IT.
- In your IUCLID 5 installation, go to “Legal entity” in the main task panel. Select “Update” and double-click on the Legal entity of interest in the “Query results” list. The UUID of the company is displayed in the “Information” tab at the bottom of the IUCLID 5 window.

-  In the case of several Legal entities in IUCLID 5 with the same name but different UUID, it may be helpful to keep only the one that matches with REACH-IT as “Active trade partner”. To this end, right-click on the Legal entity in the “Query results” list and activate/deactivate the Legal entities as appropriate. The “Active trade partner” legal entities are displayed in bold text, whereas the inactive ones are in standard text. This operation is only for visual assistance and can be modified at any point.

Figure 2. Transfer of a LEO between the IUCLID 5 web site and REACH-IT via a LEOX file



-  The standard way of providing company information to REACH-IT during sign-up is to import a ready-made IUCLID 5 LEO in the form of a LEOX (Figure 2).

On sign-up, if a party does not have a ready-made LEO in a LEOX, REACH-IT can create a LEO using information entered manually by the party into the interface of REACH-IT (Figure 2).

-  For further information on how to create a Legal Entity Object (LEO) and how to synchronise it between IUCLID 5 and REACH-IT, please consult chapter 2.4 (“Legal Entity Object”) of the REACH-IT “Industry User Manual Part 02 – Sign-up and account management” at:

http://echa.europa.eu/doc/reachit/industry_user_manual/reachit_signup_accmngt_en.pdf

-  REACH-IT uses only the company ID to identify the company in all the data processing it carries out. Therefore it is important that the UUID of the LEO is identical in all contexts the company identity appears in.
-  Joint application: each co-applicant of a joint application must have an account in REACH-IT and hold an official Legal entity.

3 REFERENCE SUBSTANCES

-  If you are already a proficient user of IUCLID 5 and know how to create reference substances you may go directly to chapter 5 of this manual where you will find information on how to fill-in your application for authorisation dossier.

To correctly identify the Annex XIV substance subject to authorisation, it is important to understand the concept of Substance, Substance dataset and Reference substance in IUCLID 5.

The “application for authorisation” (dossier) is prepared for one or several substances that meet the definition of a group of substances in section 1.5 of Annex XI of REACH.

-  Even if an application for authorisation may be submitted for several substances that meet the definition of a group of substances in section 1.5 of Annex XI to REACH, this specific aspect is not covered in details in this manual.

In case you intend to submit an application for authorisation for a group of substances please contact the ECHA Helpdesk.

In IUCLID 5, the information related to the Annex XIV substance (such as the identity of the substance, its composition, etc) should be specified in the Substance dataset created for that substance.

To insert information on the identity of your substance and its constituents in the Substance dataset, you will need to use the concept of Reference substance. A Reference substance is a link to the identity of a chemical. The concept of 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 (e.g. EC number, CAS number), molecular and structural information, in a central place. This information can then be re-used in other datasets without having to retype the information. The Reference substance inventory is directly maintained by you, in your local installation.

To extend the number of entries in your Reference substance inventory, we recommend you to download the ca. 70,000 pre-filled Reference substances from the IUCLID 5 website and import them to your local installation (unless already done so during the IUCLID 5 installation). These pre-defined Reference substances have been prepared to improve data quality and minimise data entry.

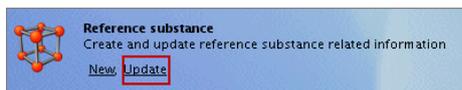
In addition, you should also download the EC inventory from the IUCLID 5 website (unless already done during the IUCLID 5 installation). This inventory consists of a list of substance identities which is based on a combination of the following EU inventories: EINECS, ELINCS and NLP-list.

In this section of the manual, you will find the procedure to be followed for searching, updating and creating the Reference substances to be assigned to your substance directly from the main task panel. Note that it is also possible to create a Reference substance directly from the Substance dataset (chapter 4).

3.1 Querying / updating Reference substances in your inventory

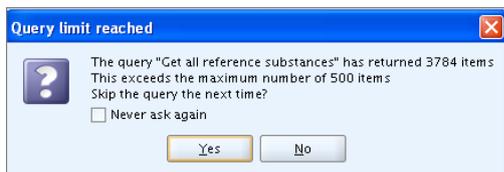
- Click “Update” under “Reference substance” on the main task panel (Figure 3).

Figure 3: Update link under the Reference substance



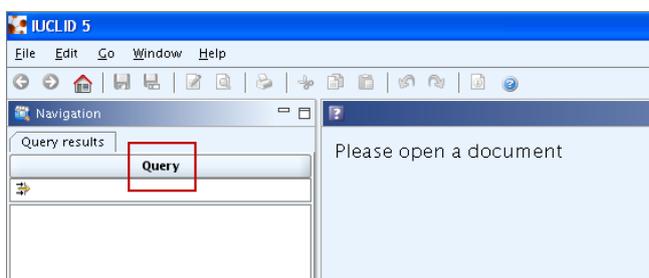
- If during the installation of IUCLID 5 you have chosen to download and install the Reference substance inventory, you will have approximately 70,000 Reference substances stored in your computer. A warning will appear, indicating that the default query limit is 500 items (Figure 4). If you answer “Yes”, the query for all Reference substances will be skipped the next time you update the inventory. If you answer “No”, IUCLID 5 will retrieve the full list of Reference substances the next time you choose to update the Reference substance inventory. Either way, you will be redirected to the Reference substances screen.

Figure 4: Query limit reached



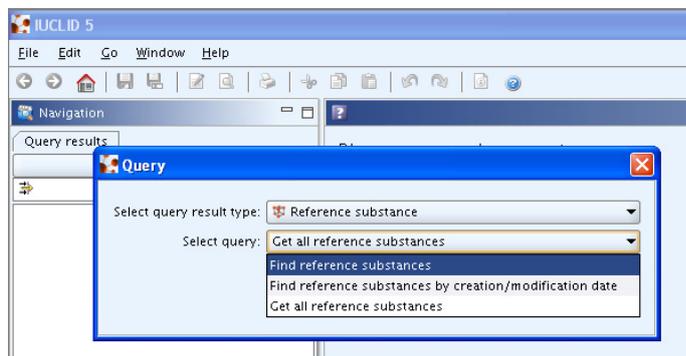
- Click the <Query> button (Figure 5).

Figure 5: Query button



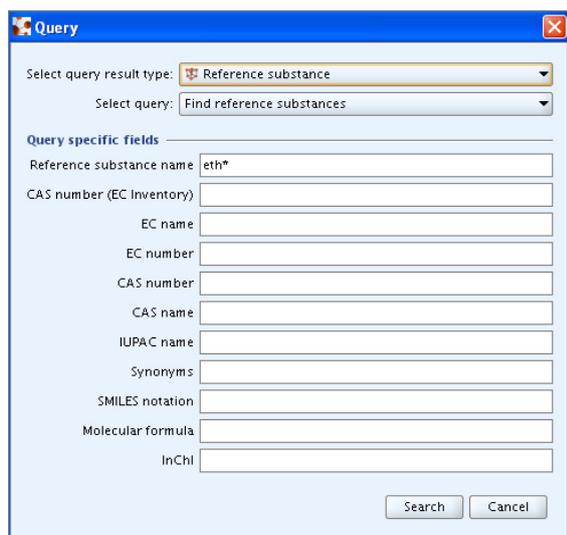
- A dialog box will appear. Select “Find Reference substances” from the “Select query” pick-list.

Figure 6: Query pick-list



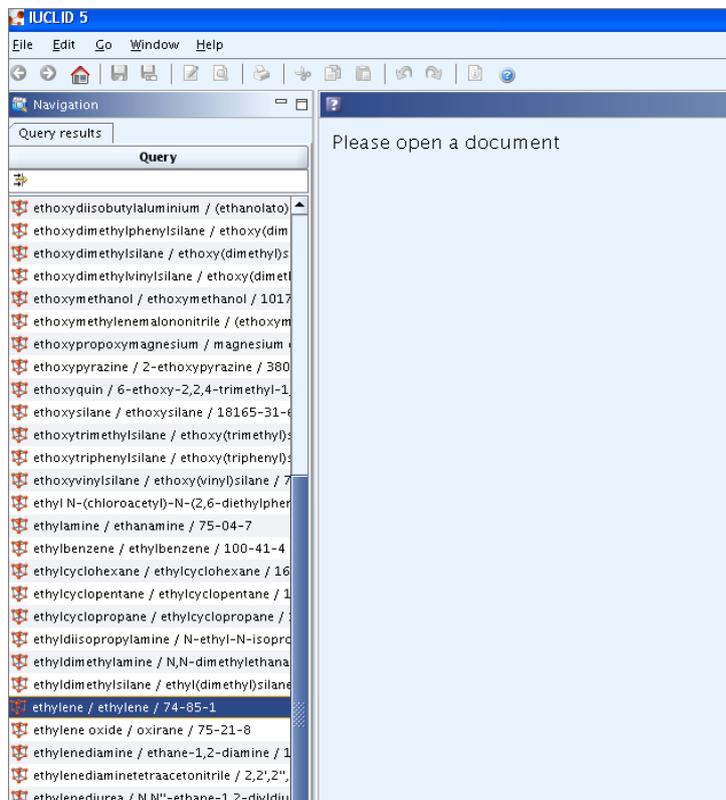
- Type the search criteria for the substance you are looking for and click <Search>. You can use the asterisk (*) as a wild card. For example, to get all the substances starting with “eth” you would type “eth*”. To get all the substances ending in “amine” you would type “*amine” (note that only 2000 results will be shown).

Figure 7: Searching for a reference substance



- Double click the Reference substance to display the related data (Figure 8).

Figure 8: Displaying data



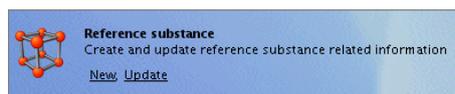
- Check the data on the Reference substance. To update/add any information on the Reference substance, click the <Edit item> button , edit the information on the Reference substance, and save the changes.

3.2 Creating a Reference substance

If you do not find in your Reference substance inventory the Reference substance you need, you can create it by the following procedure:

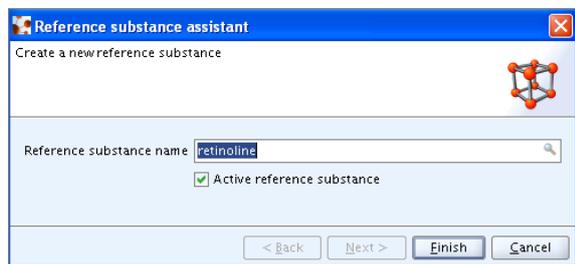
- In the Main menu, go to Inventories and click “New” under “Reference substance” (Figure 9).

Figure 9: New link under Reference substance



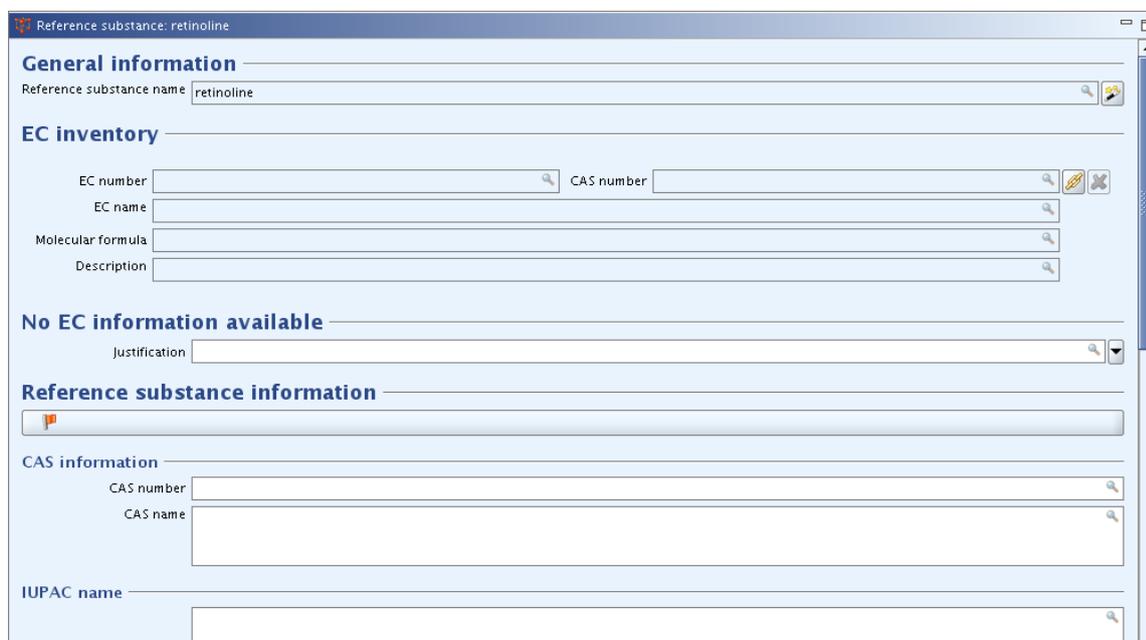
- Type the name of the Reference substance in the “Reference substance assistant” pop-up window. The box “Active Reference substance” should be checked, as only Reference substances marked as “active” can be used during the creation of a Substance dataset.

Figure 10: Adding a Reference substance name



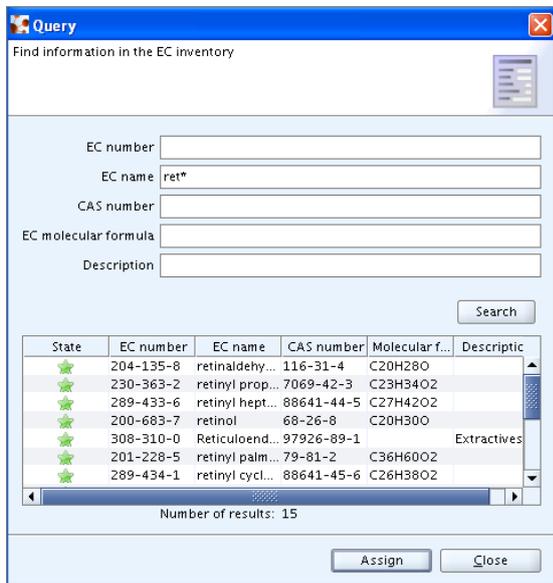
- Select the <Finish> button; the Reference substance is created and an empty Reference substance section appears (Figure 11). Click the <Edit item> button.

Figure 11: Reference substance section



- If the Reference substance is listed in the EC-inventory:
 - assign the EC entry by clicking the  button. The query dialog appears, where EC inventory entries can be searched (Figure 12);
 - search using any of the criteria listed, such as the EC name of the substance. Again, you can use "*" as a wild card;

Figure 12: Searching for a Reference substance



State	EC number	EC name	CAS number	Molecular f...	Descriptic
★	204-135-8	retinaldehy...	116-31-4	C20H28O	
★	230-363-2	retinyl prop...	7069-42-3	C23H34O2	
★	289-433-6	retinyl hept...	88641-44-5	C27H42O2	
★	200-683-7	retinol	68-26-8	C20H30O	
★	308-310-0	Reticuloend...	97926-89-1		Extractives
★	201-228-5	retinyl palm...	79-81-2	C36H60O2	
★	289-434-1	retinyl cycl...	88641-45-6	C26H38O2	

- highlight from the list the entry that matches your Reference substance;
- click the <Assign> button. The information for this Reference substance will be included in your new Reference substance.
- If your Reference substance is not in the EC inventory, select a justification from the pick-list proposed under the “No EC information available” section (Figure 13).

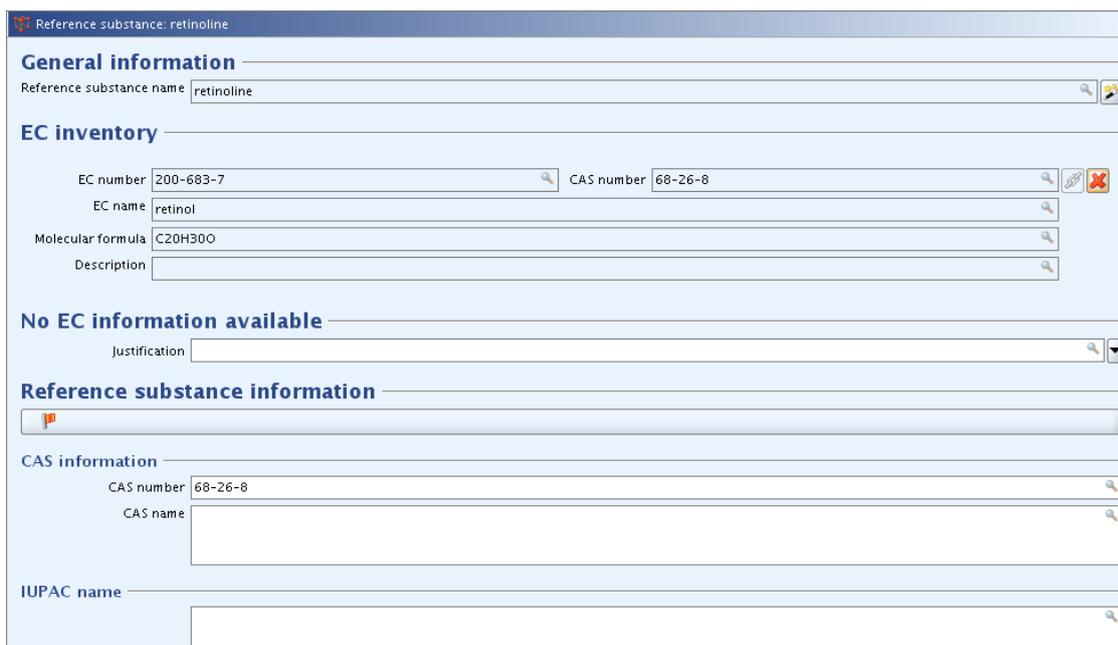
Figure 13: Justification field



- Provide sufficient information in the remaining fields to enable the identification of the Reference substance.

When completing the information for your Reference substance, the following information shall be submitted:

- EC number and EC name (if available);
- CAS number and CAS name (if available);
- IUPAC name;
- Description (specify any additional information relevant for the description of the Reference substance in this field);
- 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 screen);
- Molecular weight range (if applicable);
- SMILES notation (if applicable);
- InChI (when available) (if applicable);
- Structural formula (if applicable).

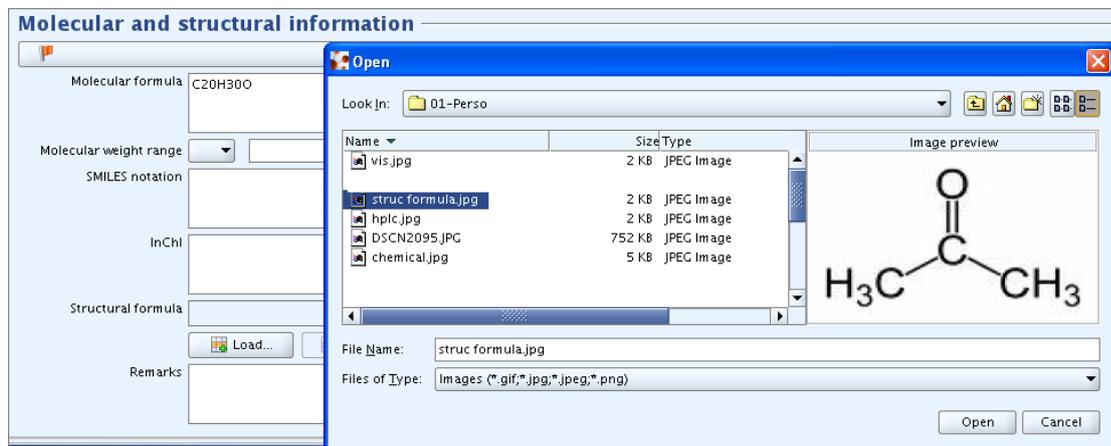
Figure 14: Completed Reference substance

The screenshot shows a web form titled "Reference substance: retinoline". The form is divided into several sections:

- General information:** Reference substance name: retinoline
- EC inventory:**
 - EC number: 200-683-7
 - CAS number: 68-26-8
 - EC name: retinol
 - Molecular formula: C20H30O
 - Description: (empty)
- No EC information available:** Justification: (empty)
- Reference substance information:** (empty)
- CAS information:**
 - CAS number: 68-26-8
 - CAS name: (empty)
- IUPAC name:** (empty)

For the structural formula, go to “Structural formula”, under “Molecular and structural information” and click the <Add> button. You can then upload an image file with the structural formula (Figure 15).

Figure 15: Uploading the structural formula



- ❌ Ensure that a Reference substance exists or has been created for every constituent of the Annex XIV substance, and for each impurity and additive, if any.

4 CREATING A SUBSTANCE DATASET

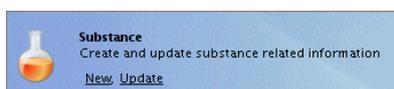
- ! If you are already a proficient user of IUCLID 5 and know how to create a substance dataset you may go directly to chapter 5 of this manual where you will find information on how to fill-in your application for authorisation dossier.

4.1 Create a substance dataset – Authorisation template

To create an “application for authorisation” (dossier) in IUCLID 5, you need first to create a Substance dataset. A Substance dataset is the repository of data, which is used as a basis to create the application for authorisation dossier to be submitted to ECHA.

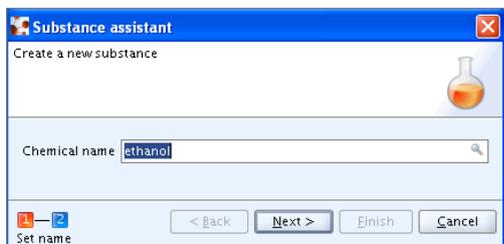
On the IUCLID 5 main screen (Task Panel), under Tasks, select “New” from Substance (Figure 16).

Figure 16: Link for creating new substance data set



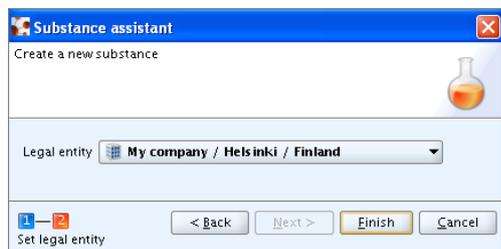
- Type the name of your substance for which you wish to create an “application for authorisation” dossier (Figure 17). The name can be anything, but it is logical to use an identifier that you are familiar with such as a trade name or chemical name.

