25 Steps for Member Registrant Dossier Submission

Step 1

Download IUCLID 5.2 and synchronise your legal entity object (LEOX) that was created in REACH-IT when you pre-registered. There are two possible ways to synchronise, you can import your LEOX whilst in the IUCLID software from REACH-IT or export your LEOX from REACH-IT.

Method 1 (recommended): From REACH-IT click on the 'export' button after company sign-up to export your company in IUCLID exchange format to your desktop. Then in IUCLID 5.2 select the 'import' icon on the bottom panel of the main home page, select the file on your desktop and 'if newer than existing' and then select finish.

Method 2: In the IUCLID website, select 'user info' and 'LEO creation' and complete the contact and address information fields and select 'submit'. Return to 'Your LEOs' and select 'download' and save to desktop. In REACH-IT select 'sign up as company', fill in your contact name and email in the 'user account' tab. In the 'company information' tab browse for the file saved to desktop and load the file.

Tip: Make sure you provide the same legal entity information in IUCLID section 1.1, the dossier header and in REACH-IT. To check you have the correct LEO /UUID, check in IUCLID in section 1.1 the information panel beneath the main screen and check in REACH-IT under company and view.

Step 2

If you are a **manufacturer only**, you must complete a 'legal entity site' in IUCLID prior to beginning on the substance dataset. You must complete at least one site and indicate if it is a production or use site linked to your legal entity. Select 'new' under the 'legal entity site' icon and complete the information. The minimum information must include name, town, city and country.

Step 3

Select 'new' under the 'substance' icon in IUCLID and name your substance dataset, usually with the name of the substance, and link to your legal entity and select 'finish'. You have now created your substance dataset, this is the file where you will complete all information required for your submission.

Step 4

From the pick list under the tab 'query results', select the dossier type. For member registrants of substances at greater than 1000 tonnes per annum, please select 'REACH Registration member of a joint submission – general case'. Once you select this, the section tree will show red and green for the information needed and not needed, respectively.

Step 5

The first section to complete '1.1 Identification', already includes the substance dataset name and legal entity. You may select a red flag  where you want to keep that field confidential from public dissemination on the ECHA website, however each field selected as confidential will ensue a fee. Please see the Fees Regulations.

- Select your role in the supply chain
- Assign a reference substance for the substance you are registering by clicking on the golden link chain  . Search in the inventory using any of the fields and 'assign', this will automatically fill in all details linked with that substance. If your substance is not in the inventory, you will need to click on 'new' and fill in all known information at a minimum either an EC number OR CAS name and number OR IUPAC name and description.
- Select the composition and origin from the pick lists. If selecting 'other', you **must complete** the adjacent text box.
- You may add in any trade names of the substance you are registering by selecting 'add', however this is not a required field.
- Enter the contact details of the individual responsible for the IUCLID file.

Tip: If your substance is not in the reference substance inventory and you have to create your own, you must ensure that at a minimum you provide one of the following identifiers: EC number OR CAS name and number OR IUPAC name.

Step 6

You must complete section 1.2, first fill in the name of the substance and a brief description, the composition id will automatically complete. The degree of purity of the substance is required here, if you are a manufacturer you will have this information, importers should ascertain this from their suppliers.

At least one constituent **must be** completed and any impurities and additives entered by creating a repeatable block for each constituent, impurity and additive. If it is a mono-

constituent, the reference substance used in section 1.1 must be the same as the constituent reference substance. A reference substance and percentage range **must be** selected for each constituent, impurity and additive.

Step 7

Section 1.3 is optional, but if you have a number of substances to register, it might be useful to complete for your own records.

Under 'regulatory programme identifiers' select 'add' and create an entry by selecting 'REACH preregistration number' from the pick list and add in your pre-registration number in the field 'ID'.

Step 8

You must complete section 1.4 analytical information with the types of analytical methods used and the results obtained pertaining to substance identification. Under 'analytical methods and spectral data' list the methods used, if they are different from those specified in Annex VI of REACH, you must provide a description of the methods sufficient enough to allow the methods to be reproduced. If you have these in pdf, word processing (e.g. word, excel) format, you can attach instead using the paper clip icon. If any optical information is available, you must complete 'optical activity'. The results must be provided in the repeatable blocks, using a new block for each result, completing all fields and attaching results.