Figure 17: Name of your substance



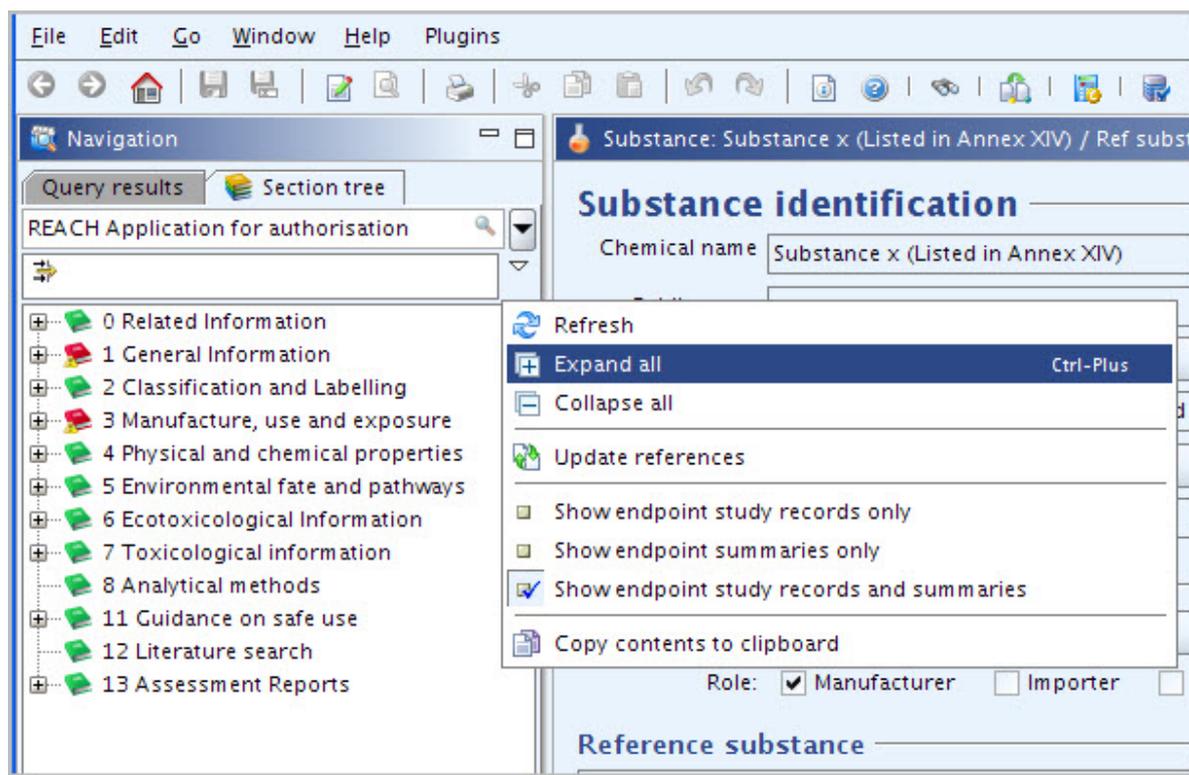
- Click the <Next> button. Select the Legal entity to be assigned to the Substance dataset (Figure 18).
- ✗ Joint applications: the Legal entity assigned to the substance shall belong to the submitting applicant or one of the co-applicants of the joint application.

Figure 18: Assigning a Legal entity



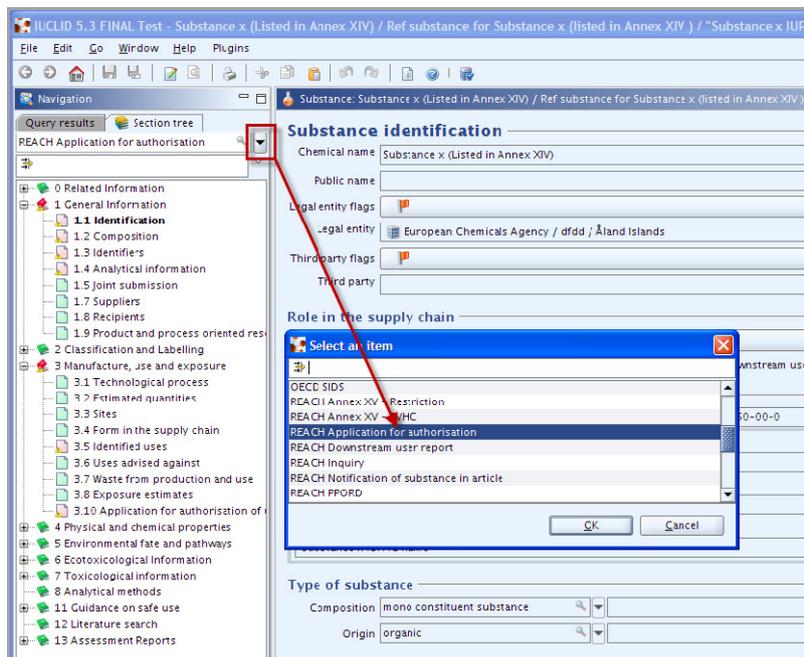
- Click the <Finish> button. You have now created a Substance dataset.
- The section tree of your Substance dataset is displayed in the navigation part of the screen (Figure 19) (to see the complete tree view click the  button and select “expand all” from the pop-up menu).

Figure 19: Expanding the section tree



- IUCLID 5 also offers the possibility of highlighting sections that are suggested for completion to assist in the preparation of various types of dossiers. For application for authorisation, click the  button and select “REACH Application for authorisation” from the pick-list (Figure 20).

Figure 20: Selecting the template from the pick-list



- ✘ The 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 section 13 for attachments). The details of the information required to complete each of these sections is explained later in this manual (chapter 5).

4.2 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, 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 chapter D.4.10 of the IUCLID 5 End User Manual at:

<http://www.iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual>

Particular attention should be paid to compatibility between different versions of IUCLID 5: migration tools and information about them are available at the IUCLID 5 website at: <http://iuclid.echa.europa.eu>

4.3 Multi-substances dataset - 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.

For each category member, a separate Substance dataset has to be created, in which all required data are to be entered as for any other non-grouped substance i.e. sections 1.1, 1.2, 1.3, 3.5, 3.10 and 13.

When creating the category in IUCLID 5, applicants are required to provide justifications and discussions including category definition and rationale in section 0.2 (Figure 21).

Figure 21: Justifications and discussions for applying category approach



For full guidance on how to build a dataset for a category please refer to chapter D.6 of the IUCLID 5 End User Manual at:

<http://www.iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual>

- ✘ Only the “OECD category approach” is valid for a multi substance application for authorisation. For instructions on how to create a dossier based on an OECD category approach, please refer to chapter D.8.2.5 of the IUCLID 5 End User Manual at <http://www.iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual>

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://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf

- ⚠ 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, and the application for authorisation is made for all of the uses of the group of substances. In more complex cases, it may be preferable to submit separate applications for each substance of the group.

In any case, we recommend you to contact the ECHA Helpdesk before submitting such an application for authorisation.

4.4 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”, Appendix 2 “Applications by several legal entities” at:

http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf

Due to the possible complexity and technical issues of joint applications, ECHA recommends that you develop and submit a joint application preferably when i) all co-applicants of the group apply for all uses in the joint application for authorisation, and when ii) they 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.

-  Joint applications made for several substances and several uses can lead to very complex and unclear situations. ECHA recommends that you carefully consider the benefits of such submissions and that you preferably submit in the most favourable cases as mentioned above and in part 4.3 of this manual.
-  The Substance dataset of a joint application shall be submitted to ECHA by one Legal entity herein called “submitting applicant”. Chapter 9 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 mapping of the “uses applied for”. Such a mapping shall be done during the first step of the submission using the relevant web-form¹ and is aimed at properly identifying which applicant applies for which use(s) and for which substance(s). It will be automatically generated as part of the application form (see chapter 9 for further details) that you need to attach in section 13 of the IUCLID 5 dossier.

¹http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_submission_en.asp

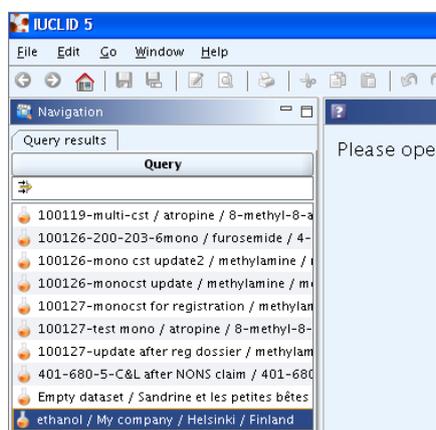
5 IUCLID 5 SECTIONS TO COMPLETE FOR AUTHORISATION PURPOSES

This chapter outlines which information must be provided through the different sections of the IUCLID 5 tree and within the dossier header.

Once you have created (or copied) a Substance dataset for your substance and assigned it to the Legal entity of the applicant, you can enter data on the substance in this dataset.

To retrieve the Substance dataset you have already created, click “Update” under “Substance” in the main task panel, and select your substance from the list by double clicking it (note: to facilitate the retrieval of your Substance dataset, you may either use the filtering system by typing the name (or part of it) of the substance in the query field or use the query system by clicking the <Query> button).

Figure 22: Displayed substance in query

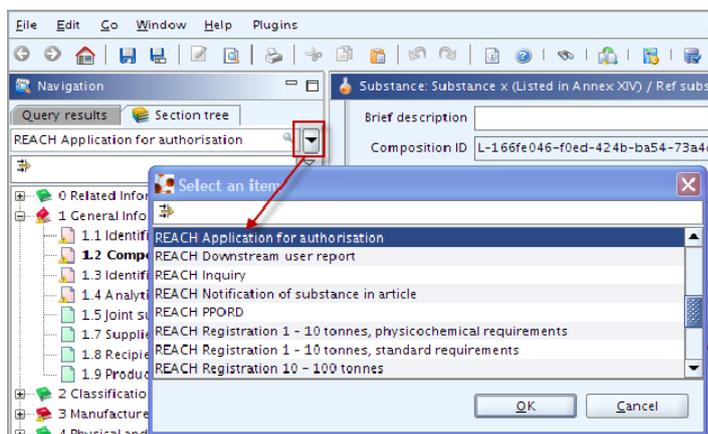


Once the substance is displayed in the data entry pane, expand the section tree (by clicking the “Section tree” tab) and proceed to complete the necessary sections. Double click in each section to display it, and click the <Edit item> button  in the upper part of the screen to complete the fields.

5.1 IUCLID 5 view mode selector

When the Substance dataset is opened, you can select the specific view mode “REACH Application for authorisation” by clicking on the black arrow indicated in Figure 23.

Figure 23: IUCLID 5 view mode



Once the desired view mode is selected in the drop-down list, the section tree changes in such a way that the leaf  or book  symbols preceding the IUCLID 5 sections are coloured in red for required sections or in green for optional sections.

 Keep in mind that this view mode selector is merely a tool to help in determining which sections to fill in. However, the present manual prevails upon this view mode selector regarding the requirements for an application for authorisation under REACH. The conformity of an application for authorisation will be checked by ECHA's Committees (Risk Assessment Committee and Socio-economic Assessment Committee), which may request further data to bring the application into conformity with the requirements of Article 62 of REACH.

5.2 Information requested for authorisation

This chapter of the manual describes in detail how to fill in the relevant IUCLID 5 sections and provides some general administrative/practical information which is needed for a proper processing of your application by ECHA.

The required information in the REACH legal text comprises the following:

- 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, IUCLID 5 – section 1.1);
- identity and composition of the substance(s) as referred to in section 2 of Annex VI to REACH (web-form, IUCLID 5 – sections 1.1, 1.2 and 1.3);
- the use(s) for which the applicant(s) applies for authorisation (web-form, IUCLID 5 – sections 3.5 and 3.10);
- 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 5 – section 13). Alternatively, reference to a registration dossier which includes such a CSR can be provided (IUCLID 5 – section 1.3);
- an analysis of the alternatives, (IUCLID 5 – section 3.10);
- a substitution plan if relevant (IUCLID 5 – section 3.10);
- a socio-economic analysis if relevant (IUCLID 5 – section 3.10);
- a justification for not considering certain risks if relevant (IUCLID 5 – section 3.10);
- reference(s) to other applications or previous authorisations if relevant (IUCLID 5 – sections 1.3 and 3.10);
- other attachments: application form (including mapping of uses), concordance table, mapping of changes performed (for updates in response to ECHA's Committees requests) (IUCLID 5 – section 13);
- argumentation for substance grouping (access category object through IUCLID 5 – section 0.2).

The subsequent chapters of this manual describe in details how to fill-in a IUCLID 5 “application for authorisation” dossier in order to fulfil your obligations under the REACH Regulation.



The following information is not specifically requested by the REACH Regulation. You can nevertheless provide it on a voluntary basis in the relevant IUCLID 5 sections (indicated in brackets) for a better assessment of your application by the opinion and decision makers:

- information on the analytical information (IUCLID 5 – section 1.4);
- information on the classification and labelling (IUCLID 5 – section 2.1);

- information on the form of the substance in the supply chain (IUCLID 5 – section 3.4);
- endpoints information (IUCLID 5 – section 4 to 7)
- information on the estimated quantities (IUCLID 5 – section 3.2);
- information on the production sites (IUCLID 5 – section 3.3);
- information on the technological process (IUCLID 5 – section 3.1);
- information on the uses advised against (IUCLID 5 – section 3.6);
- information on the waste from production and use (IUCLID 5 – section 3.7);
- information on the exposure estimates (IUCLID 5 – section 3.8);
- information on the recipients (IUCLID 5 – section 1.8);
- information on the suppliers (IUCLID 5 – section 1.7);
- information on analytical methods (IUCLID 5 – section 8);
- information on the literature search (IUCLID 5 – section 12).

5.3 Information to be provided in IUCLID 5 section 1.1 – Identification (mandatory)

- ! Use this section to specify some of the information requested on substance identification and identity of the applicant(s).

5.3.1 Identity of the applicant(s)

- Although the Legal entity is available in REACH-IT as part of the sign-up process and in the context of the application web-form, it is also necessary to indicate a Legal entity in the IUCLID 5 dossier. This information must be provided in the block “Substance identification” (Figure 24).

Figure 24: Legal entity identification in section 1.1



Substance: ethanol / My company / Helsinki / Finland

Substance identification

Chemical name ethanol

Public name

Legal entity flags

Legal entity My company / Helsinki / Finland

Third party flags

Third party

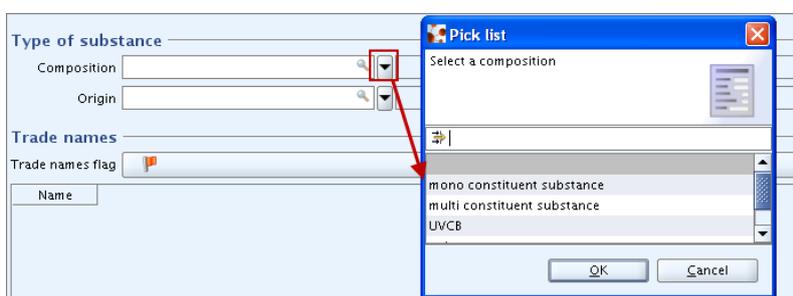
- ✘ It is not possible to appoint a third party representative for an application for authorisation.

- ✘ The Legal entity (Legal entity of the submitting applicant) should have already signed up in REACH-IT (with the same Company Universal Unique Identifier, UUID).

5.3.2 Substance identification

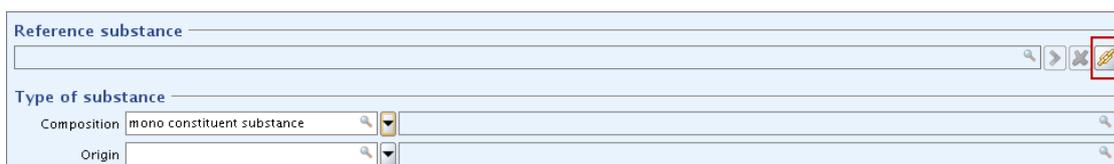
- The role in the supply chain (Manufacturer, Importer, Downstream user) needs to be indicated when creating the application form (see chapter 9.2, Figure 84)
- Select the appropriate type of substance among the different types proposed in the composition pick-list (Figure 25).

Figure 25: Type of substance



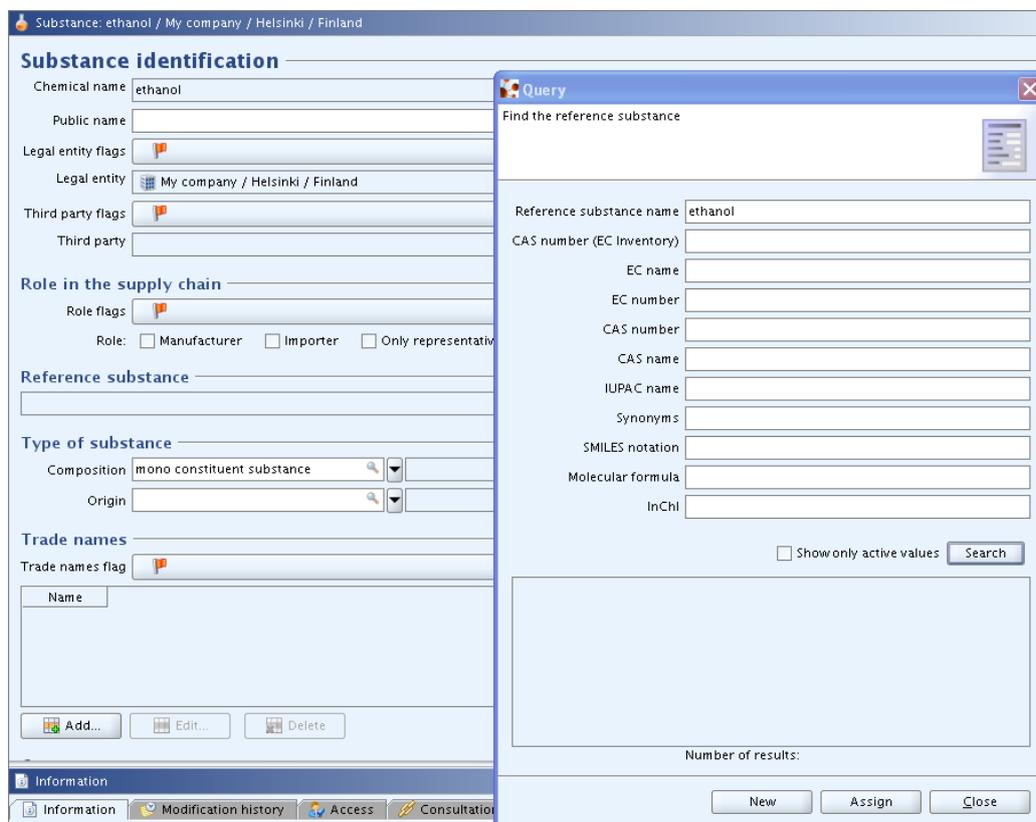
- In “Reference substance” click the  button to assign a “Reference substance” to your Annex XIV substance (Figure 26). In this block, a Reference substance must always be linked. In case of a mono-constituent substance, the same Reference substance must be linked in section 1.1 and the block “Constituents” of IUCLID 5 section “1.2 Composition”.

Figure 26: Assigning a Reference substance



- A query dialog box appears. Search for your “Reference substance” using the appropriate identifier (Figure 27).

Figure 27: Query dialogue box



Substance: ethanol / My company / Helsinki / Finland

Substance identification

Chemical name ethanol

Public name

Legal entity flags

Legal entity My company / Helsinki / Finland

Third party flags

Third party

Role in the supply chain

Role flags

Role: Manufacturer Importer Only representative

Reference substance

Type of substance

Composition mono constituent substance

Origin

Trade names

Trade names flag

Name

Add... Edit... Delete

Information

Information Modification history Access Consultation

Query

Find the reference substance

Reference substance name ethanol

CAS number (EC Inventory)

EC name

EC number

CAS number

CAS name

IUPAC name

Synonyms

SMILES notation

Molecular formula

InChI

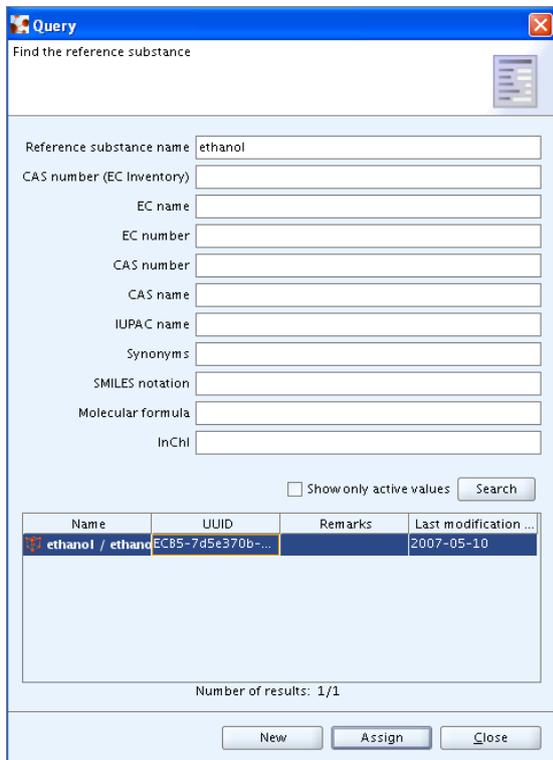
Show only active values Search

Number of results:

New Assign Close

- Highlight the Reference substance from the result list and click <Assign> (Figure 28).

Figure 28: Assigning the Reference substance

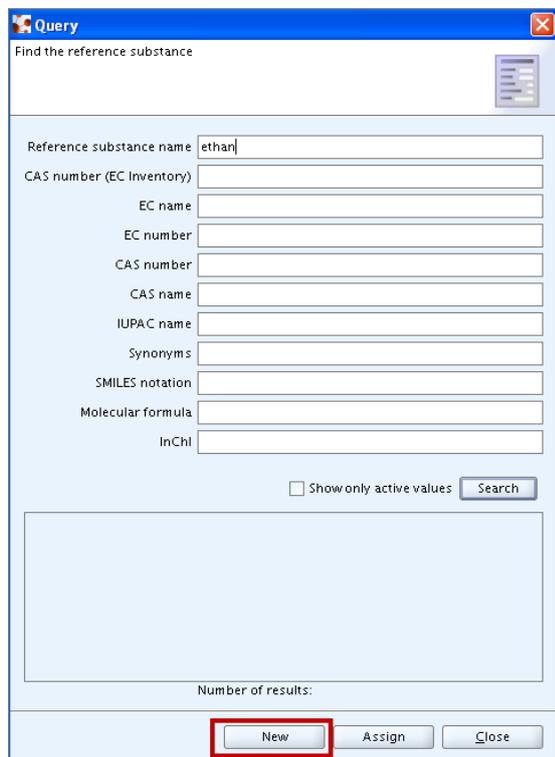


Name	UUID	Remarks	Last modification ...
ethanol / ethan...	ECB5-7d5e370b-...		2007-05-10

⚙ It is possible that the Reference substance already exists but you have not set it as “Active”. In this case, un-tick the “Show only active values” checkbox to display both the Reference substances marked as active and inactive. Right-click the non activated substance you want to assign. Click the <Active Reference substance> to activate it. Then click <Assign>.

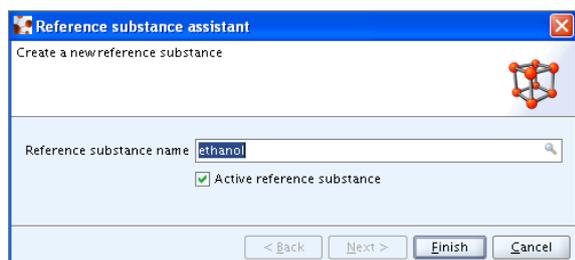
- If you cannot find your Reference substance because it has not been created yet:
 - click <New> to create a new Reference substance (Figure 29);

Figure 29: Button for creating a new Reference substance



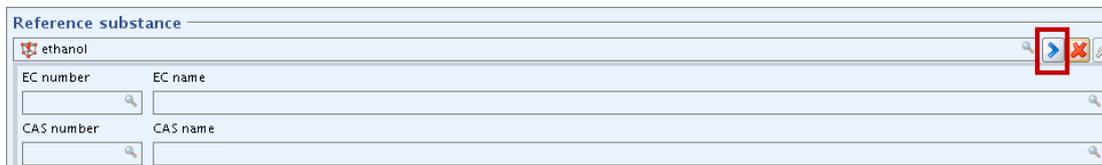
- you will be redirected to the “Reference substance assistant”;
- type the name of the Reference substance you need to create and click the <Finish> button (Figure 30);

Figure 30: Name of the Reference substance



- o to specify the information on the new Reference substance, click the blue arrow button (Figure 31);

Figure 31: Blue arrow button



- o you will be redirected to the screen for the new Reference substance. Complete the fields as described in chapter 3 "Creating a Reference substance" (SMILES notation, molecular formula, molecular weight range, structural formula...);
 - o click the <Save> button;
 - o click the  button to go back to the substance (save when requested).
-  The section 1.1 of your IUCLID 5 authorisation application shall contain the identity of the Annex XIV substance. This identity shall be consistent with the one described in the corresponding Annex XIV entry available at:

http://echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp

The reference substance in section 1.1 shall therefore contain the following minimum information:

- EC number as specified in Annex XIV list
 - CAS number
 - IUPAC name
-  For multi-constituent substances you are advised to indicate in the field "IUPAC name" that it is a reaction mass (e.g. Reaction mass of A and B). The constituents should be indicated in the IUCLID 5 section "1.2 Composition".
-  For UVCB substances you are advised to indicate the name of the UVCB substance in the field "IUPAC name" while the process description, refinement process, etc. should be indicated in the field "Description".
-  It is also recommended to read the "Guidance for identification and naming of substances under REACH", available at:

http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

5.3.3 Contact person

You can also indicate the information details of the contact person for that specific substance (Figure 32). Complete as many of the fields as possible. In case you leave these fields empty, REACH-IT will use, by default, the contact information you have specified in your

REACH-IT account. However please note that in any case ECHA will use the information details as specified by the applicant in REACH-IT for any further communication.

Figure 32: Contact details fields

Contact person	
Person flags	
Organisation	My company
Department	Regulatory affairs
Title	Dr
First name	James
Last name	Smith
Phone	+12345678
Mobile	
Fax	+123456789
E-mail	name@mycompany.com
Address	Katu 1
Address	
Postal code	1100
Town	Helsinki
Region / State	
Country	Finland
Remarks	

5.4 Information to be provided in IUCLID 5 section 1.2 - Composition (mandatory)

At least one composition must be indicated. For each composition the degree of purity shall be specified.

Ensure that a Reference substance exists or has been created for each constituent, and for each impurity (if any) or additive (if any). The fields “Typical concentration” and/or “Concentration range” shall be filled in, and the unit indicated.

- Double click section 1.2 (Composition) and click the <Edit item> button (Figure 33).
- Click the <Add> button .
- Enter the name and a brief description of the composition.

Figure 33: Name and description of composition

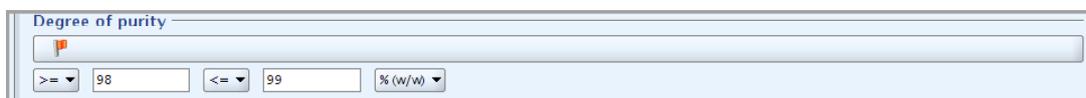
Substance composition	
Annex XIV substance - Purity > 98% (w/w)	
Name	Annex XIV substance - Purity > 98% (w/w)
Brief description	
Composition ID	L-166fe046-f0ec-424b-ba54-73e4cc6e7823

- Complete the “Degree of purity” section (Figure 34). The degree of purity to be specified should correspond to the purity of the main constituent(s) of the substance.

The drop-down list box allows you to pick symbols or units from a pick-list, and the boxes allow you to type numbers. In this part you can give the normal range of purity for the substance. For instance, a substance with purity between 98-99% (w/w) will be given as shown below. It is necessary to specify the unit to complete this section. You can indicate ranges if exact information on the degree of purity is not accessible to you.

- ✘ Degree of purity: at least one of the boxes shall be filled in and the unit should be selected.

Figure 34: Degree of purity



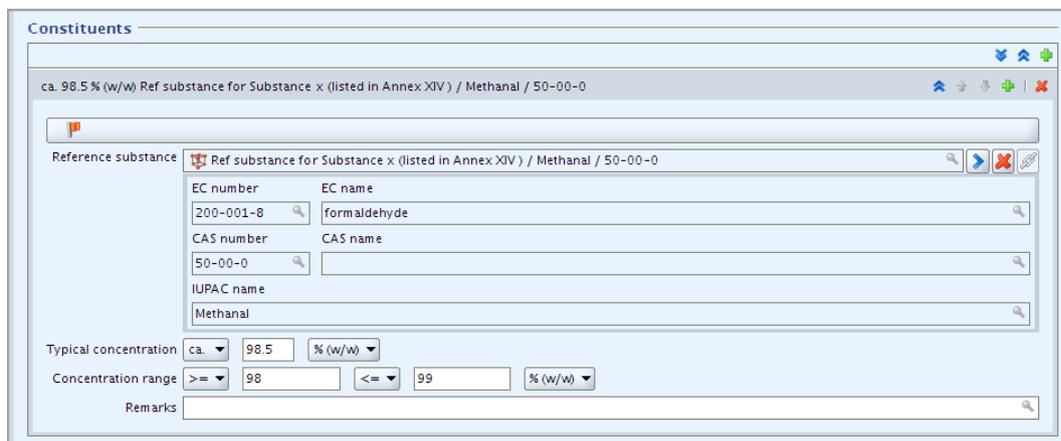
- Create a repeatable block for “Constituents” by clicking the green <Add> button.
- ✘ At least one constituent should be indicated for the composition.
- Assign a “Reference substance” to the newly created constituent by clicking the  button. Search for the appropriate Reference substance and add it by selecting it and clicking <Assign>. Create the Reference substance you need if it was not created in advance. See chapter 3 for more details.
- ✘ In case the substance is a mono-constituent, then the first composition block in section 1.2 of the IUCLID 5 dossier should contain only one constituent. The Reference substance linked to this constituent must be the same as the one specified in section 1.1.
- ✘ If the substance is a multi-constituent the Reference substance assigned in section 1.1 cannot be any of the Reference substances specified for the individual constituents in section 1.2.
- ✘ If the substance is a multi-constituent or a UVCB substance, then all constituents of one composition block in IUCLID 5 section 1.2 must represent distinct substance identities.

This means that this case will be considered invalid:

- constituent 1 identifies "formaldehyde" as a IUPAC name;
- constituent 2 identifies "200-001-8" as the EC number (the EC number of formaldehyde).

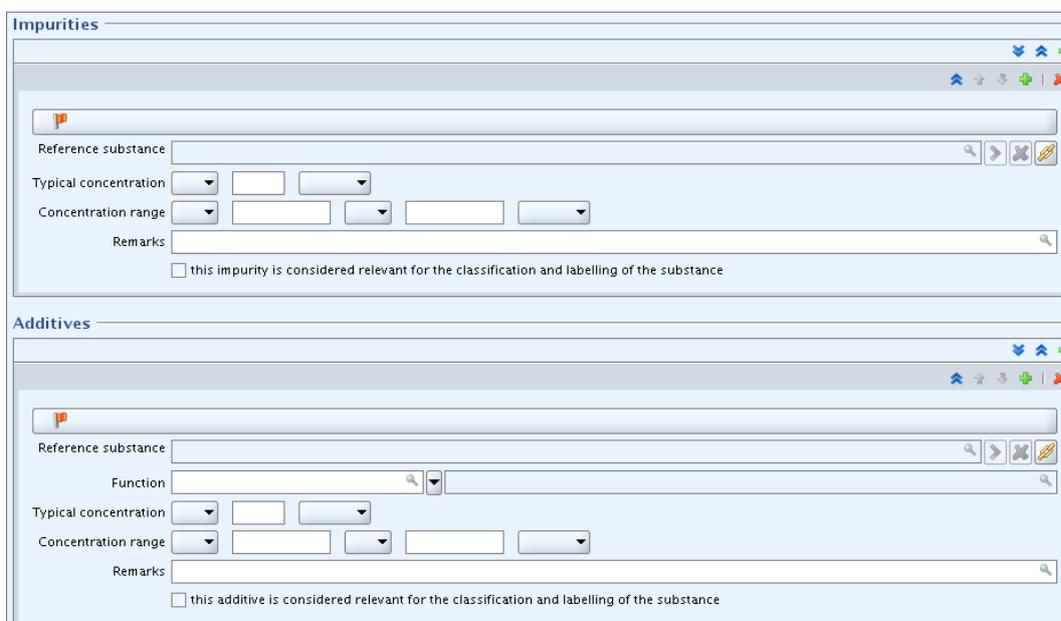
- Indicate the “Typical concentration” or the “Concentration range” for every constituent in the same manner as indicated below (Figure 35). You can indicate ranges if the exact or typical concentration of the constituent is not accessible to you.

Figure 35: Typical concentration for each constituent



- If you need to specify more than one constituent, click the <Add> button  in the relevant section, and more boxes will appear.
- Follow the same procedure to complete the impurities and additives fields (Figure 36).

Figure 36: Additional boxes for the impurities and additives fields



- In case of unknown impurities, you should account for them by creating a new Reference substance and indicating in the IUPAC name field "Unknown impurities". You should also specify the number of these unknown impurities in the “Remarks”

field.

- Indicate concentration ranges if the total (typical) concentration of the unknown impurities is not accessible to you.
- If an impurity or additive is considered relevant for classification and labelling of a substance, the corresponding checkbox should be ticked (Figure 37 and Figure 38).

Figure 37: Indicate if an impurity is relevant for the C&L of the substance

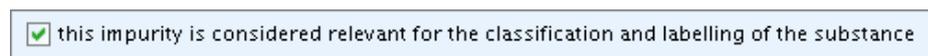
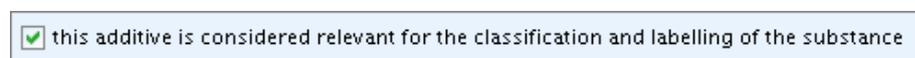


Figure 38: Indicate if an additive is relevant for the C&L of the substance



- Multiple compositions:

It is possible to specify more than one composition for a substance. The composition of an Annex XIV substance may differ for instance from one Manufacturer/Importer to another or 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 (Figure 39).

- ✘ If several “Substance composition” blocks are created in section 1.2 then every block must be completed.

Click the <Add> button under “Substance composition” in IUCLID 5 section 1.2 and more boxes will appear (Figure 39).

Figure 39: Add another composition



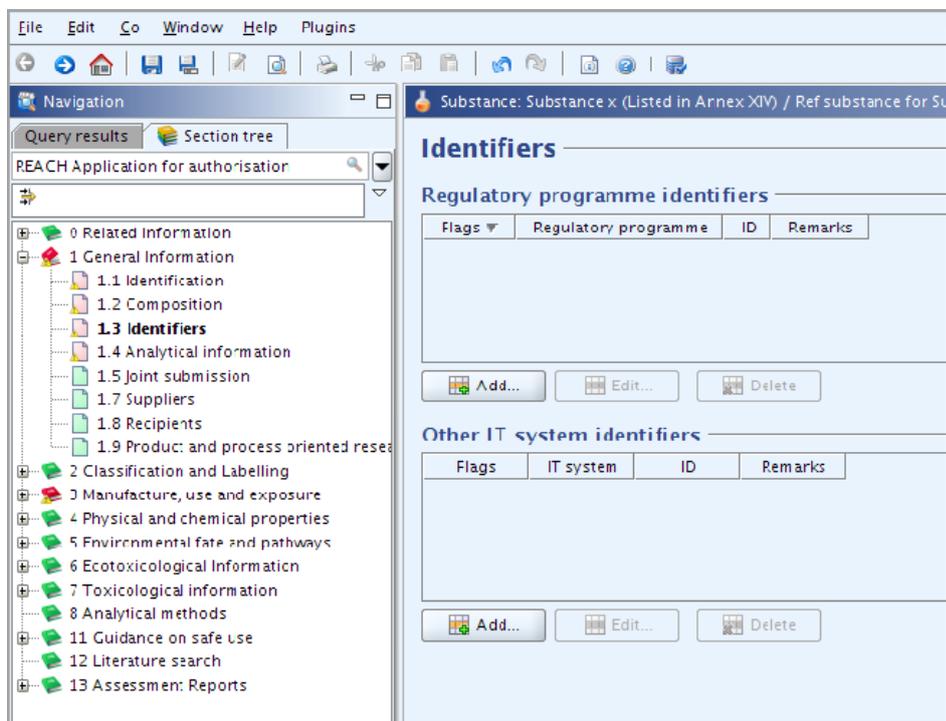
-  Section 1.2 of your application for authorisation shall contain the following minimum information:
- the “Degree of purity” of the substance;
 - for each constituent (at least one constituent has to be specified):
 - “EC number” OR “CAS number” OR “IUPAC name”;
 - AND
 - “Molecular formula” AND “Structural formula” AND “Molecular weight” OR a Remark if any of the three before mentioned fields cannot be indicated
 - AND
 - “Typical concentration” OR “Concentration range”.
 - for each impurity (if any):
 - “EC number” OR “CAS number” OR “IUPAC name”;
 - AND
 - “Molecular formula” AND “Structural formula” AND “Molecular weight” OR a Remark if any of the three before mentioned fields cannot be indicated
 - AND
 - “Typical concentration” OR “Concentration range”.
 - for each additive (if any):
 - “EC number” OR “CAS number” OR “IUPAC name”;
 - AND
 - “Molecular formula” AND “Structural formula” AND “Molecular weight” OR a Remark if any of the three before mentioned fields cannot be indicated
 - AND
 - “Typical concentration” OR “Concentration range”.
-  Applicants are advised to carefully check before the submission of the dossier that the information provided in section 1.1 and section 1.2 is sufficient to clearly identify the substance covered by the authorisation. In particular, this information should not be so generic resulting in potentially describing more than one substance or leading to discrepancies with the substance identity laid down in Annex XIV. The substance identification in the application for authorisation dossier should follow the “Guidance for identification and naming of substances under REACH” (http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf). Any deviation from the guidance should be properly documented in the dossier. Detailed and illustrative technical assistance in how to report and structure the substance identification in a IUCLID 5 dossier is available in “Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH” (http://echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf).

5.5 Information to be provided in IUCLID 5 section 1.3 - Identifiers (mandatory)

-  Section 1.3 of IUCLID 5 is relevant for:
 - initial applications;
 - requested updates;
 - subsequent applications;
 - review reports.
-  For further information on the above application types please see also chapter 6 “Creating an initial application for authorisation dossier” and chapter 8 “Specific submissions”
-  A series of identifiers may need to be added in this section:
 - **REACH Annex XIV substance entry number:** for all types of applications;
 - **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 5 dossier when applying for an authorisation, no registration number should be provided here;
 - **REACH Authorisation number:** for subsequent applications which refer to a granted authorisation according to Article 63(2);
 - **REACH Authorisation number:** for reviews of authorisation which refer to a granted authorisation according to Article 61(1);
 - **Submission number:** for subsequent applications which refer to a submitted application according to Article 63(1). Note: 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 8).

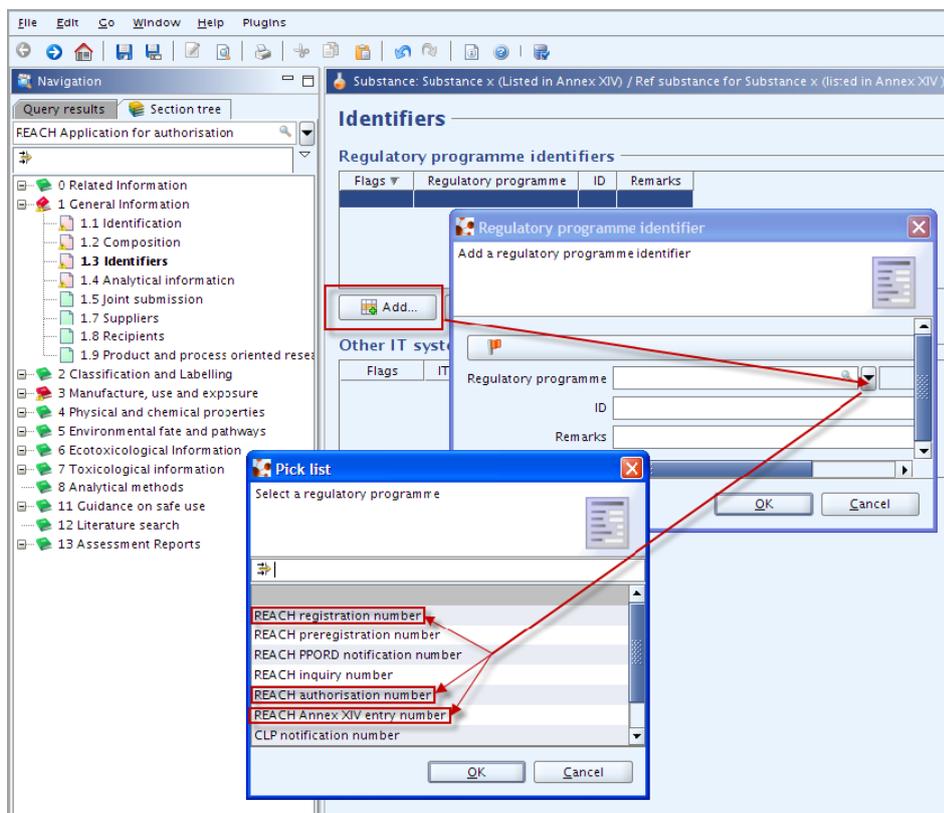
Open the section 1.3 of the IUCLID 5 Substance dataset by double clicking on “1.3 Identifiers” from the section tree view and click the <Edit item> button (Figure 40).

Figure 40: Opening section 1.3 in IUCLID 5



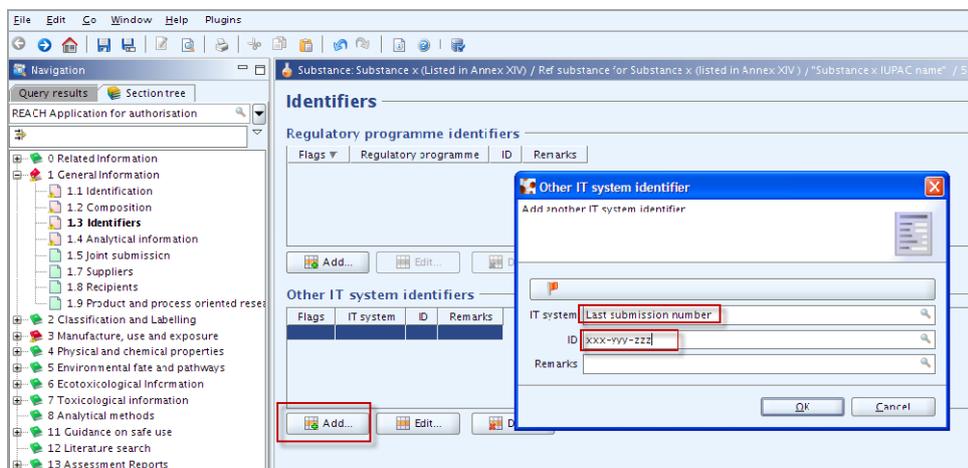
- In the “Regulatory programme identifiers”, select “Add” to edit the list of identifiers. A pop-up window entitled “Regulatory programme identifier” appears on the screen (Figure 41).
- To specify Annex XIV entry numbers, authorisation numbers and registration numbers, complete the fields as follows in the “Regulatory programme identifier” column (Figure 41):
 - select “REACH Annex XIV entry number” in every case;
 - select “REACH Authorisation number” for subsequent applications (Article 63(2)) or review reports;
 - select “REACH Registration number” in the case you refer to a CSR already submitted as part of the registration;
 - the numbers shall be specified in the “ID” field.

Figure 41: Pop-up window “Regulatory programme identifier”



- To specify a submission number in case of a subsequent application (according to Article 63(1)), complete the fields as follows in the “Other IT systems identifiers” table (Figure 42):
 - select “Add”;
 - type “Last submission number” in the IT system field;
 - the number should be specified in the “ID” field.

Figure 42: Pop-up window “Other IT systems identifiers” for the last submission number



- Submission number and annotation number in case of a requested update (according to Article 64(3)) are to be given in the dossier header (see chapter 8).

The table below gives an overview of where to report in IUCLID 5 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	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		Section 1.3 Other IT system identifiers	
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

5.6 Information to be provided in IUCLID 5 section 1.4 - Analytical information (optional)

-  Use section 1.4 of IUCLID 5 to specify, if available, some of the information requested under Article 62(4)(a) of the REACH Regulation, on the identity of the Annex XIV substance.

The following information referred in Annex VI of the REACH Regulation can be provided in IUCLID 5 section 1.4:

- information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate);
- spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum);
- high pressure liquid chromatogram, gas chromatogram;
- description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items above, the reasons shall be clearly stated. For substances for which any of the items above are not suitable, data from a suitable characterisation method should be included.