Step 9

In section 1.5, you should complete the joint submission name e.g. joint submission for formaldehyde, and the regulatory programme (EU: REACH). The names of the lead and member registrants is optional and for your information.

If you are not submitting jointly, i.e. as a member registrant dossier, do not complete information in this section.

Tip: If you are not submitting jointly, i.e. as a member registrant dossier, do not complete information in this section.

Step 10

If you are an **only representative only**, it is advised that you complete section 1.7 by entering the name of the non-EU manufacturer and attach the letter of appointment in the 'assignment from non-EU manufacturer' field. It is also advisable to complete the names of the EU importers covered by this registration in the 'other importers' field by clicking 'add'.

Step 11

If you are a **manufacturer only**, you must provide information in the free text box 'methods of manufacture', describing the technological process used for the manufacture of a substance or the production of the articles in which the substance is being used. You should specify the type of reaction, the system in which it is processed, duration and frequency of processing, maximum capacity per unit time, pressure and temperature during processing. If this information is not available, a justification must be provided.

Step 12

The year and tonnage subject to registration must be completed in section 3.2 and details of the tonnage must be competed where applicable.

Step 13

If you are a **manufacturer only**, you must provide information on the site of production or use, in section 3.3. You must select at least one repeatable block, in the 'site' field, select the golden chain and it will link to the legal entity site created in step 2 above. Accordingly, you must check whether the site is a production or use site.

Step 14

For the substance you are registering, you must complete the information on 'form in the supply chain' in section 3.4. You may manufacture, import or produce the substance on its own, in a mixture or in an article or any combination. Select the check box, and in the case of a mixture or article provide the information requirements and most importantly the typical concentration of the substance in the mixture or article by creating a repeatable block. Any number of repeatable blocks can be selected.

Step 15

Registrants must provide at least one identified use in section 3.5, for each use a line must be created and all fields of that line must be completed. Your own uses and any uses provided to you by your customers in either industrial settings, other professional uses and uses by consumers, should be provided here. To enter a use, select 'add' in the one of the three fields, complete the IU number (a code for your own records), a use name, and select the remaining information from the provided pick lists. You may select any number of exposures or uses from the pick lists appropriate to that particular use, if your category or use is not

Tip: Use codes are available at http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf.

provided select 'other' and complete the free text box. If you don't provide any use, you must have a justification, provide a justification from the pick list 'justification why no identified uses are reported' and enter any free text remarks.

You must select or deselect if all uses take place in a closed system (i.e. no worker exposure), select the most common technical function of the substance from the pick list and tick any or all of the routes of exposure linked to your identified use(s).

Step 16

Registrants may or may not provide any uses advised against in section 3.6, the information in this section is entered in the same way as in step 15. Again, if you complete a line, you must complete all data fields for that use.

Step 17

Registrants should complete section 3.7 'waste from production and use'. To enter information on the waste from each production process and use, create a new repeatable block per process or use. Enter the tonnage waste, composition of the waste (i.e. how much of the substance being registered is present in the waste) and any remarks related to each process and use. If you are not a manufacturer or have no waste in your process, please provide a justification.

Step 18

The chemical safety report (CSR) may be submitted by the member registrant or by the lead registrant, covering the uses of the member registrant. It is optional for the lead registrant to submit a joint CSR. All registrants are required to create an endpoint in section 13 'Assessment reports', whether they are submitting a CSR for their use(s) or not.

Right click 'assessment reports' in the section tree, and select create an endpoint. Name the endpoint accordingly (most likely CSR or justification for absence of CSR). From the pick list under 'type of report', select "REACH chemical safety report", if you are providing one attach using the paper clip beside the "documents" field but if you are not providing one provide a justification in either the "remarks" or "discussion" field.

Tip: Be consistent, if you indicate that the LR is providing the CSR do so in section 13 of IUCLID, the dossier header and in REACH-IT.

You must communicate with the LR, because he/she must indicate that they are providing in their dossier. Otherwise, a failure will show-up.