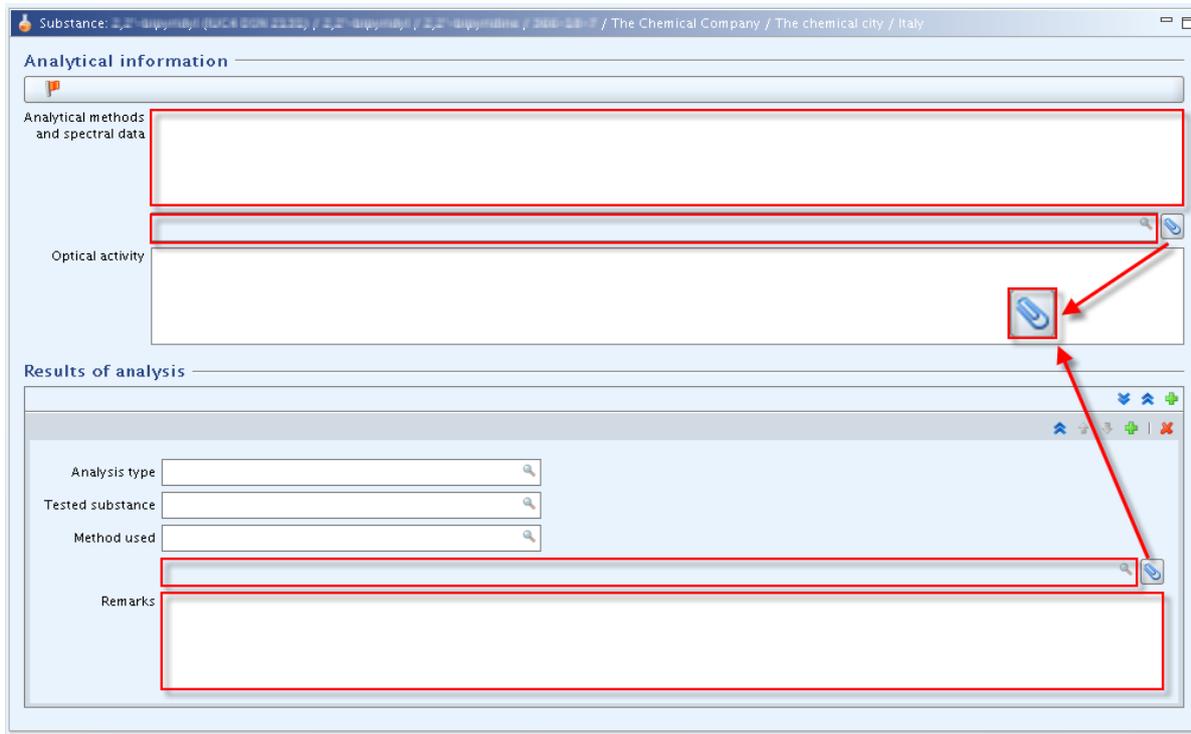
The description of the analytical methods must be provided either in the “Analytical methods and spectral data” field or as an attachment under this field (by clicking the paperclip button, indicated in Figure 43).

-  For joint applications you can use the same field or the attachment under this field to describe analytical methods which are specific to some of the applicants.

The analytical results used to characterise the substance must be provided in the repeatable blocks under “Results of analysis” as an attachment (by clicking the paperclip button) or in the “Remarks” field (Figure 43).

-  For joint applications you can use the repeatable block subsection to give analytical results which are specific to some of the applicants.

Figure 43: Analytical information

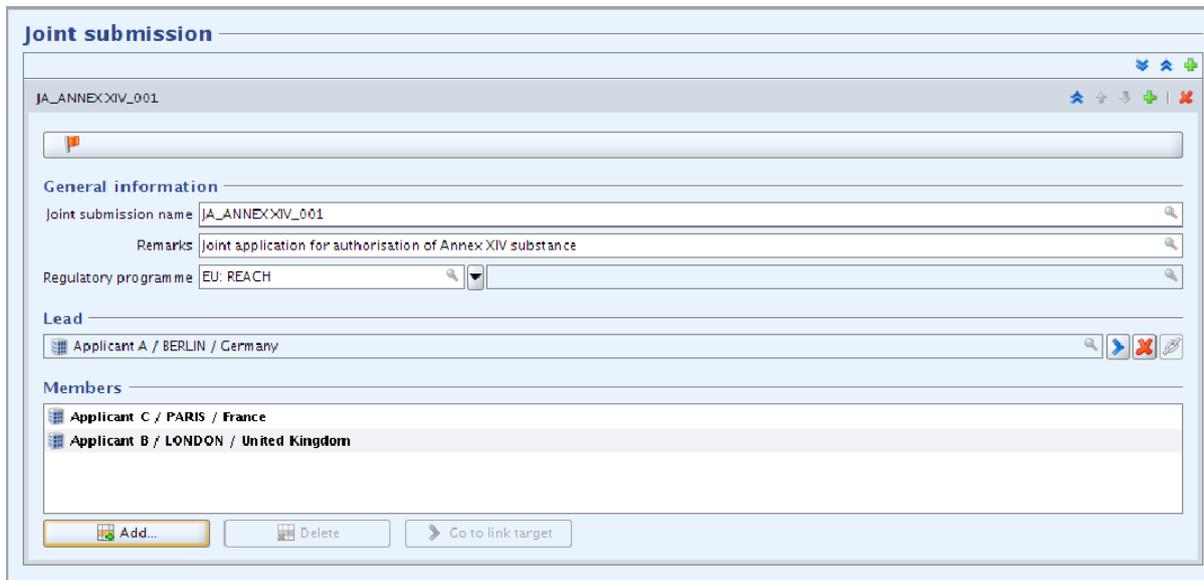


5.7 Information to be provided in IUCLID 5 section 1.5 – Joint Application (optional)

-  This section is optional. Moreover, it is only appropriate in the case of joint applications.
-  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 (chapter 9), to be attached in section 13 of the IUCLID 5 dossier) have precedence over any information provided in IUCLID 5 section 1.5. If these data are inconsistent with each other, ECHA will consider the REACH-IT data as valid.

Section 1.5 is a repeatable block subsection. It enables to specify different groupings of companies to prepare joint applications for authorisation (Figure 44).

Figure 44: Joint submission for authorisation applications



Joint submission

JA_ANNEXXIV_001

General information

Joint submission name: JA_ANNEXXIV_001

Remarks: Joint application for authorisation of Annex XIV substance

Regulatory programme: EU: REACH

Lead

Applicant A / BERLIN / Germany

Members

- Applicant C / PARIS / France
- Applicant B / LONDON / United Kingdom

Add... Delete Go to link target

The submitting applicant creates the joint application in his local IUCLID 5 installation and may request from the co-applicants their Legal entity information so that data consistency may be ensured between IUCLID 5 installations. Each co-applicant exports his own Legal entity object (LEO – see chapter 2 of this manual) and sends the export file (LEOX) electronically to the submitting applicant.

Submitting applicant: Indicate the name of the submitting applicant in the field “Lead”. Click the Link 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 5 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 <Link> button  to select the co-applicant and establish the link. The same recommendations as those provided for assigning the Lead apply.

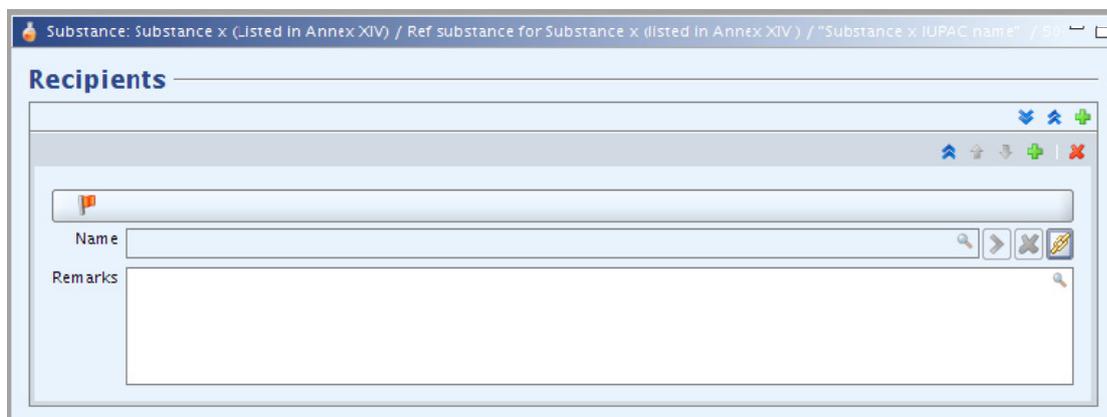
5.8 Information to be provided in IUCLID 5 section 1.7 – Suppliers (optional)

This optional section can be used to report an actor up your supply chain (e.g. Manufacturer/Importer, formulator etc.) who supplies the Annex XIV substance.

5.9 Information to be provided in IUCLID 5 section 1.8 – Recipients (optional)

This optional section can be used to report a downstream user, a distributor or a customer being supplied with the Annex XIV substance. These definitions never include consumers.

Figure 45: Recipients



5.10 Information to be provided in IUCLID 5 section 2.1 – GHS (optional)

This optional section can be used to provide the Classification and Labelling information of the substance to be authorised. The C&L shall at minimum reflect the intrinsic properties given in Annex XIV as the authorisation is assessed on the basis of these properties.

-  To fill in this section please consult chapter 5.7 of the Data Submission Manual 12: How to Prepare and Submit a Classification and Labelling Notification Using IUCLID at http://echa.europa.eu/doc/reachit/data_submission_manual_12_c&l.pdf
-  It is recommended to consult Annex I of the CLP Regulation for the classification criteria and the related guidance at http://guidance.echa.europa.eu/docs/guidance_document/clp_introduutory_en.pdf 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 blocks 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.

5.11 Information to be provided in IUCLID 5 section 3.1 - Technological process (optional)

This optional section is a repeatable block section which offers the possibility to provide several descriptions of technological processes, especially those used in the production of articles.

Information to be provided in this section includes specification of the type of reaction (e.g. fluid-bed reaction), the system in which the substance is processed (open/closed, continuous/batchwise), duration and frequency of processing, maximum capacity per time-unit, pressure and temperature during processing, solvents used, processing efficiency.

If no information is available, a justification may be entered in this field.

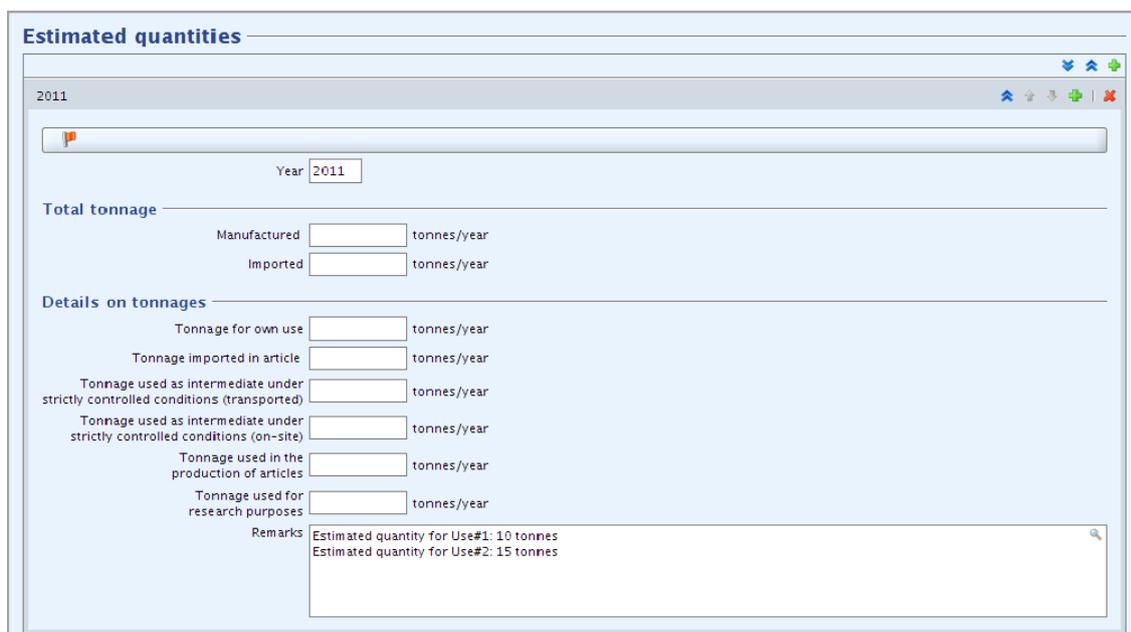
Click the green <Add> button  to open a new repeatable block. An empty block is now ready to be filled in. Add as many repeatable blocks as necessary.

5.12 Information to be provided in IUCLID 5 section 3.2 - Estimated quantities (optional)

This optional section can be used to provide the estimated production/imports quantity in tonnes per calendar year or multi-yearly average.

You can also provide in the remark field estimated tonnages per use and per year (Figure 46). 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.

Figure 46: Estimated quantities



Estimated quantities

2011

Year

Total tonnage

Manufactured tonnes/year

Imported tonnes/year

Details on tonnages

Tonnage for own use tonnes/year

Tonnage imported in article tonnes/year

Tonnage used as intermediate under strictly controlled conditions (transported) tonnes/year

Tonnage used as intermediate under strictly controlled conditions (on-site) tonnes/year

Tonnage used in the production of articles tonnes/year

Tonnage used for research purposes tonnes/year

Remarks

5.13 Information to be provided in IUCLID 5 section 3.3 – Sites (optional)

This optional section is a repeatable block section, which offers the possibility to list all sites where the Annex XIV substance is used. This is done by creating for each site a link with the relevant information stored in the Legal entity site inventory.

This section might be relevant in the cases where the conditions of use of Annex XIV substance are site-specific and/or where:

- the applicant provides a justification in IUCLID 5 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;
- the applicant provides a justification in IUCLID 5 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.

For more information on Legal entity sites, please refer to chapter D.10 of the IUCLID 5 End User Manual at:

<http://www.iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual>

5.14 Information to be provided in IUCLID 5 section 3.4 - Form in the supply chain (optional)

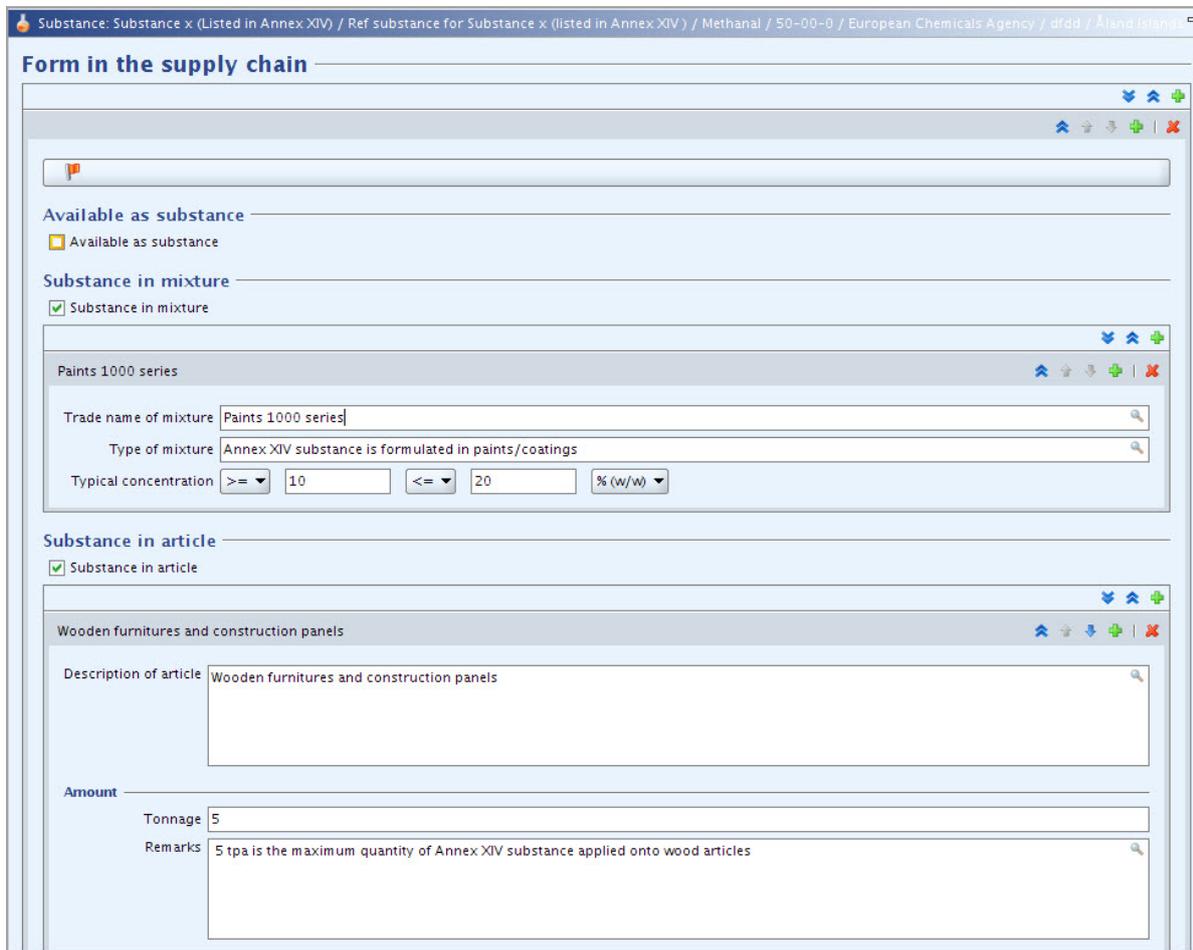
Information on the form (Substance, Mixture or Article) and on the physical state under which the substance is made available in the supply chain can be entered here.

This section is relevant for applications which describe uses at different life-cycle stages of the Annex XIV substance (formulation, end-uses, incorporation into articles etc). When filling out this section, at least one of the following should be specified:

- either the checkbox “Available as substance” is ticked;
- or the checkbox “Substance in mixture” is ticked and a value is given in the field “Typical concentration” (with its unit);
- or the checkbox “Substance in article” is ticked and a value is given in the field “Tonnage”.

This section is a repeatable block section. Click the green <Add>  button to open a new repeatable block. An empty block is now ready to be filled in. Add a new repeatable block if it is necessary to specify different forms in which the substance is present in the supply chain (Figure 47).

Figure 47: Specify the form(s) of the Annex XIV substance in the supply chain



Substance: Substance x (Listed in Annex XIV) / Ref substance for Substance x (listed in Annex XIV) / Methanal / 50-00-0 / European Chemicals Agency / dddd / Åland Islands

Form in the supply chain

Available as substance

Substance in mixture

Paints 1000 series

Trade name of mixture: Paints 1000 series

Type of mixture: Annex XIV substance is formulated in paints/coatings

Typical concentration: >= 10 <= 20 % (w/w)

Substance in article

Wooden furnitures and construction panels

Description of article: Wooden furnitures and construction panels

Amount

Tonnage: 5

Remarks: 5 tpa is the maximum quantity of Annex XIV substance applied onto wood articles

5.15 Information to be provided in IUCLID 5 section 3.5 – Identified Uses (mandatory)

- ⓘ Before filling out this section, it is recommended to read the ECHA Guidance on “Use descriptor system” (R.12) at:

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf

This section enables applicants to provide information on the uses they apply for an authorisation. In particular, section 3.5 of IUCLID 5 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.

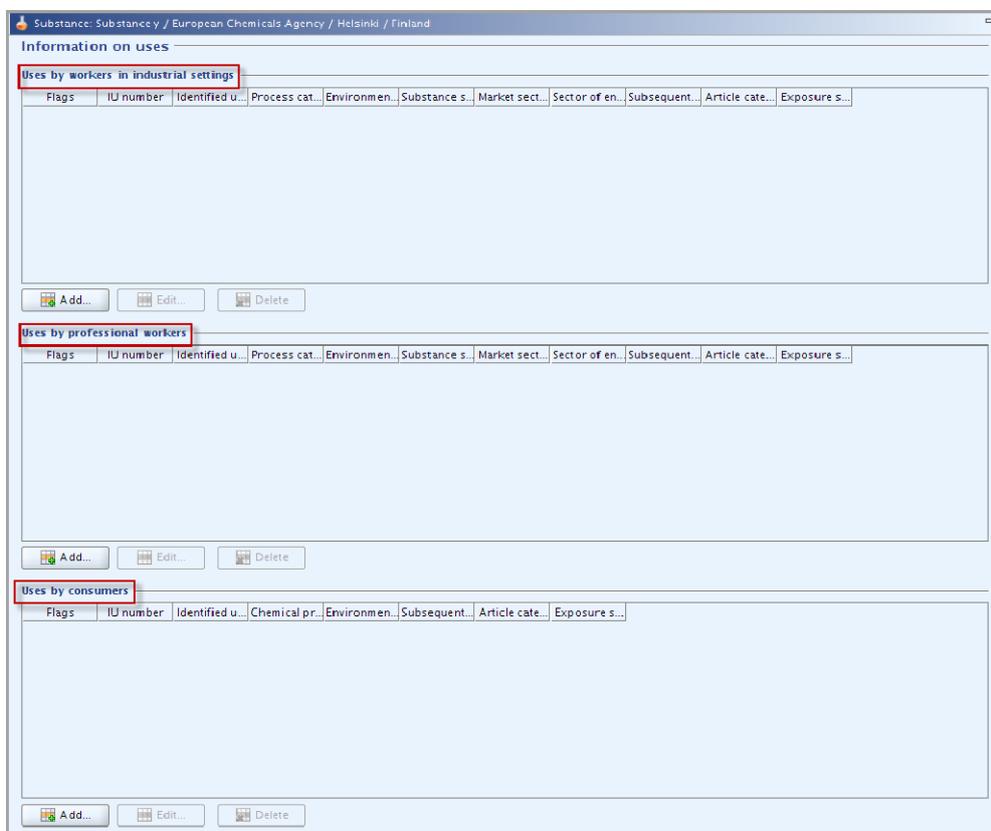
5.15.1 Information on uses

The information on the identified uses has to be reported in three different tables depending on whether the substance is used by:

- workers in industrial settings;
- workers in non industrial settings (professional workers);
- consumers.

Applicants can select an appropriate set of descriptors for each use within the three tables of main user groups (Figure 48).

Figure 48: Information on identified uses



When completing this section, please note the following:

- If several rows are created in a table then all of these rows have to be complete (e.g. if there are two rows under "Uses by professional workers" then both rows have to be complete).
- If rows are created in more than one table then all of these rows have to be complete (e.g. if there is one row under "Uses by professional workers" and one row under "Uses by consumer" then both rows have to be complete).
- The field "Subsequent service life relevant for that use?" is filled in by default with a "yes". Therefore, you should change this value appropriately.

- If "Other:" is selected in any of the pick-lists then the adjacent free text field must be filled in.
- ✘ Ensure that each row (i.e. each use description) is complete and contains a reference to an exposure scenario in a chemical safety report accessible to ECHA.

5.15.2 Use identifiers and descriptors

In order to enter a use, click the Add button at the bottom of the table and report the relevant information in the different fields.

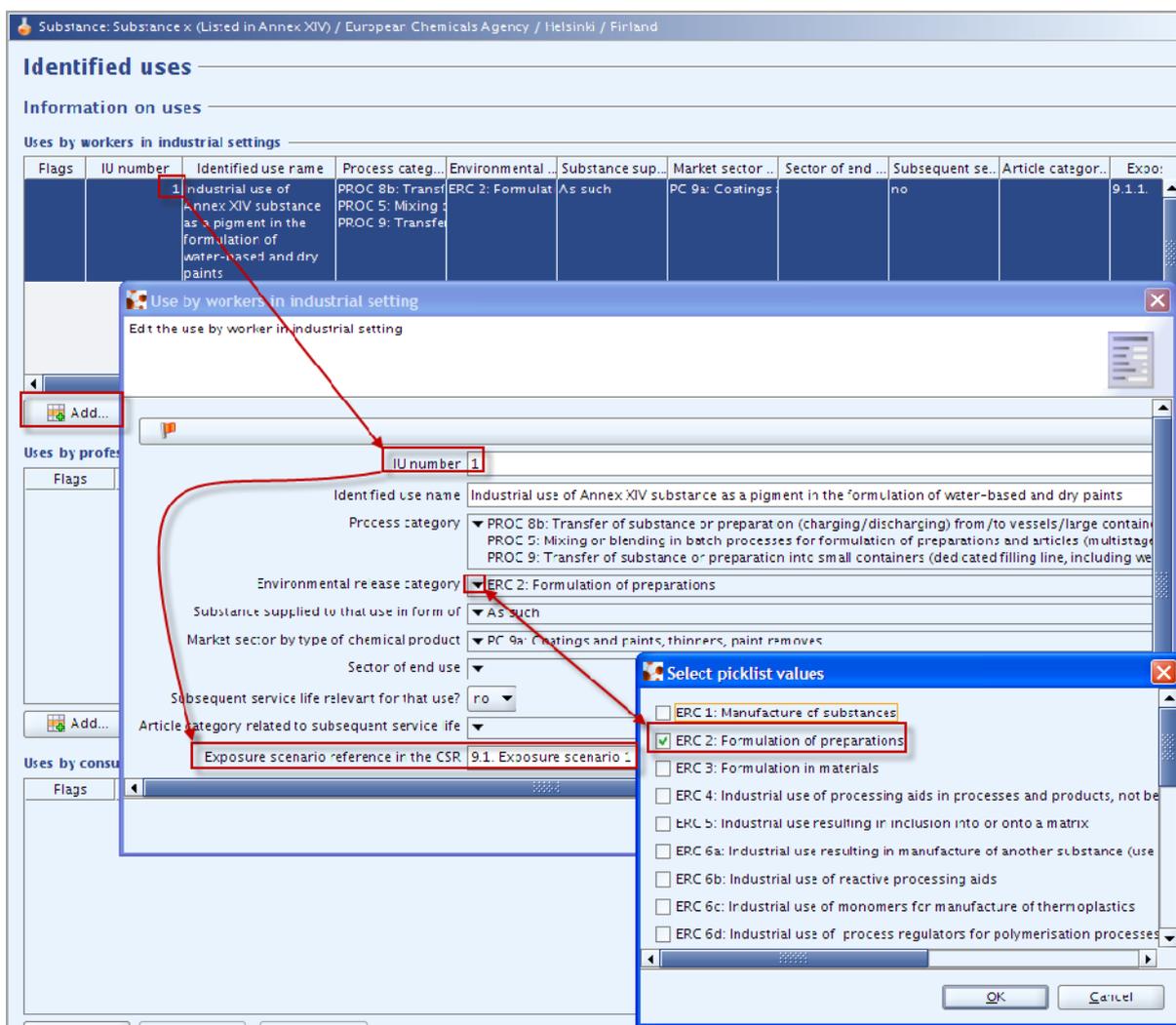
- ✘ An identified use is to be described by:
 - a number;
 - a name;
 - a selection of use descriptors;
 - information on whether the use leads to the inclusion of the substance into an article;
 - a reference to (an) exposure scenario(s) relevant for that use.
- **IU (Identified Use) number:** A unique number must be entered by the applicant for each row (see also part 5.17.4).
- **Identified use name:** The name of the identified use identifies the activity carried out within that use, and must be consistent with the corresponding description of the "Use concerned by the request" in section 3.10 of IUCLID 5.

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.

- **Process category (PROC):** this descriptor describes the application techniques or process types defined from the occupational perspective.
- **Environmental release category (ERC):** this descriptor describes the broad conditions of use from the environmental perspective.
- **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' (preparation) for that use.
- **Market sector by type of chemical product (PC):** the chemical product category describes in which types of chemical products (= substances as such or in preparations [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.

Applicants can select an appropriate set of descriptors for each use within the three tables of main user groups: Industrial workers, professional workers and consumers (Figure 49).

Figure 49: One set of descriptors per use



The screenshot displays the 'Identified uses' section of the IUCLID 5 software. A table lists uses with columns for Flags, IU number, Identified use name, Process category, Environmental release category, Substance supplied, Market sector, Sector of end use, Subsequent service life, Article category, and Exposure scenario. A dialog box titled 'Use by workers in industrial setting' is open, allowing the user to edit the descriptors for a specific use. The 'Identified use name' is 'Industrial use of Annex XIV substance as a pigment in the formulation of water-based and dry paints'. The 'Environmental release category' is set to 'ERC 2: Formulation of preparations'. A 'Select picklist values' dialog box is also open, showing a list of ERCs with 'ERC 2: Formulation of preparations' selected.

Flags	IU number	Identified use name	Process category	Environmental release category	Substance supplied	Market sector	Sector of end use	Subsequent service life	Article category	Exposure scenario
	1	Industrial use of Annex XIV substance as a pigment in the formulation of water-based and dry paints	PROC 8b: Transfer of substance or preparation on (charging/discharging) from/to vessels/large containers PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage) PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including water-based)	ERC 2: Formulation of preparations	As such	PC 9a: Coatings		no		9.1.1

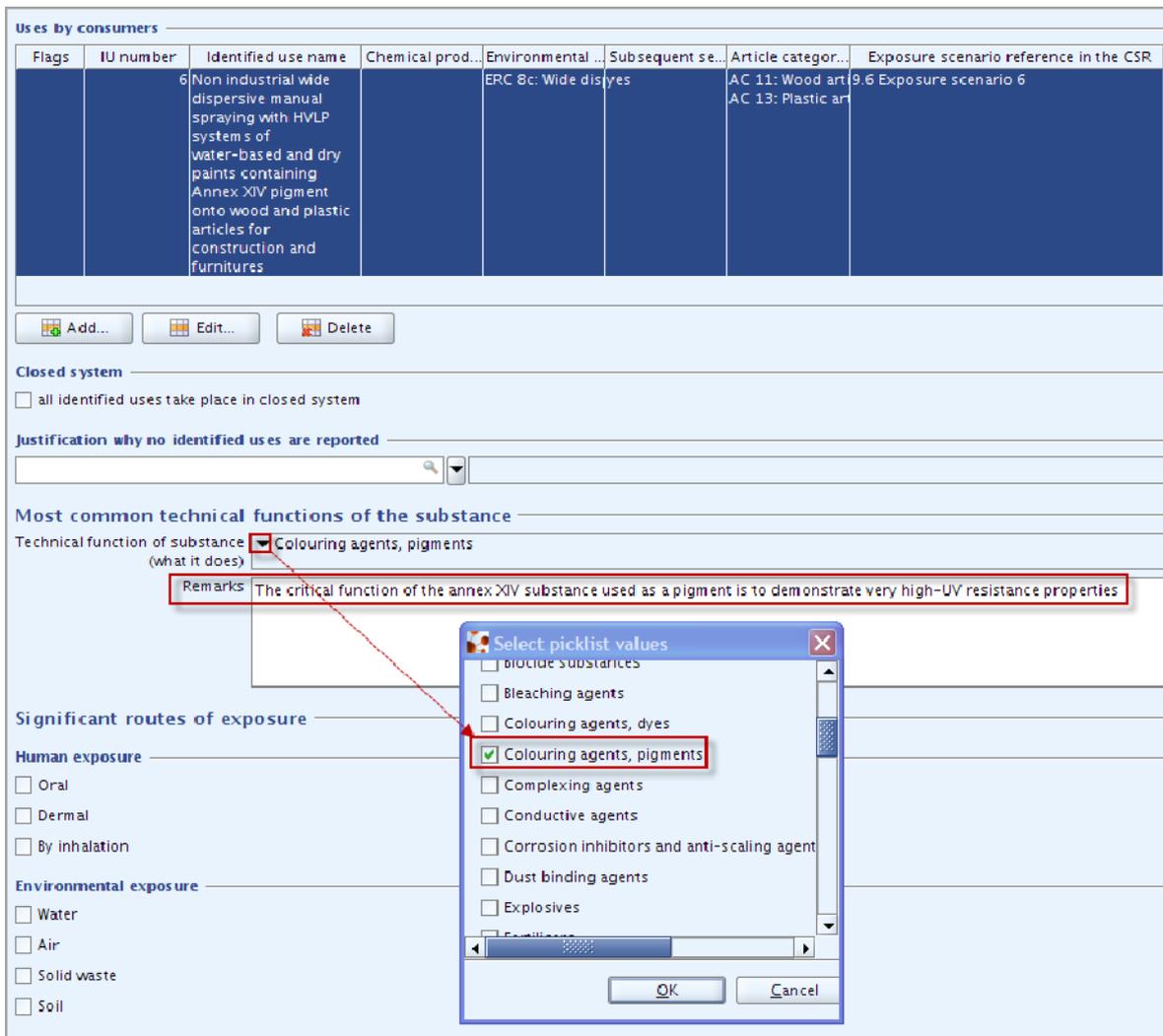
Further guidance on how to assign these use descriptors can be found in the ECHA Guidance on "Use descriptor system" (Chapter R.12) at:

http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf

5.15.3 Function of the substance

- ✘ In addition to the use descriptors, applicants should also indicate the function of the Annex XIV substance in the pick-list "Technical function of substance" (Figure 50).

Figure 50: Function of the Annex XIV substance



Uses by consumers

Flags	IU number	Identified use name	Chemical prod...	Environmental ...	Subsequent se...	Article categor...	Exposure scenario reference in the CSR
	6	Non industrial wide dispersive manual spraying with HVLP systems of water-based and dry paints containing Annex XIV pigment onto wood and plastic articles for construction and furnitures		ERC 8c: Wide dis...	yes	AC 11: Wood art AC 13: Plastic art	9.6 Exposure scenario 6

Closed system

all identified uses take place in closed system

Justification why no identified uses are reported

Most common technical functions of the substance

Technical function of substance: Colouring agents, pigments
(what it does)

Remarks: The critical function of the annex XIV substance used as a pigment is to demonstrate very high-UV resistance properties

Significant routes of exposure

Human exposure

Oral
 Dermal
 By inhalation

Environmental exposure

Water
 Air
 Solid waste
 Soil

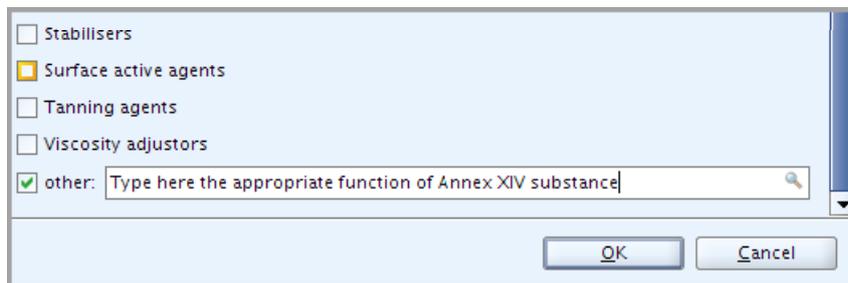
Select picklist values

- biocide substances
- Bleaching agents
- Colouring agents, dyes
- Colouring agents, pigments
- Complexing agents
- Conductive agents
- Corrosion inhibitors and anti-scaling agent
- Dust binding agents
- Explosives

If the function of the Annex XIV substance is not available in the pick-list, you should select "Other" and type the appropriate information in the adjacent text field (Figure 51).

More specific details about the substance function can be provided in the "Remarks" field (this can also constitute important information especially in relation with the analysis of alternatives in IUCLID 5 section 3.10, in which applicants need to assess the existence of alternatives that can provide an equivalent function).

Figure 51: Function of the Annex XIV substance



5.15.4 Use description and numbering

For clarity and consistency reasons, particular attention should be paid to the numbering of uses.

- Ensure that no identical use number is allocated within the same table of industrial workers, professional workers, or consumers².
- The numbering in section 3.5 shall be consistent with the numbering reported in all the parts of the application and particularly:
 - in section 3.10 of IUCLID 5;
 - in the mapping of uses in the application form (generated by the Web-form 1: Create application form, at http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_submission_en.asp);
 - in part B of the Chemical Safety Report (section 2.2: 'Identified uses');
 - in each of the other assessment reports (Analysis of alternatives, Substitution Plan and Social Economic Analysis where relevant);
 - in the so called concordance table (http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp);
 - in any correspondence with ECHA concerning the application.

Particular attention should be paid to **the descriptions of uses** reported in the "Identified use name" field: these free text descriptions shall be consistent with the ones reported in section 3.10 of IUCLID 5 under the "Use concerned by the request" field³.

- ✘ Each "use applied for authorisation" described in section 3.10 (under the field "Use concerned by the request") shall be reported with the same number in section 3.5.
- ✘ **Each use in section 3.5 that is also listed in section 3.10 shall refer to an exposure scenario.** The reference shall allow ECHA to retrieve the exposure scenario covering this use in the related Chemical Safety Report.

² Note: however, if for example the description of "Use#1" in section 3.10 covers the use by both industrial and professional workers, it can be reported in section 3.5 with the same use number - once in the industrial workers table and once in the professional workers table.

³ In section 3.5 the function of the substance is described via a pick-list, and the type of use is determined by the relevant table, whereas in section 3.10 the function and the type of use need to be directly inserted as free text in the field "use concerned by the request".

5.16 Information to be provided in IUCLID 5 section 3.6 – Uses advised against (optional)

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 5 section 3.6 is similar to the structure of section 3.5 (Identified Uses) described in chapter 5.15.1 “Information on uses” of this manual. Moreover, the standard descriptor system is strictly the same as for the “Identified Uses”. Please refer to all indications described in chapters 5.15.1 and 5.15.2 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 IUCLID 5 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 must add a row for each use advised against and fill in as a minimum the field “Use advised against name” or the field “Remarks”.

5.17 Information to be provided in IUCLID 5 section 3.7 – Waste from production and use (optional)

This optional section is a repeatable block section: applicants can provide information on waste quantities and composition of waste resulting from the “uses applied for”.

If no waste has been identified, then you should not create any repeatable blocks under this section.

If you have identified waste from production and use, then you are advised to create a repeatable block for each waste type and fill in at least one of the fields of this block: “Estimated quantities”, “Composition” or “Remarks”.

5.18 Information to be provided in IUCLID 5 section 3.8 – Exposure estimates (optional)

This optional section enables the applicant to provide information on the exposure estimates related to the uses applied for.

Exposure related to use:

Working environment: The most relevant activities of exposure related to the use(s) should be described, for instance, during filling, weighing, cleaning activities, sampling for quality and process control, in case of irregularities, etc. Also, the likely pattern of control should be provided.

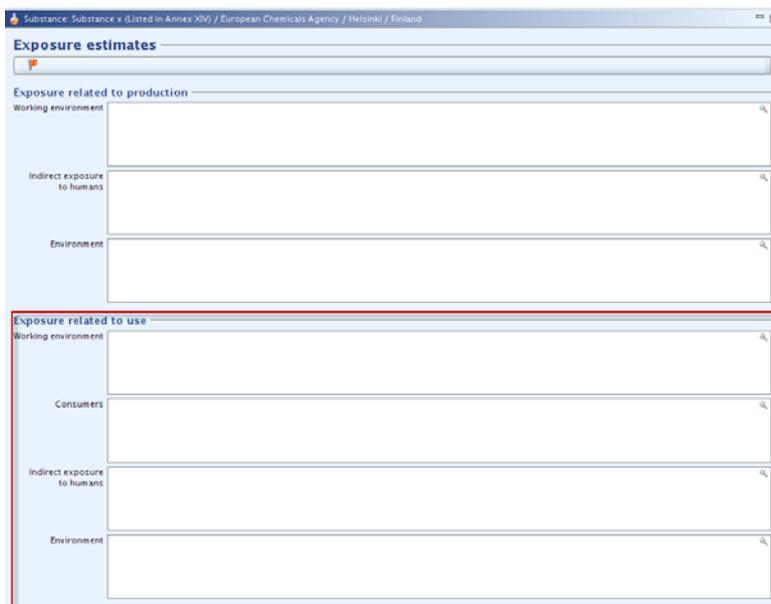
Consumers: The most relevant activities of exposure related to the final consumers should be described. Also, the likely pattern of control (if requested by the legislation) could be provided here.

Indirect exposure to humans: The most relevant activities of indirect exposure related to humans of the substance (i.e. along the supply chain) should be described. Also, the likely pattern of control (if requested by the legislation) could be provided here.

Environment: Describe the duration and frequency of emissions of the substance to the different environmental compartments, and sewage treatment systems derived from the use

of the substance. Also, the likely pattern of control (if requested by the legislation) could be provided here (Figure 52).

Figure 52: Exposure related to uses

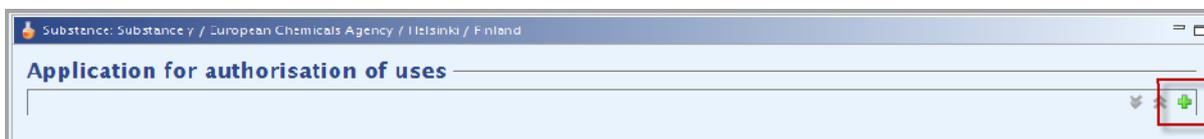


5.19 Information to be provided in IUCLID 5 section 3.10 – Application for authorisation (mandatory)

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

This section is a main repeatable block section and enables the applicant to apply for multiple uses for authorisation. Click the green <Add> button  to open the main repeatable block. If more than one use needs to be specified, add a new main repeatable block for each one (Figure 53).

Figure 53: One main repeatable block per “use applied for”



-  One main repeatable block under “Application for authorisation of uses” must contain one description of a “use applied for” in the field “Use concerned by the request” under the repeatable block “Request for authorisation”.
-  Each main repeatable block shall also contain the following assessment reports:
 - an analysis of alternatives;

- a substitution plan (where relevant);
- a socio-economic analysis (where relevant) and;
- a justification for not considering certain risks (where relevant).

 If you have developed generic assessment reports which cover all “uses applied for”, ECHA recommends that you attach them only in the first main repeatable block (i.e. for Use#1). For the following blocks (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 repeatable block.

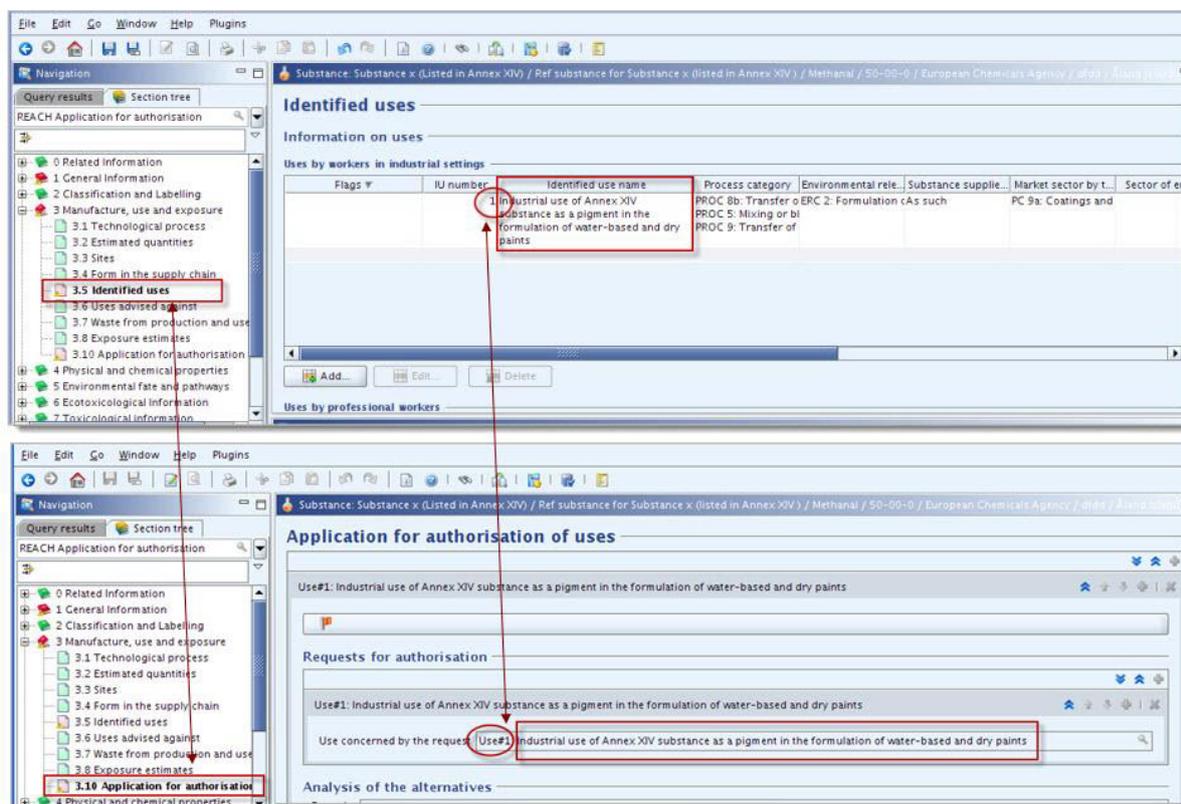
In the following sub-chapters, the contents to be provided in one main repeatable block are detailed.

5.19.1 Requests for authorisation (for one use: Use#1)

Click the green <Add> button  to open the subsection block. An empty block containing the field “Use concerned by the request” is now ready to be filled in with a pre-filled string “Use#”. This description is considered by ECHA to be a “use applied for” i.e. a use for which the application is intended and an authorisation is sought (Figure 54).

 It is crucial that the use number given in the “Use concerned by the request” field (IUCLID 5 section 3.10) exactly matches the one given in “Identified use name” field (IUCLID 5 section 3.5), and also the one in the application web-form. 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.

Figure 54: Description of the “Use concerned by the request”



Despite the repeatable feature of the “Requests for authorisation” block, it is important that only one “Use concerned by the request” is entered under this block.

5.19.2 Analysis of alternatives

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

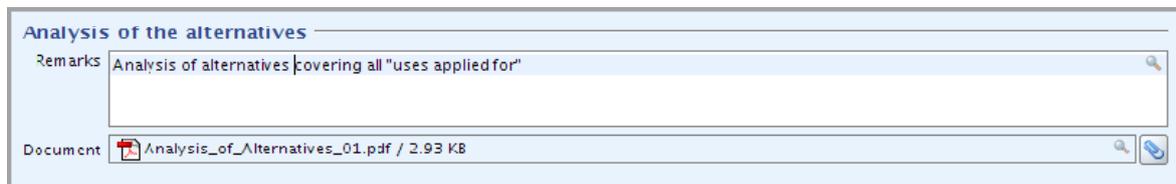
The analysis of alternatives shall be provided following the format available on the ECHA website (http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp) and chapter 3 of the “Guidance on the preparation of an application for authorisation” at:

http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf

- “Document” field: Add the analysis of alternatives documentation by clicking the <Attachment>  button and the green <Add>  button from the context menu appearing. Specify the path and the name of the file to be inserted and indicate any remarks if appropriate in the “Properties” window.

“Remarks” field: If necessary, provide any additional comment here (Figure 55).