Step 19

Run the TCC tool on the substance dataset, it is advised to run the tool here prior to creating the dossier. In the IUCLID main page, the bottom panel "plugins" contains the TCC tool, click on run. You will be asked to select a document to run, click on the golden chain. In the new window select 'substance' as the select query result type and 'find substances' as select query. Type the substance dataset name or other identifier and click on search, select the correct substance dataset and click on assign.

Tip: Use the TCC plug-in tool on the substance dataset, because you can amend the file here. Once the dossier is created it cannot be changed and a new dossier must be created.

Click on next and on the next screen select 'yes' for joint submission, if applicable and indicate that you are a member registrant and your associated tonnage. You are required to indicate if the guidance on safe use and chemical safety report are provided by the lead registrant and then can click next. The next screen will show you any TCC or BRV errors (lines in yellow are headers and lines in white are actual errors). You can navigate to the errors by clicking on the error type and amend in accordance with the failure description provided. When you have corrected any errors, you can refresh the window. You can hide and show the TCC tool while correcting the data by clicking on  in the top bar.

Step 20

Prior to exporting the information, you must create the dossier using the information provided in the substance dataset. From the main page, select 'new' under the substances icon and the query results tab on the left column, highlight the substance dataset. Go to file on the top bar and select 'create dossier'.

The dossier creation wizard will appear, select the correct dossier template (In most cases: REACH Registration member of a joint submission – general case) and click on next. If you have selected any confidentiality flags in the creation of the substance dataset, indicate that here and under 'use restricted to selected regulatory programmes' keep the default 'No regulatory purpose' box checked and click on next. (???) On the next page, select the parts of the substance dataset to be included in the dossier (the parts that you have filled in) and click on next. The 'Detail level of endpoint fields' is not applicable to the member dossier, keep the default and click next. The next page is a summary of the information to be included in the dossier, ensure this is correct and click next. In the next page give the name of the dossier and indicate if the lead is providing the CSR and guidance on safe use and indicate the tonnage band of the joint dossier. Do not check the submission update box and indicate if the substance is a

phase-in of not and any remarks, click on next. The wizard will skip step 7 if you have not opted-out of any of the endpoints in the joint submission, if you have opted-out you justifications need to be provided in step 7. On the following page you may or may not select to copy protect the dossier, the dossier is read-only regardless and you are advised not to check this box and click on finish.

As a final check, you are advised to run the TCC tool again as per step 19, but this time on the dossier. Ensure that there are no errors from dossier creation.

Step 21

From the main page select 'view' under the dossier icon, from the query results tab double click on the dossier. Go to file on the top bar and select 'export'. Select the default 'export without annotations' and click on next, on the following page select somewhere on your computer drive to store the exported dossier e.g. the desktop, and click on finish.

Step 22

Tip: The Security Token has a validity of 30 days. If the Member Registrant does not Join the Joint submission within 30 days the Lead must re-allocate a token to the member

The Lead Registrant creates the joint Submission Object in REACH IT and the member receives an alert in their message inbox. The Lead Registrant will communicate the Security Token and the Joint Submission Name to the Member. The member joins the Joint submission (at any time)

Step 23

The participants of a Joint Submission will submit dossier to ECHA via REACH IT which supports the submission of dossier files that have been prepared outside of REACH IT in IUCLID 5.2. The Lead must submit the Lead dossier first and pass Business Rules Verification before the member

can submit the member dossier. A message will appear in the Joint submission page of REACH IT indicating that the Lead Dossier has passed BRV.

Step 24

The member dossier will process through the Business rules check and then through the Technical Completeness Check at ECHA. ECHA will process and invoice through REACH IT during the TCC. REMEMBER! Claims for confidentiality or opting out will increase the fees to be paid to ECHA. Remember when making submissions so that there are no surprises when the invoice is received, as the registration number is only provided once the invoice has been paid.

Note: Run the fee calculator plug in tool on your dossier before submission

Step 25

When submitting to REACH IT users will first get a preliminary submission number. Once the dossier successfully passes the business rules, REACH IT will confirm this submission number (which will be one and the same) and the submission will receive a stamp. A message indicating that the submission has been successful will arrive in the member registrant internal REACH IT message box and a direct link to 'Download Submission report' will be available. The registrant can select' Go to the Dossier' in order to see how the dossier is progressing through the various checks being performed by ECHA.