Figure 55: Analysis of alternatives



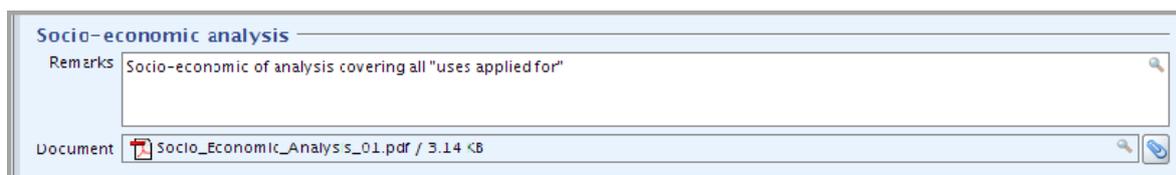
5.19.3 Socio-economic analysis

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/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp) and the “Guidance on the preparation of socio-economic analysis as part of an application for authorisation” at:

http://guidance.echa.europa.eu/docs/guidance_document/sea_authorisation_en.pdf

- “Document” field: Add the SEA documentation by clicking the <Attachment> button  and the green <Add> button  from the context menu appearing. Specify the path and the name of the file to be inserted and indicate any remarks if appropriate in the “Properties” window.
- “Remarks” field: If necessary, provide any additional comment here (Figure 56).

Figure 56: Socio-economic analysis



5.19.4 Substitution plan

Where relevant, the application may include a substitution plan following the format available on the ECHA website (http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp) and chapter 4 of the “Guidance on the preparation of an application for authorisation” at:

http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf

- “Document” field: Add the substitution plan document by clicking the <Attachment> button  and the green <Add> button  from the context menu appearing. Specify the path and the name of the file to be inserted and indicate any remarks if appropriate in the “Properties” window.

- “Remarks” field: If necessary, provide any additional comment here (Figure 57).

Figure 57: Substitution plan.



5.19.5 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 document by clicking the <Attachment> button  and the green <Add> button  from the context menu appearing. Specify the path and the name of the file to be inserted and indicate any remarks if appropriate in the “Properties” window (Figure 58).

Figure 58: Justification for not considering certain risks



5.19.6 Reference to other applications or previous authorisations (for subsequent applications)

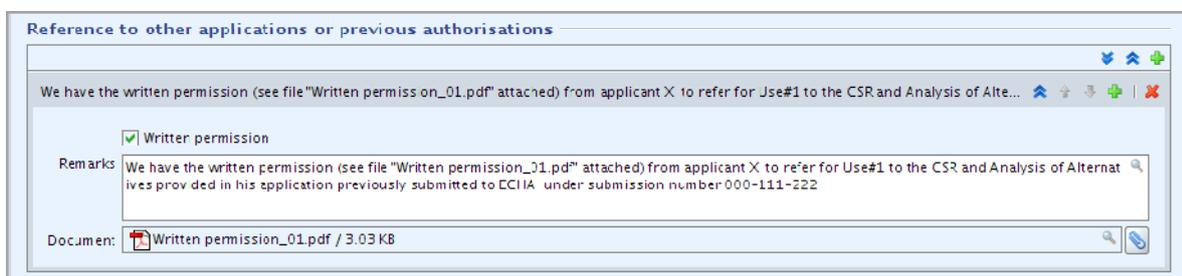
An application for authorisation may refer to previous applications for authorisation for the same substance(s) and use(s). This is mentioned in the REACH Regulation as “subsequent application”. The following two situations are possible:

- if you have the permission from a previous applicant who has applied for an authorisation for the same substance and use, you can refer to the appropriate parts of the previous application submitted;
- alternatively if you have the permission from the holder of a previously granted authorisation, you may refer to the appropriate parts of the previous application submitted.

 For more information please refer to chapter 2.3 (Subsequent Applications) of the “Guidance on the preparation of an application for authorisation” at: http://guidance.echa.europa.eu/docs/guidance_document/authorisation_application_en.pdf

- Click the green <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 <Attachment> button .
- “Remarks” field: If necessary, provide any additional comment on the previous authorisation (Figure 59).

Figure 59: Reference to other applications/authorisations

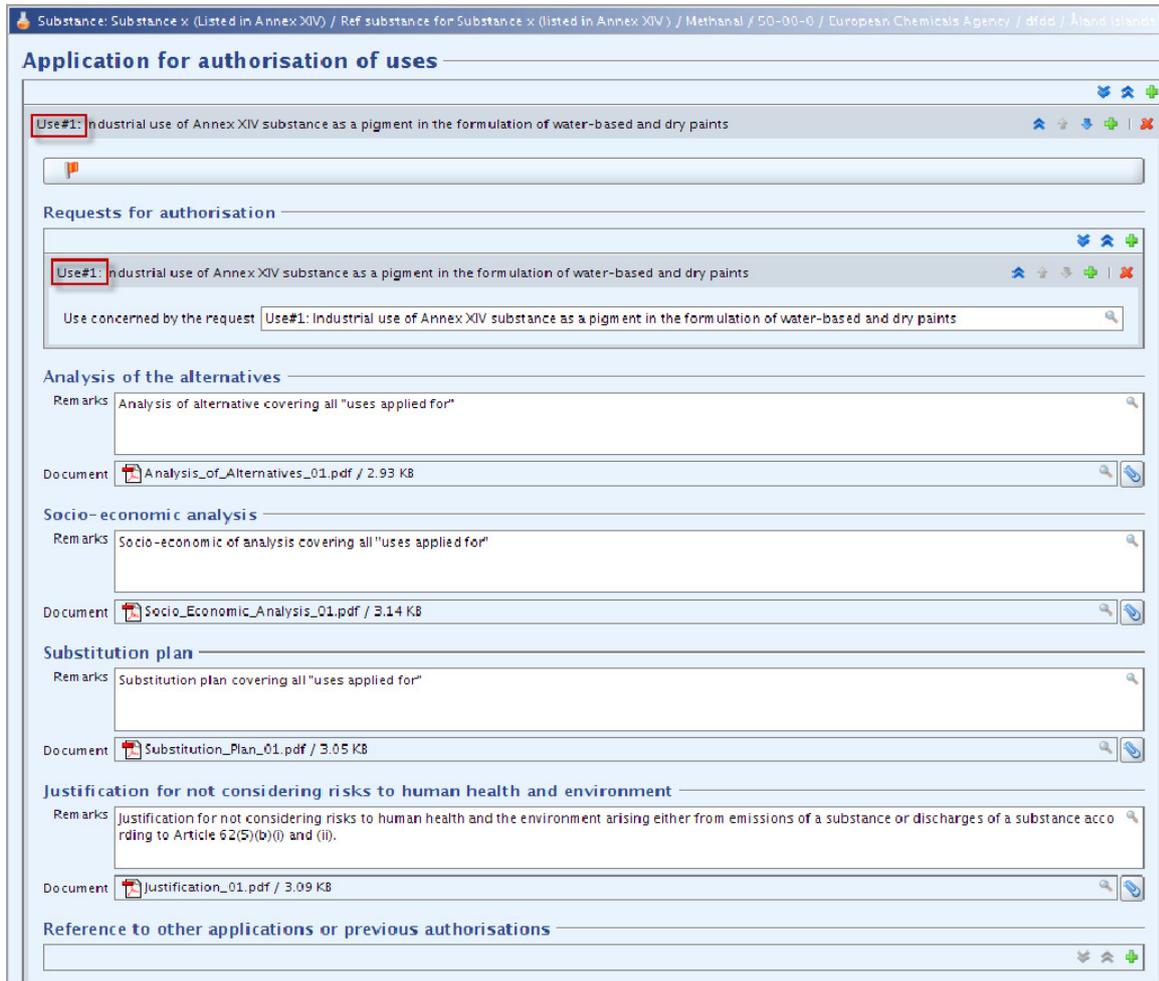


- ✘ For subsequent applications, reference numbers from other applications or granted authorisations (submission numbers and/or authorisation numbers) must be reported in section 1.3 of IUCLID 5 (see section 5.5 of this manual).
- ⚠ When referring to different parts of other applications particular attention 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. See also chapter 8.3 “Subsequent application” of this manual.

5.19.7 Requests for authorisation for additional uses (Use#n)

Once the first main repeatable block has been filled in for Use#1 (Figure 60), the same approach can be taken for Use#2 in the second block and any additional uses.

Figure 60: Main repeatable block for Use#1



Substance: Substance x (Listed in Annex XIV) / Ref substance for Substance x (listed in Annex XIV) / Methanol / 50-00-0 / European Chemicals Agency / dfdd / Åland Islands

Application for authorisation of uses

Use#1: Industrial use of Annex XIV substance as a pigment in the formulation of water-based and dry paints

Requests for authorisation

Use#1: Industrial use of Annex XIV substance as a pigment in the formulation of water-based and dry paints

Use concerned by the request: Use#1: Industrial use of Annex XIV substance as a pigment in the formulation of water-based and dry paints

Analysis of the alternatives

Remarks: Analysis of alternative covering all "uses applied for"

Document: Analysis_of_Alternatives_01.pdf / 2.93 KB

Socio-economic analysis

Remarks: Socio-economic of analysis covering all "uses applied for"

Document: Socio_Economic_Analysis_01.pdf / 3.14 KB

Substitution plan

Remarks: Substitution plan covering all "uses applied for"

Document: Substitution_Plan_01.pdf / 3.05 KB

Justification for not considering risks to human health and environment

Remarks: 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).

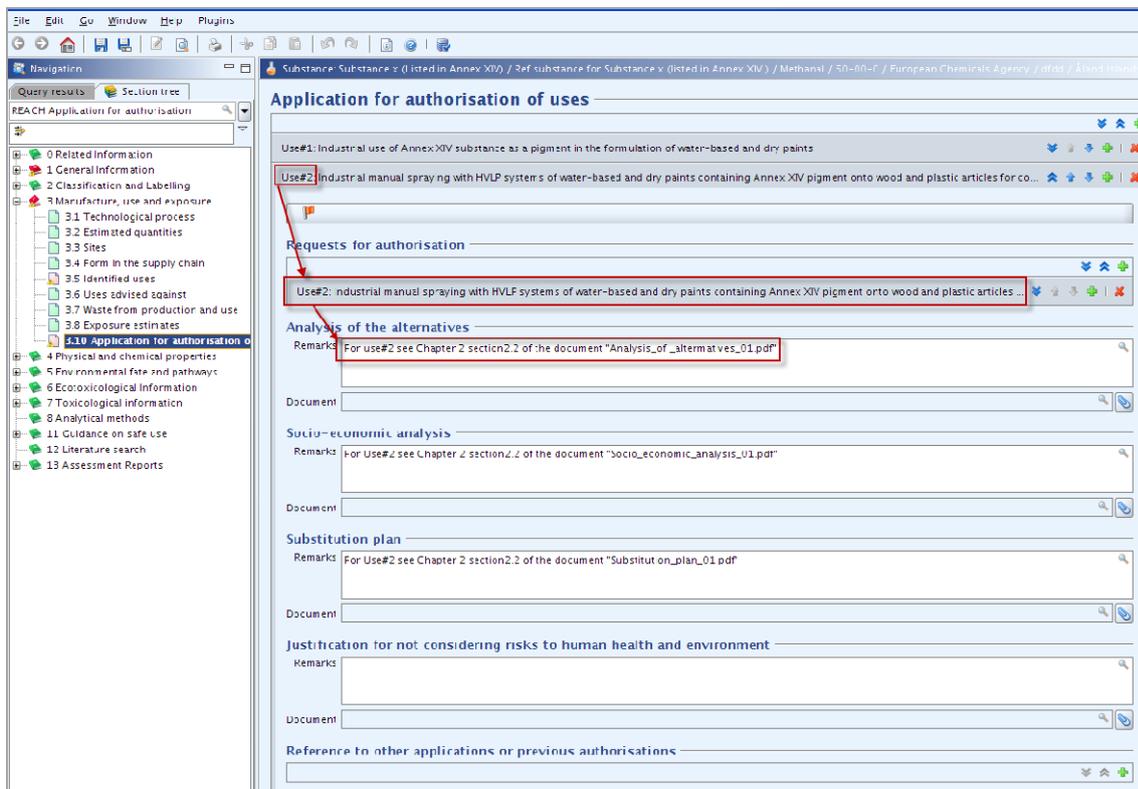
Document: Justification_01.pdf / 3.09 KB

Reference to other applications or previous authorisations

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 block.

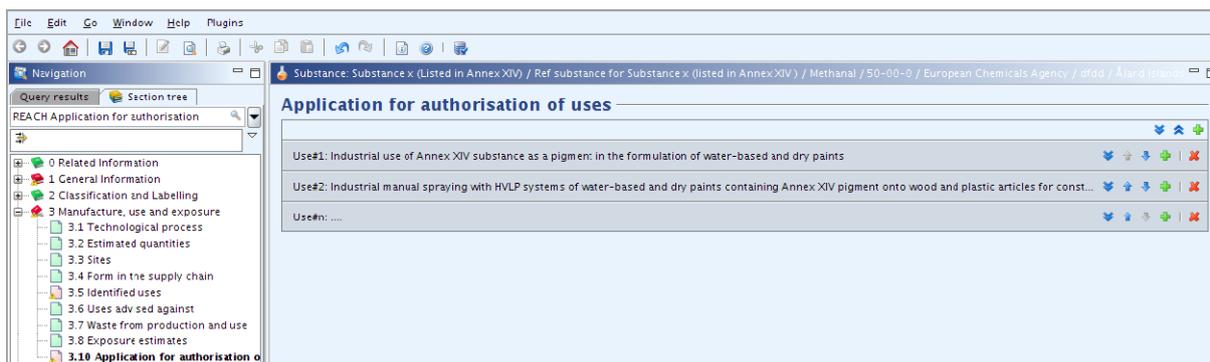
However, if the scope of the assessment report covers several uses, you are not obliged to duplicate the same document in the next blocks and you can refer to certain parts of the reports already attached in the first block (Figure 61).

Figure 61: Block for Use#2



 Note that a new main repeatable block must be created for each different “use applied for” (Figure 62).

Figure 62: One main repeatable block per use



 **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 9 of this manual), and the generated .PDF (application form) should be attached to the section 13 of the IUCLID 5 dossier.

5.19.8 Broad information on uses

- ✘ Applicants are requested to propose for each “use applied for” a non-confidential broad description. The broad description should be provided in the web-form at the ECHA website (see chapter 9 of this manual). The application form generated by the web-form shall be attached in section 13 of the IUCLID 5 dossier.

5.20 Information to be provided in IUCLID 5 sections 4 to 7 (optional)

Although information related to IUCLID 5 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 4.2 of this manual).

Further instructions on how to create a copy of a substance dataset and how to fill out sections 4 to 7 can be found in chapters D.4.10 and E.4–E.7 of the IUCLID 5 End User Manual at:

<http://www.iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual>

5.21 Information to be provided in IUCLID 5 section 8 – Analytical methods (optional)

IUCLID 5 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 section 8 can be found in chapter E.8 of the IUCLID 5 End User Manual at:

<http://www.iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual>

5.22 Information to be provided in IUCLID 5 section 11- Guidance on safe use (optional)

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

- First aid measures;
- Fire-fighting measures;
- Accidental release measures;
- Handling and storage;
- Transport information
- Exposure controls / personal protection;
- Stability and reactivity;
- Disposal consideration.

Further instructions on how to fill out section 11 can be found in chapter E.11 of the IUCLID 5 End User Manual at:

<http://www.iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual>

5.23 Information to be provided in IUCLID 5 section 12 – Literature search (optional)

This optional 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 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” pane at the bottom of the IUCLID 5 screen (right-click into the left pane and then click the “Add” button).

5.24 Information to be provided in IUCLID 5 section 13 - Assessment Reports (mandatory)

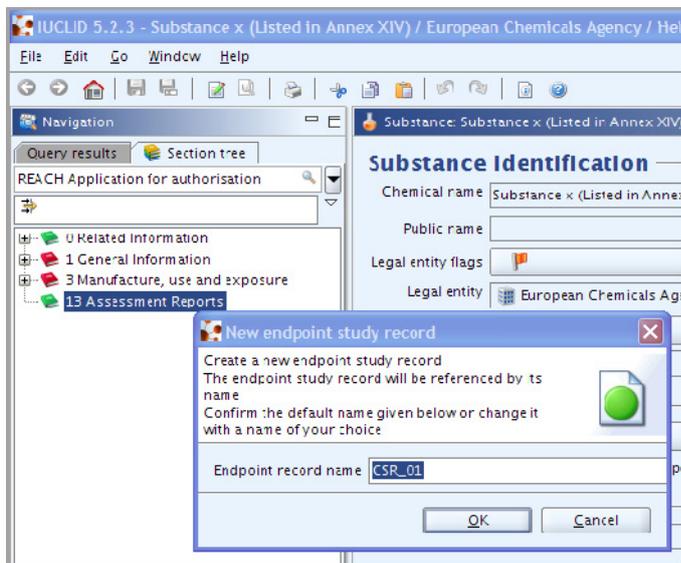
- ! IUCLID 5 section 13 is an endpoint study record–type section in which different assessment reports can be attached covering information not documented in other IUCLID 5 sections.
- ✘ All applications must contain at least two endpoint study records in section 13: one containing or referring to the Chemical Safety Report (CSR) and one containing the application form generated by the web-form (see chapter 9).

5.24.1 Chemical Safety Report

A Chemical Safety Report (CSR) should be referenced in IUCLID 5 section 13 as shown below.

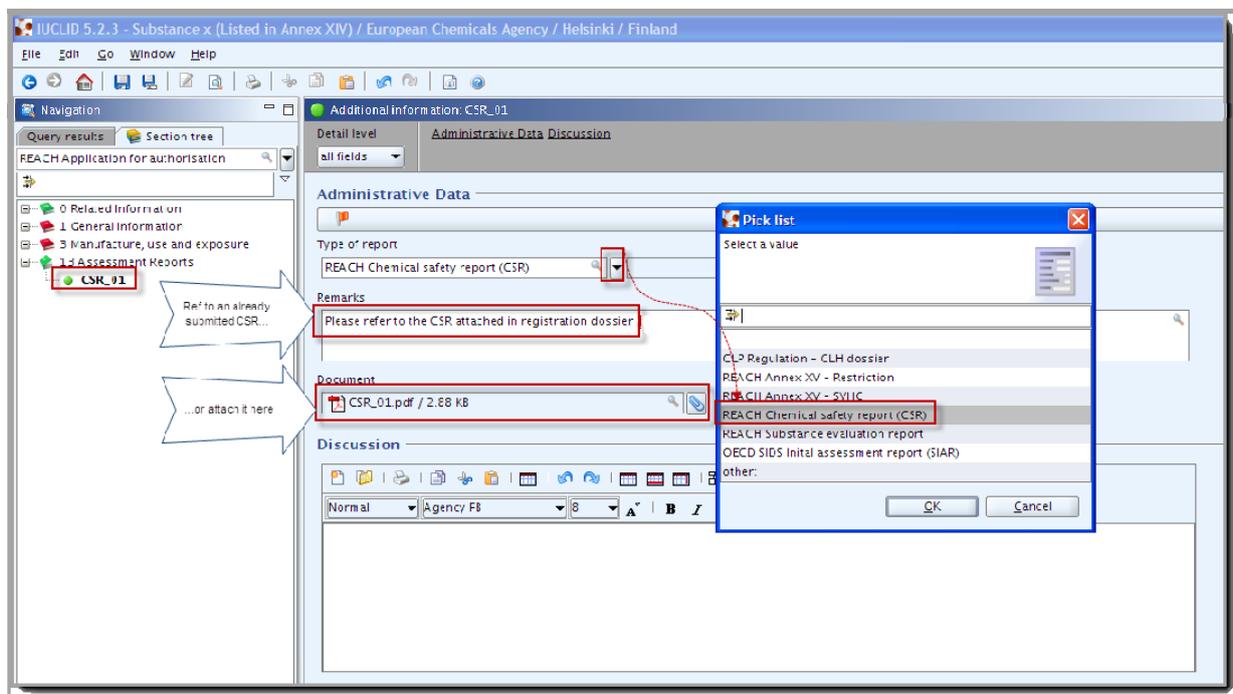
- Right-click section “13 Assessment Reports” and select “New endpoint study record” (Figure 63).

Figure 63: Adding a new endpoint study report in section 13



- From the pick-list under “Type of report” select “REACH Chemical safety report (CSR)” (see Figure 64).
- In the “Document” field click the <Attachment>  button and the green <Add>  button that appears. You can subsequently attach the document (Figure 64).

Figure 64: Attach the CSR or refer to the appropriate registration dossier



Alternatively, the application can refer to a CSR already provided as a part of a registration dossier. In this case, 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 “Remarks” field (see Figure 64). 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 5 (see chapter 5.5).

- ✘ The registration number provided in section 1.3 must belong to the submitting applicant or to one of the co-applicants of the group.

5.24.2 Application form and other forms

- ✘ In section 13 the application form generated by the web-form must be attached (see chapter 9 of this manual for more detailed information).

Furthermore, any additional reports which provide information which cannot be documented in the other IUCLID 5 sections should be included:

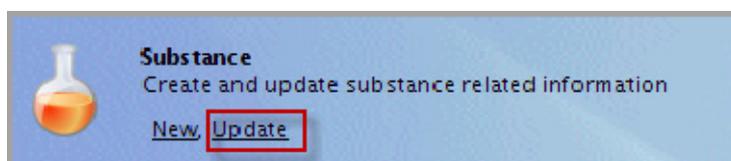
- **application form** (including, mapping of uses and a proposal for their broad information);
- **concordance table** – The information in this table is requested to facilitate the processing of your application for authorisation. The template can be downloaded at: http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp;
- **mapping of changes performed** (for updates in response to ECHA’s Committees requests) (see chapter 8).

6 CREATING AN INITIAL APPLICATION FOR AUTHORISATION DOSSIER

This section of the manual provides instructions on how to create an initial application for authorisation for one substance, and does not include subsequent applications as defined in Article 63 of REACH. For specific submissions such as subsequent applications, updates and review reports please go to chapter 8 (“Specific submissions”) of this manual.

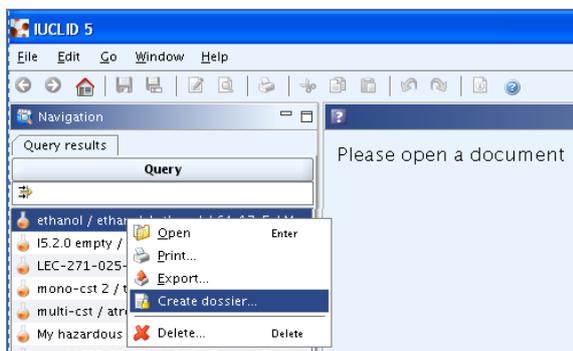
- On the IUCLID 5 main screen (Task Panel), select “Update” under Substance (Figure 65).

Figure 65: Update the (Annex XIV) substance



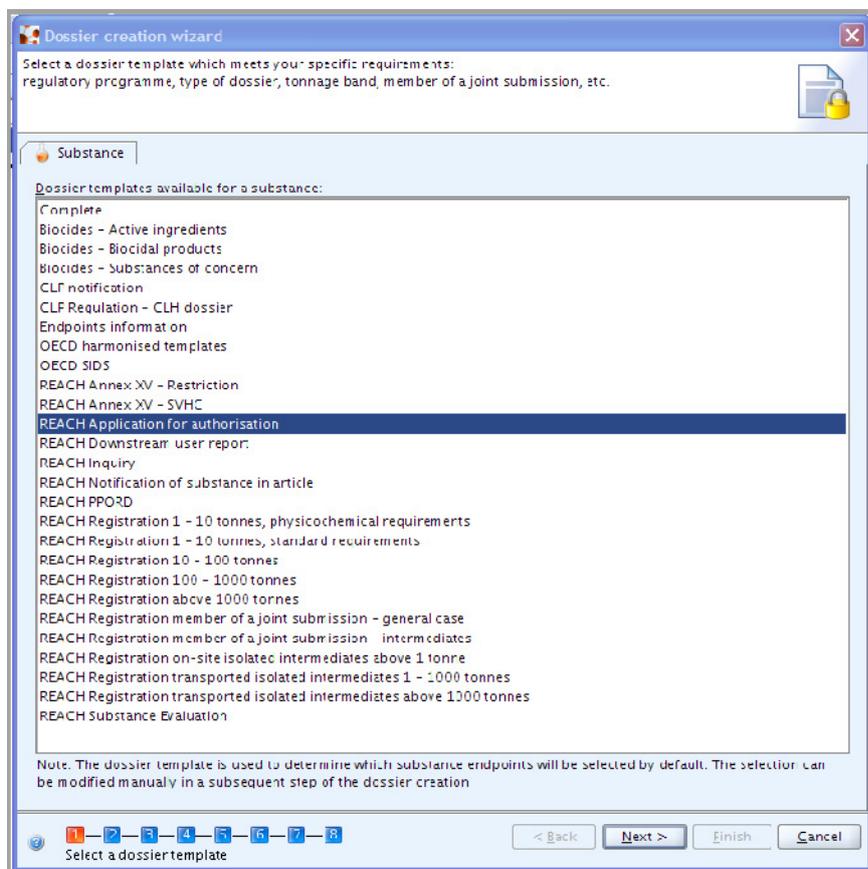
- All available substances are displayed; select the substance for which you want to create the application for authorisation dossier.
- Right-click the appropriate substance in the “Query results” list. From the pop-up menu select “Create Dossier” (Figure 66).

Figure 66: Selecting ‘Create dossier’ from the pop-up menu



- The “Dossier creation wizard” is displayed.
- Step 1: Select the Dossier template “REACH Application for authorisation” (Figure 67).

Figure 67: Selecting the dossier template



- Step 2: Select all Confidentiality and Regulatory purpose flags (Figure 68). Note that any section in your IUCLID 5 Substance dataset containing a Confidentiality or Regulatory purpose flag that is not selected at this stage will be omitted from the final dossier. It is recommended to select all flags when creating the dossier in order to avoid omission of any relevant information.

Figure 68: Selection of Confidentiality and Regulatory purpose flags



Dossier creation wizard

Select all Confidentiality and Regulatory purpose flags or clear checkboxes for properties for which the information shall not be included into the dossier
 Dossier template: REACH Application for authorisation

Confidentiality

Deselect all

- CBI - confidential business information
- IP - intellectual property
- no PA - not public available
- Not confidential

Use restricted to selected regulatory programmes

Deselect all

- EU: BPD - Biocidal Products Directive 98/8/EC
- EU: CLP - Classification, Labelling and Packaging
- EU: PPP - Plant Protection Products Directive 91/414/EEC
- EU: REACH - Registration, Evaluation and Authorisation of Chemicals
- CA: CEPA - Existing Substances Program under CEPA
- CA: PCPA - Pest Control Products Act
- JP: CSCL - Chemical Substances Control Law
- OECD: HPVC - HPV Chemicals Programme
- US: EPA HPVC - HPV Chemical Challenge Programme
- US: FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
- US: TSCA - Toxic Substances Control Act
- Any other
- No regulatory purpose

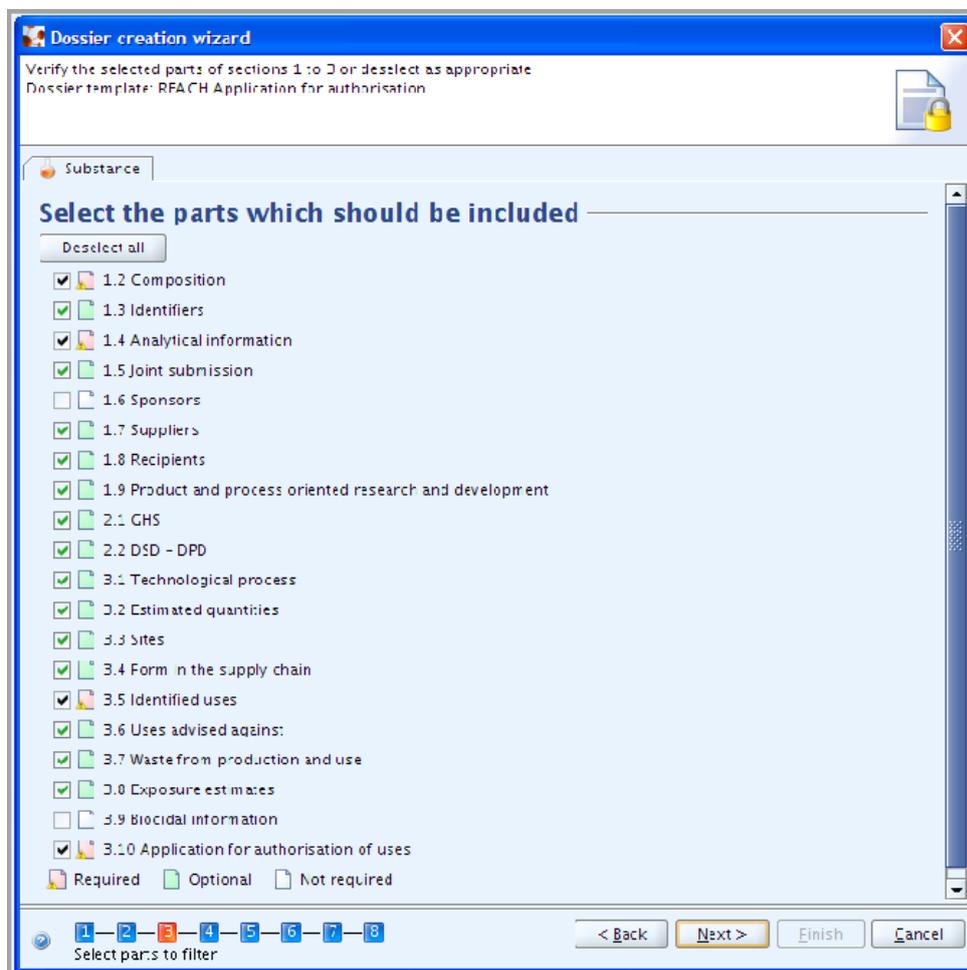
Note: for a REACH dossier, all information should be part of the dossier, i.e. all flags should be selected or the default values should be used

1 2 3 4 5 6 7 8 < Back Next > Finish Cancel

Select data protection flags

- Step 3: Leave the default settings (i.e. all optional subsections of IUCLID 5 sections 1–3 are included in the final dossier) or select/deselect as appropriate. At this stage, please make sure that all the necessary sections for your “application for authorisation” dossier appear ticked, as only these documents will appear in your dossier (Figure 69). The relevant IUCLID 5 sections for applications for authorisation are 1.1, 1.2, 1.3, 1.5 (as appropriate), 3.5, 3.10 and 13.

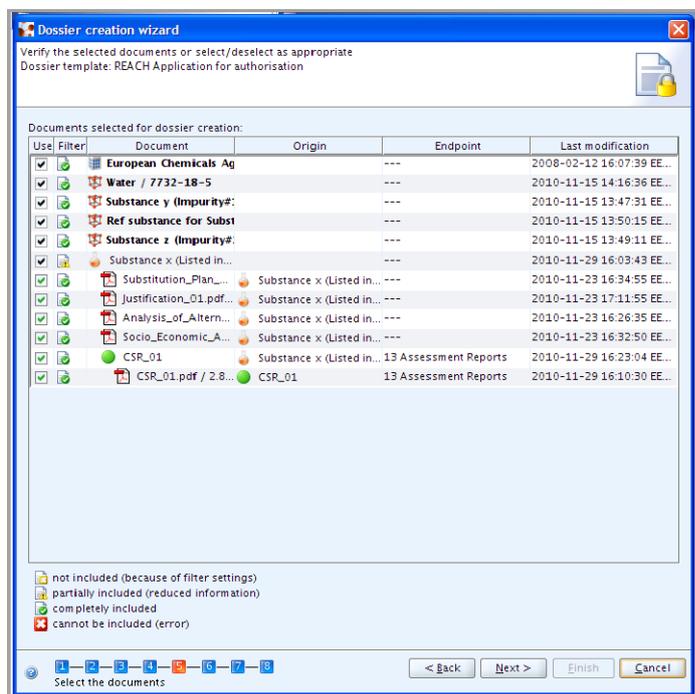
Figure 69: Inclusion of data from IUCLID 5 sections 1–3 in the dossier



! It is normal that section 13 does not appear on this screen; it will be checked in step 5 of the dossier creation wizard.

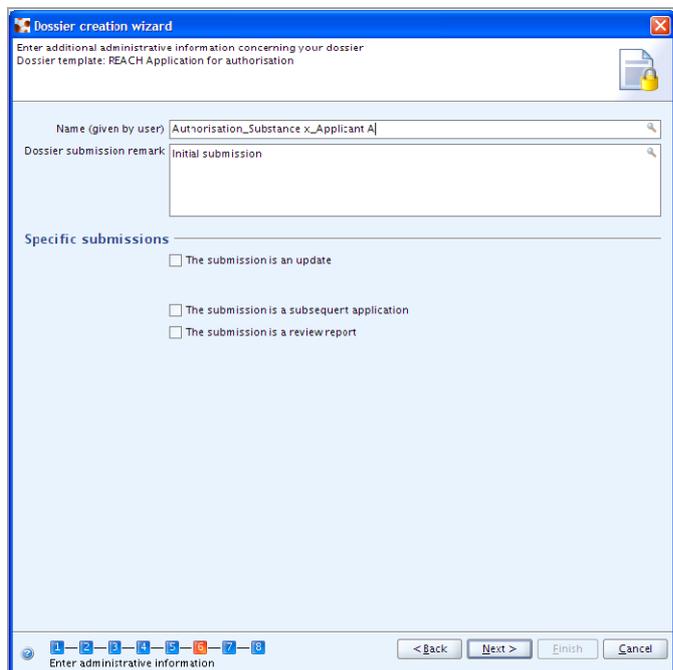
- Step 4: Select the appropriate “Detail level of endpoint fields”.
- Step 5: Verify that all the appropriate endpoint study/summary records are selected for the final dossier (Figure 70). You have to ensure at this step that the section 13 assessment reports (e.g. the Application form, and the CSR, if appropriate) are included in the final dossier. It is not possible to deselect the Legal entity, Substance, or Reference substance records.

Figure 70: Verify selected objects



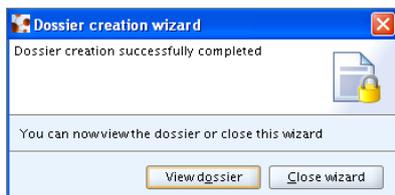
- Step 6: In the field “Name”, enter an appropriate name which enables you to easily identify the dossier when searching or exporting it from IUCLID 5. It may be useful to refer to the substance name and the dossier version, in case several were created (Figure 71). See chapter 8 for specific submissions (i.e. updates, subsequent applications and review reports).

Figure 71: Fields for name and administrative information of an initial submission



- A window informs about the success of the dossier creation. When clicking the <View dossier> button, the dossier will be displayed (Figure 72).

Figure 72: Success message of dossier creation



- ✘ Verify that sections 1.1, 1.2, 1.3, 1.5 (if appropriate), 3.5, 3.10 and 13 were included in the generated dossier and are correctly filled out. If a missing/incomplete section is detected, proceed to amend the substance dataset and generate a new dossier.

7 EXPORTING YOUR APPLICATION FOR AUTHORISATION DOSSIER

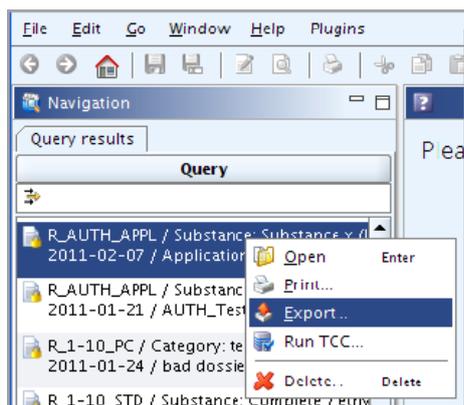
- The application for authorisation dossier needs to be exported before it can be submitted to ECHA.
- In the main task screen of your IUCLID 5 installation, click on the dossier icon or the “View” link (Figure 73).

Figure 73: Viewing a dossier



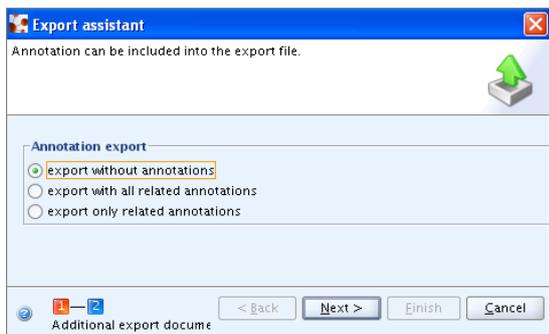
- Select your “application for authorisation” dossier, right-click it and select “Export” (Figure 74).

Figure 74: Exporting a dossier



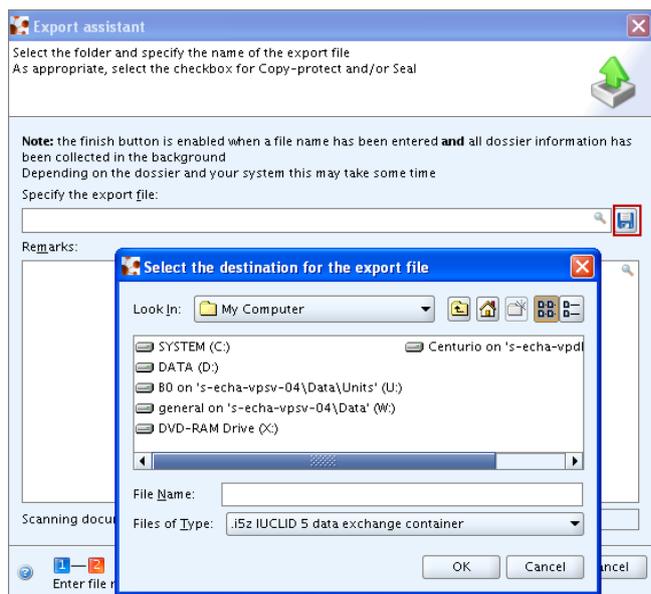
- The export assistant will ask you if you wish to include your annotations in the dossier. Normally, select “Export without annotations” (unless you have included relevant information as annotations in your dossier) and click the <Next> button (Figure 75).

Figure 75: Selection of annotations in the export



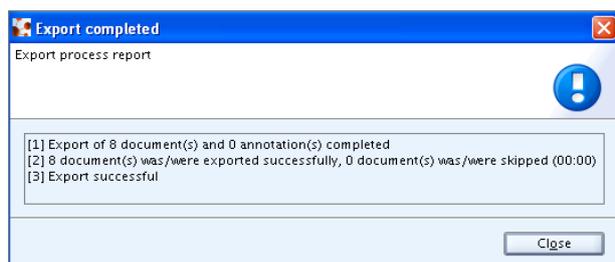
- In the next step specify the location where you want to store your dossier by clicking the  button (Figure 76). You also need to indicate a name for the exported dossier in the “File Name” field. To avoid confusion, it is advisable to indicate the same name you specified when creating the dossier.

Figure 76: Save button and location



- Now click the <Finish> button. The dossier has now been exported to the location you specified; a confirmation message will appear (Figure 77).

Figure 77: Export progress report



8 SPECIFIC SUBMISSIONS

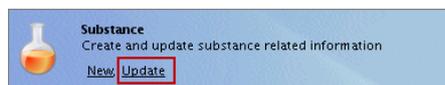
This section provides instructions on how to submit:

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

If 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.

- In the main screen go to tasks, and click “Update” under “Substance” (Figure 78).

Figure 78: Selection of the update link



- Select from the list the substance for which you wish to submit the updated or reviewed information (not applicable for subsequent applications - see chapter 8.3), and double click it. From the Substance dataset Section tree pane, select the section(s) that you wish to update. Edit the necessary IUCLID 5 dossier sections by clicking the <Edit item> button .
- When creating your dossier, specify the type of specific submission in step 6 of the dossier creation wizard (dossier header).

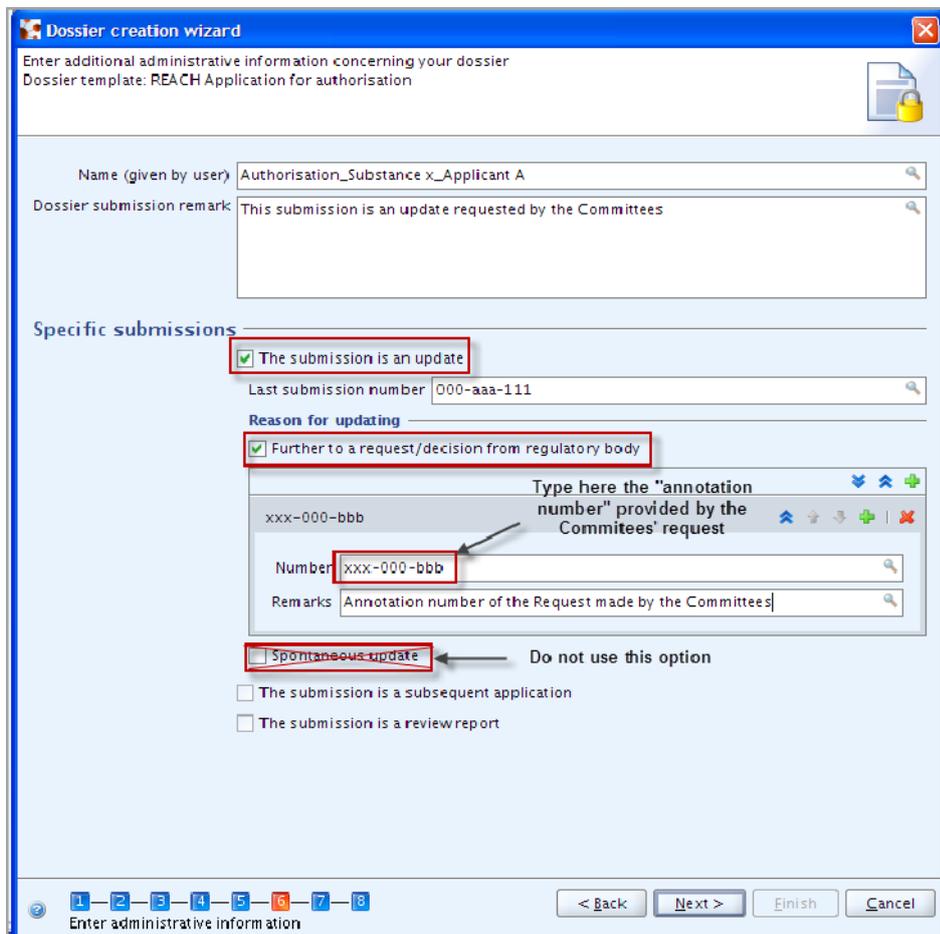
To create and export the dossier, please refer to chapters 6 and 7 of this manual.

8.1 Requested update

In case of an update made on request of the Committees as per Article 64(3), please resubmit to ECHA the updated version of your initial IUCLID 5 dossier and attach in section 13 a document indicating where exactly you have made the updates (e.g. IUCLID 5 sections and/or sub-sections, attachments and/or their related parts etc).

When creating your updated dossier the button “The submission is an update” and the checkbox “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 (Figure 79).

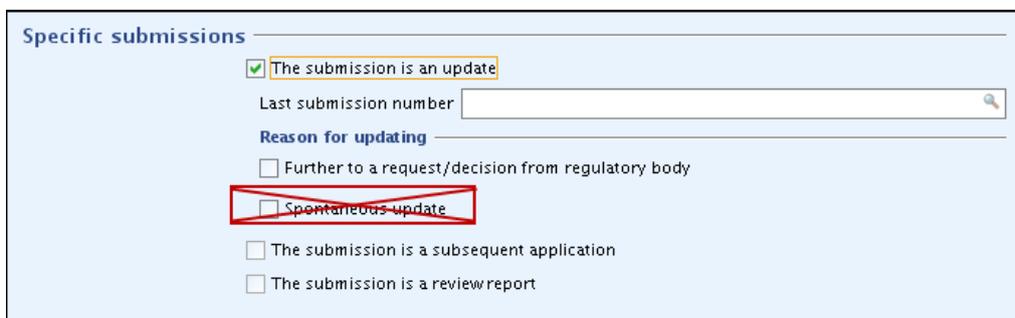
Figure 79: Dossier creation wizard – Requested update



8.2 Spontaneous update

-  This type of update is not allowed and will not be processed by ECHA.
Please ensure that the box “Spontaneous update” is not ticked (Figure 80).

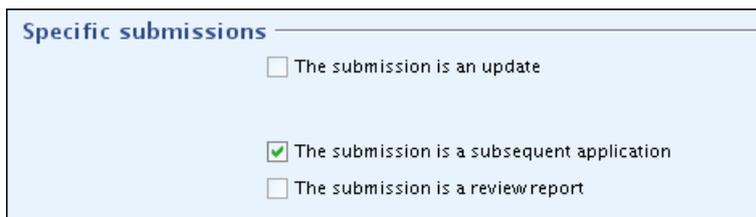
Figure 80: Dossier creation wizard – Spontaneous update is not an allowed submission type



8.3 Subsequent application

- In case of subsequent applications made in accordance with Article 63(1) and (2) please submit to ECHA your initial IUCLID 5 dossier as instructed in chapters 2, 3, 4 and 9 of this manual.
- ✘ IUCLID 5 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 5.3, 5.4, and 5.5 of this manual.
- All “uses applied for” in a subsequent application must be listed in section 3.10 of IUCLID 5:
 - uses that do not refer to other applications must be documented in section 3.10 as instructed in part 5.19 of this manual. They must also be linked to an accessible CSR via the reference to the exposure scenarios in section 3.5. (see chapter 5.16 of this manual);
 - uses that refer to other applications must keep the same description, and if possible the same numbering. Reference to assessment reports from other applications can be made in the corresponding “Remarks” field of the main repeatable block of IUCLID 5 section 3.10. Updated versions of assessment reports can be attached in section 3.10 as described in chapter 5.19.
- ✘ Written and valid permissions from the previous applicant(s) must be attached under the block “Reference to other applications or previous authorisations” in IUCLID 5 section 3.10.
- It is recommended that you clearly indicate the parts of the other applications that you refer to. This information should be attached as a document in IUCLID 5 section 13. A concordance table may be a useful basis to report such a mapping.
- ✘ Furthermore, IUCLID 5 section 13 must contain the application form as generated by the web-form (see chapter 9 of this manual).
- When creating your dossier: ensure that section 1.3 is included in the final dossier in dossier creation step 3. In dossier creation step 6 “The submission is a subsequent application” (Figure 81) must be selected.

Figure 81: Dossier creation wizard – Subsequent application



Specific submissions

The submission is an update

The submission is a subsequent application

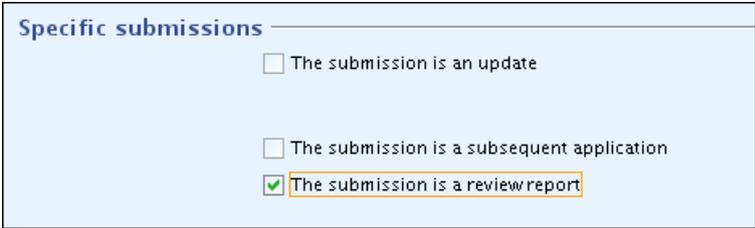
The submission is a review report

8.4 Review report

In case of a review report, please resubmit to ECHA your reviewed/updated IUCLID 5 dossier.

- section 13 can be used to attach a document indicating exactly the parts that you have updated;
- section 1.3 must be filled in with the previous authorisation number. See chapter 5.5;
- ensure that section 1.3 is included in the final dossier in dossier creation step 3. In dossier creation step 6 the button “The submission is a review report” must be selected (Figure 82).

Figure 82: Dossier creation wizard – Review report



Specific submissions

- The submission is an update
- The submission is a subsequent application
- The submission is a review report

9 SUBMITTING AN APPLICATION FOR AUTHORISATION DOSSIER

9.1 Step 1: Company sign-up in REACH-IT

- If you already have a REACH-IT account you can skip this step.
- If you do not have an account in REACH-IT, please refer to the Industry User Manual – Part 2, located at: http://echa.europa.eu/reachit/createaccount-it_en.asp
- For joint applications, both the submitting applicant and the co-applicants must sign up in REACH-IT.

 It is important that the company size, contact information, and the company address indicated under the tab “Company information” in REACH-IT 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.

9.2 Step 2: Create the application form

To create the application form, go to the webpage for “Submission of an application for authorisation” (located at: http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_submission_en.asp) and click on <Web-form 1: Create application form>.

 For joint applications, this form must be created by the submitting applicant.

To fill in the Web-form 1 (Figure 83), follow the steps below:

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 5 application file.

 Even if an application for authorisation may be submitted for several substances that meet the definition of a group of substances in section 1.5 of Annex XI to REACH, this specific aspect is not covered in details in this manual.

In case you want to submit an application for authorisation for a group of substances please contact the ECHA Helpdesk before.

- 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 5 dossier.
- Indicate the number of “uses applied for” included in the application.

- For each “use applied for”, enter the use description in the free text field below the total number of uses.
 - ✘ The numbering and the descriptions of uses should be identical with the ones in section 3.10 of the IUCLID 5 dossier under the “Use concerned by the request” field.
 - Include the proposed “broad information on use” in the respective field under the use description (Figure 83).
-  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 description should provide sufficient information to enable interested parties to provide meaningful information. Based on the descriptions proposed by the applicant (if any) and the information contained in the application, ECHA will establish an initial 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 wording of the broad information on uses.
- After ECHA has received the fee for an application for authorisation, the broad information on uses will be published on ECHA’s website for the purpose of public consultation.
- 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.

Figure 83: Web-form 1 - Creation of the application form

Substance(s) applying 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.) and the "proposed broad information on use" in the respective fields below the use descriptions.

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.

Note regarding the "proposed broad information on uses":
 Pursuant to Article 64(2) of REACH Regulation 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 description should provide sufficient information to enable interested parties to provide meaningful information. Based on the descriptions proposed by the applicant (if any) and the information contained in the application, ECHA will establish an initial 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 wording of the broad information on uses. After ECHA has received the fee for an application for authorisation, the broad information on uses will be published on ECHA's website for the purpose of public consultation.

* Total number of uses:

* Use 1:

Proposed broad information for Use 1:

* Use 2:

Proposed broad information for Use 2:

Applicant(s)

Joint application

* Uses and substances applied for:

- Use 1 for Substance 1
- Use 2 for Substance 1

- In case of a joint application, select the checkbox <Joint application> in section <Applicant(s)>. Indicate the number of applicants by choosing the correct value from the drop-down menu (Figure 84).

Figure 84: Applicants information in case of joint application (Web-form 1)

Applicant(s)

Joint application

* Total number of applicants:

* Applicant legal entity name <small>as indicated in the REACH/IT account</small>	* Applicant UUID <small>as indicated in the REACH/IT account</small>	* Role(s) in the supply chain <small>press 'Ctrl' for multi-selection</small>	* Uses and substances applied for
<i>Applicant 1 (submitting)</i>			
<input type="text" value="Company name of applicant 1"/>	<input type="text" value="IUC5-01e1d7f7-edec-49d1-b32a-81e0"/>	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input type="checkbox"/> Downstream User	<input checked="" type="checkbox"/> Use 1 for Substance 1 <input checked="" type="checkbox"/> Use 2 for Substance 1 <input checked="" type="checkbox"/> Use 3 for Substance 1
<i>Applicant 2</i>			
<input type="text" value="Company name of applicant 2"/>	<input type="text" value="IUC5-02e1d7f7-edec-49d1-b32a-81e0"/>	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input type="checkbox"/> Downstream User	<input checked="" type="checkbox"/> Use 1 for Substance 1 <input checked="" type="checkbox"/> Use 2 for Substance 1 <input checked="" type="checkbox"/> Use 3 for Substance 1
<i>Applicant 3</i>			
<input type="text" value="Company name of applicant 3"/>	<input type="text" value="IUC5-03e1d7f7-edec-49d1-b32a-81e0"/>	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Downstream User	<input type="checkbox"/> Use 1 for Substance 1 <input checked="" type="checkbox"/> Use 2 for Substance 1 <input type="checkbox"/> Use 3 for Substance 1
<i>Applicant 4</i>			
<input type="text" value="Company name of applicant 4"/>	<input type="text" value="IUC5-04e1d7f7-edec-49d1-b32a-81e0"/>	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Importer <input checked="" type="checkbox"/> Downstream User	<input checked="" type="checkbox"/> Use 1 for Substance 1 <input type="checkbox"/> Use 2 for Substance 1 <input checked="" type="checkbox"/> Use 3 for Substance 1

* Email of submitting applicant
Please note that a PDF version of this application form and a submission code or token will be sent to this email address.

I have read and accept the following [Terms & Conditions](#)

User identification



Enter the text from image without spaces. Letters are not case-sensitive

- For the submitting applicant and the co-applicants the following information shall be entered in the section <Applicant(s)>:
 - Legal entity name and Legal entity UUID as specified in REACH-IT;
 - the Role(s) in the supply chain;
 - 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 Legal entity name and UUID can be found under the “Company information” tab 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.
- 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.
- Before submitting 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.
- Click the <Create application form> button.

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.

- In the case of a single application, the applicant will receive an email including the application form and a submission code. To proceed with the application, go to Step 4: Upload the application for authorisation.
 - In the case of a joint application, the submitting applicant will receive an email with the application form and a security token. After verifying that all information is correct, the submitting applicant shall provide the application form and the security token to the co-applicants. To proceed with the application, go to Step 3: Confirm participation in a joint application. If the application form includes incorrect information, the submitting applicant needs to create a new application form.
- ❗ The creation of the application form does not constitute the submission of an application for authorisation!

The IUCLID 5 dossier of the application for authorisation needs to be created and submitted together with the application form as described in step 4: Upload the application for authorisation. For more information on the creation of the IUCLID 5 dossier see chapters 3 to 8 of this manual.

9.3 Step 3: Confirm participation in a joint application

 If you are submitting a single application or you are the submitting applicant of a joint application, you can skip this step and proceed to chapter 9.4 “Step 4: Upload the application for authorisation”.

After the submitting applicant has completed the creation of the application form, **the co-applicants will receive the application form in .PDF format and a 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:

- 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 identical with the data in your REACH-IT account. This information can be found in REACH-IT under the tab “Company information”;
- the role(s) of your legal entity for the purpose of the application for authorisation is(are) correct;
- the mapping of the use(s) and substance(s) “applied for” is correct and corresponds to your Legal entity’s intentions.

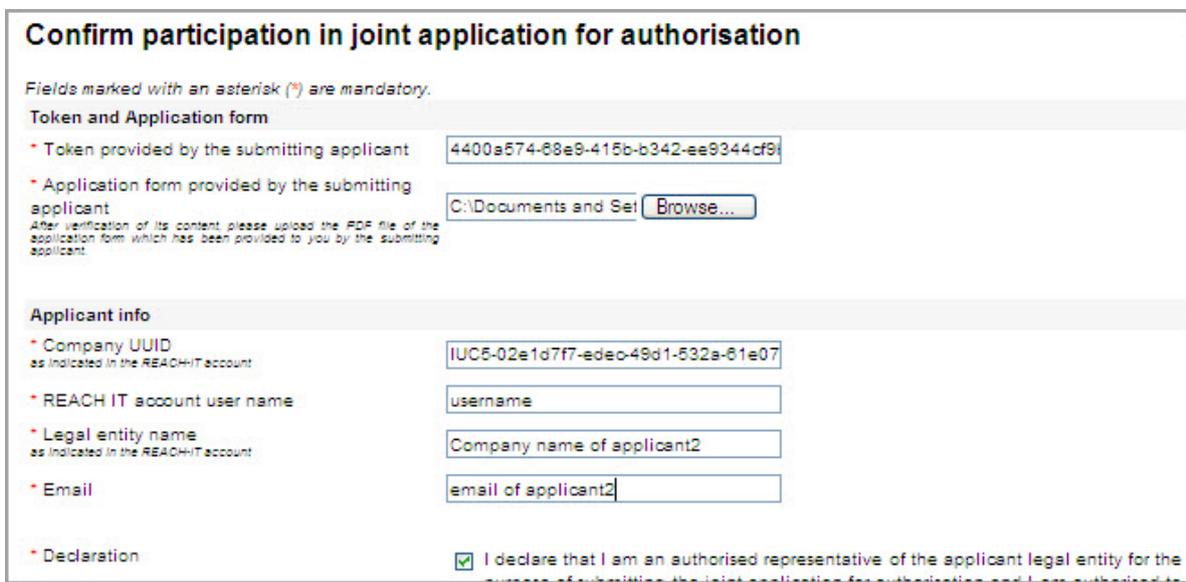
If the information in the application form is not correct, you shall notify the submitting applicant who needs to create a new application form. In that case, ignore the application form and token sent to you and wait for the corrected application form and a new token. After you have verified the new .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!

To confirm your participation in the joint application, go to the webpage for “Submission of an application for authorisation” (located at: http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_submission_en.asp), click on <Web-form 2: Confirm participation in joint application> and follow the steps below (Figure 85):

- Enter the token provided by the submitting applicant in section “Token and Application form”.
- 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.
- 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).
- 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”).
- Enter a valid email address. A preliminary confirmation of your participation in the joint application will be sent to this email address.
- Before submitting the form, type the text visible in user identification box (CAPTCHA) in the field above the <Join application> button.
- Click the <Join application> button to confirm your participation in the joint application.

Figure 85: 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

* 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

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, you will receive a notification by email to the email address you provided in the specific web-form.

- ❗ 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 5 dossier and the dossier has passed the Business Rules⁴ check at ECHA, the application is considered successfully submitted. All co-applicants will receive a notification of the successful submission of their application as an internal message via REACH-IT.

9.4 Step 4: Upload the application for authorisation

- ⚠ ECHA has established preferred submission windows http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp. 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. On the other hand, submitting your application in advance of these windows may as well be considered, if you wish to avoid / reduce the risk of missing the window deadlines (which could result in a delay up to 3 months before the invoice can be issued) due to failing of Business Rules check.

In the case of a single application, the applicant receives an email with the application form in .PDF format and a submission code as described in Step 2: Create the application form (see chapter 9.2).

Verify carefully the application form and proceed only if all the information is correct. If the information is not correct, create a new application as described in Step 2, and you will receive a new .PDF file and submission code (in that case ignore the first submission code received).

In the case of a joint application, the submitting applicant receives an email with a submission code only after all co-applicants have confirmed their participation in the joint application and ECHA has verified that the REACH-IT accounts specified exist (cf. Step 3 above). The submission code will be needed when submitting the application for authorisation.

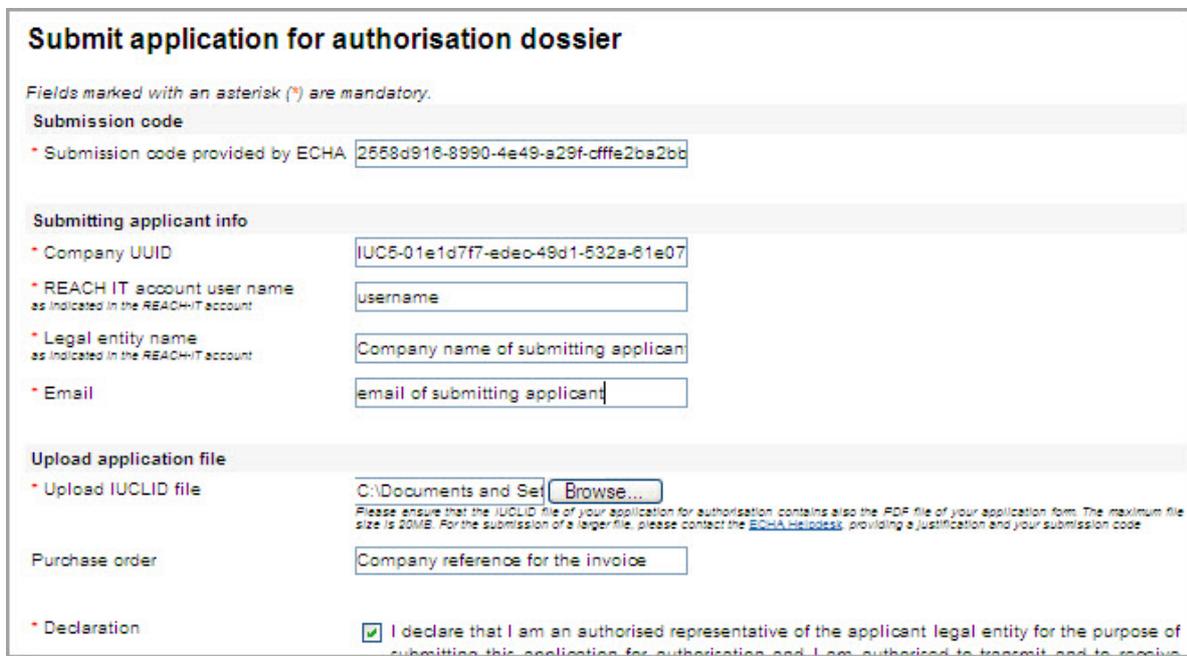
Proceed by attaching the application form to section 13 of the IUCLID 5 substance dataset as indicated in chapter 5.24 and creating the IUCLID 5 dossier for the application for authorisation.

To submit the IUCLID 5 dossier, go to webpage for "Submission of an application for authorisation" (located at: http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_submission_en.asp), click on <Web-form 3: Submit application for authorisation dossier>, and follow the steps below (Figure 86):

⁴ The Business Rules are a set of 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. Passing the business rules check, only provides a confirmation that the dossier can be accepted for processing and not that the dossier is complete.

- In the section <Submission code>, enter the submission code received by email.
- Under <Submitting applicant info>, enter the Legal entity UUID and the Legal entity name of your company, as these appear in your REACH-IT account. In case of a joint application, ensure that this information matches also the data relating to the submitting applicant 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).
- ✘ The Legal entity name and the Legal entity UUID indicated in the Web-form 3 must be identical with the corresponding data in the submitting applicant’s REACH-IT account. The Legal entity name and UUID can be found under the “Company information” tab in REACH-IT.
- 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 User” role (not “Company Reader”).
- Enter a valid email address. A preliminary confirmation of your submission will also be sent to this email address.
- Under <Upload application file> click on <Browse> to open a dialogue box which allows you to select the dossier file (.i5z file) you want to upload.

Figure 86: Web-form 3. Submission of your IUCLID 5 dossier



Submit application for authorisation dossier

Fields marked with an asterisk (*) are mandatory.

Submission code

* Submission code provided by ECHA:

Submitting applicant info

* Company UUID:

* REACH IT account user name as indicated in the REACH-IT account:

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

* Email:

Upload application file

* Upload IUCLID file:
Please ensure that the IUCLID file of your application for authorisation contains also the PDF file of your application form. The maximum file size is 20MB. For the submission of a larger file, please contact the [ECHA Helpdesk](#), providing a justification and your submission code.

Purchase order:

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

- ! The application file should have already been created in IUCLID 5.3 (or onwards version) and have the extension ‘i5z’.

- The upload of dossiers with file size above 20 MB has first to be approved by ECHA. Please contact the ECHA Helpdesk before submitting a larger file, providing a justification and your submission code, at http://apps.echa.europa.eu/forms/helpdesk_form.aspx
- You may enter a purchase order number as your own reference for invoicing purposes. This purchase order number will be referenced on the invoice.
- Before submitting the web-form, the submitting applicant needs to type the text visible in user identification box (CAPTCHA) in the field above the <Create Application> button.
- Click the <Submit to ECHA> button to upload your application for authorisation.

The uploaded application will go through a virus check. Additionally, ECHA will make some preliminary checks to ensure the consistency of the information provided in the web-form. In case of any inconsistencies, you will receive a notification by email to the email address you provided in the Web-form 3.

9.5 Step 5: Receive your submission number

After the application has passed successfully the preliminary checks, the Business Rules check is initiated.

The submitting applicant will receive the outcome of this check as an internal message to his REACH-IT account, including the submission number, or an explanation on the failing rules.

In the case of a joint application, if the Business Rules check is successful a copy of the message will be sent to all co-applicants. All messages are sent as internal messages via REACH-IT.

After the Business Rules check has been passed, ECHA will determine the fee for the application.

In parallel, ECHA will review the proposed broad information on uses to be published on ECHA's website for the purpose of public consultation [Art. 64(2)] (see also chapter 9.2).

The invoice and the notice on the broad information on uses are sent to the applicant via REACH-IT. In the case of a joint application, a single invoice and the notice on the broad information on uses are sent to the submitting applicant. Invoice information and a copy of the broad information on uses are provided to the co-applicants.

After successful payment of the invoice, a message will be sent via REACH-IT, acknowledging the "date of receipt" of the application. In the case of a joint application, the message will be sent to the submitting applicant and a copy will be provided to the co-applicants.

9.6 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 as internal messages 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.

To submit additional information after a request from ECHA's Committees, the applicant (submitting applicant, in case of joint application) needs to update the IUCLID 5 dossier (see section 8.1 on "Requested update") and submit it as described in section 9.4 "Step 4: Upload the application for authorisation". Request from ECHA's Committees will include a submission code, which has to be entered in the web-form (Web-form 3).

After the draft opinion is finalised it will be sent to the applicant(s) as internal message(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 in writing 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 user(s) (First name and Last name) of the REACH-IT account(s) specified in the web-forms. Authorisation numbers will be included in the decision letter for all the substances and uses the authorisation was granted.

Annex 1 - Checklist for an efficient preparation of your application

Before you start to prepare your application, make sure that you have the following **minimum information** available.

You can use the following tables as a check-list before completing your IUCLID 5 dossier and filling in the application web-forms.

- Substance identity and composition:

Table 2: Checklist: minimum information needed on the substance for a mono-constituent Annex XIV substance

√/X	Minimum Information
	REACH Annex XIV substance entry number.
	Degree of purity of the substance.
	EC number of the constituent as specified in the Annex XIV list and IUPAC name and CAS number
	Typical concentration of the constituent.
	For the constituent (if available): <ul style="list-style-type: none"> ○ Molecular formula + Molecular weight range + Structural formula.
	IUPAC name of each impurity or additive if any.
	Concentration range of each impurity or additive if any.

Table 3: Checklist: minimum information needed on the substance for a multi-constituent Annex XIV substance

√ / X	Minimum Information
	REACH Annex XIV substance entry number.
	Degree of purity of the substance.
	EC number of the multi-constituent substance as specified in the Annex XIV list and IUPAC name and CAS number
	IUPAC name of each main constituent.
	Concentration range of each main constituent.
	For each main constituent (at least 2 main constituents) if available: <ul style="list-style-type: none"> ○ Molecular formula + Molecular weight range + Structural formula.
	IUPAC name of each impurity or additive.
	Concentration range of each impurity or additive.

Table 4: Checklist: minimum information needed on the substance for a UVCB Annex XIV substance

√ / X	Minimum Information
	REACH Annex XIV substance entry number.
	Degree of purity of the substance.
	EC number of the UVCB substance as specified in the Annex XIV list and IUPAC name and CAS number
	Description of the UVCB substance or the process to produce the UVCB (if available).
	At least one constituent of the UVCB.
	IUPAC name of each constituent.
	Concentration range of each constituent.
	IUPAC name of each additive.
	Concentration range of each additive.

- Identification of the uses:

Table 5: 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 5 dossier, assessment reports and the application web-forms).
	Clear and consistent name for each use.
	Clear 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 (generated by Web-form 1 – see chapter 9.2).
	A concordance table (http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp).
	For each “use applied for” a non-confidential broad description that can be published on ECHA website for public consultation (specified in Web-form 1 – see chapter 9.2).

- Assessment reports:

Table 6: Checklist: minimum assessment reports needed

√ / X	Minimum Information
	Chemical Safety Report if not provided yet as 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: <ul style="list-style-type: none"> ○ an analysis of alternative; ○ a substitution plan (where relevant); ○ a socio-economic analysis (where relevant).

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

- Legal entities and mapping:

Table 7: Checklist: Legal entities and mapping

√ / X	Minimum Information
	REACH-IT legal entity name of all applicants (joint application).
	REACH-IT UUID of all applicants (joint application).
	A mapping of uses per applicant and per substance if relevant (as generated by Web-form 1 – see chapter 9.2).

- Contact information:

Table 8: 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).

- Specific additional information needed in case of requested update:

Table 9: Checklist: in case of requested update

√ / X	Minimum Information
	The submission number of the previous application for authorisation submitted.
	The annotation number (as provided in the communication from the Committees).
	A mapping of the changes made in response to a request.

- Specific additional information needed in case of subsequent application:

Table 10: Checklist: specific additional information in case of subsequent application

√ / X	Minimum Information
	The REACH authorisation number(s) already granted. OR The submission number of the previous application for authorisation.
	A written permission from the holder of a previously submitted application or granted authorisation to refer to his dossier.

- Specific additional information needed in case of “review report”:

Table 11: Checklist: specific additional information in case of review report

√ / X	Minimum Information
	The REACH authorisation number(s) already granted.

