Technical Questions and Answers on C&L NOTIFICATIONS

Version 1.0 –01/12/2010

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Choosing the right tool to create a C&L notification

1. **There are many notification tools, which one is the more suitable for me?**

There is a tool for all your needs:

There are easy questions you can ask yourself to find out what is the most suitable tool to create your C&L notification(s):

- If your substance has multiple compositions (e.g. same main constituent(s) but different impurities) and/or different classification and labelling, the only notification tool you can use is IUCLID 5;
- If you want to claim the IUPAC name of your substance confidential, then the only notification tool you can use is IUCLID 5;
- If you have a lot of substances to notify, and if your substances are identified by CAS or EC number, then the Bulk XML might be the more convenient tool for you;
- If you want to agree with a classification and labelling already notified or registered, then the online REACH-IT tool is the advised tool to use;
- If you want to notify agreed classification and labelling on behalf of several manufacturers, or importers, use the group submission (submission on behalf of a group of manufacturers or importers).

All the C&L notifications created using IUCLID 5, the Bulk XML or the online REACH-IT tool have to be submitted to ECHA via REACH-IT.

The diagram below is capturing the advices given:

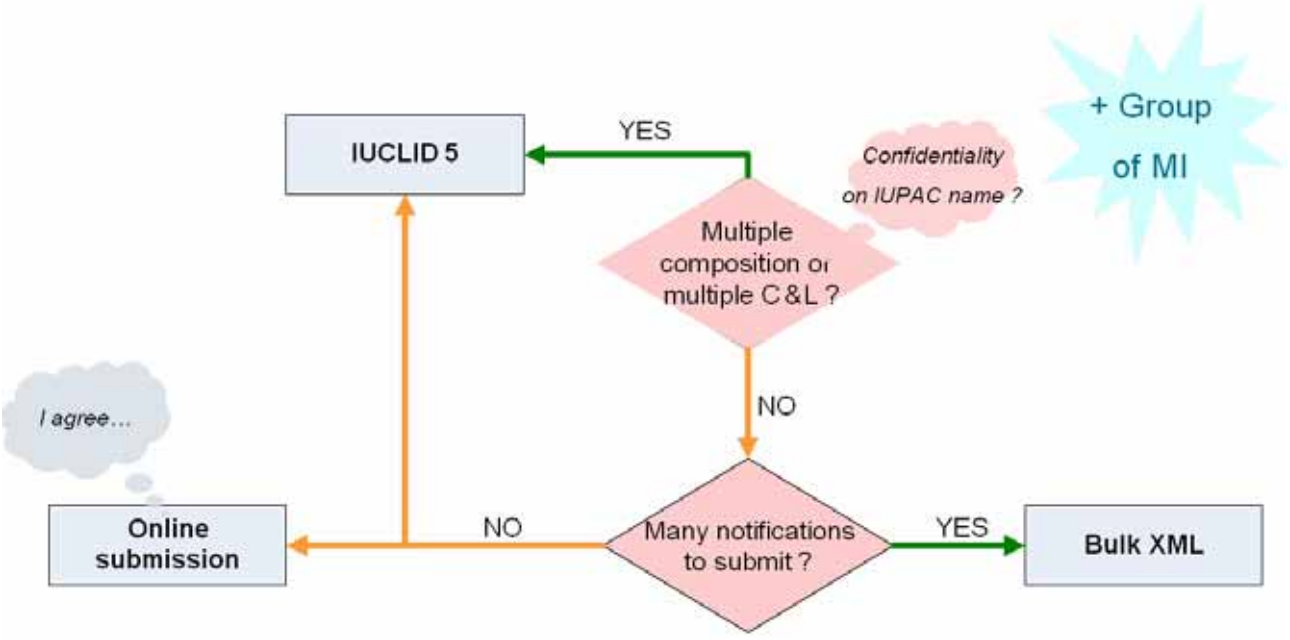


Figure 1. A tool for your need

2. **I have to notify a substance that has different "qualities" and different C&L, which tool shall I use?**

To be able to submit a classification and labelling notification for different compositions of the same substance, you will have to create a notification with IUCLID 5.

In section 1.2 of your IUCLID substance dataset, you have indeed the possibility to identify multiple compositions of your substance, as well as the different impurities contained in the different compositions.
Then, in section 2.1, you can indicate the different classification and labelling and link them to the different compositions in section 1.2.

Further information can be found in *Data Submission Manual Part 12 - How to prepare and submit a C&L notification* using IUCLID at
http://www.echa.europa.eu/clp/inventory_notification/notification_how_en.asp'
Find more details on how to create a notification for mutiple composition in chapter 5.4 on page 39.

3. I cannot edit "Hazard category" and "Hazard statement" in C&L section. Why?

You are only able to edit the "Hazard category" or "Hazard statement" if you select the option "Blank" in the "Reason for no classification". For each hazard class or differentiation either the two fields "Hazard category" or "Hazard statement" are selected or the field "Reason for no classification" must be specified.

4. Is there a tool that allows me to check my C&L notification before I send it to ECHA?

IUCLID 5: If you create your C&L notification using IUCLID5, you can use the TCC tool available on the IUCLID website at: http://iuclid.eu/index.php?fuseaction=home.menuNOTSignedUp&page=home.showUserInfo.
Check the Business Rule validation on your IUCLID dossier with the IUCLID TCC plug-in before submitting it via REACH-IT. To do so

- Click on Run;
- Select Add reference button;
- From Select query result type, select "Dossier" and in the substance chemical name field type the wildcard character (*). Search, select the dossier and assign. Click Next.

If you receive an error message, modify your substance dataset according to the information provided in that error message and create a new dossier. Check this new dossier again with the TCC plug-in.

Online submission: REACH-IT already contains parameters that verify your C&L notifications when you enter your data using the online tool module.

Bulk XML tool: When the bulk C&L notification is created, the macros inside the file will allow you to confirm if the format of your file is compliant in terms of file format and Business Rules. If some mandatory information is missing, the cell in which the data should have been entered is marked in red, and you will not be able to create a xml file using the "Validate data and create XML" button.

Some Business Rules which are related to the submission of the C&L notification, i.e. whether your submission is an initial submission or an update, can only be checked when you actually submit your C&L notification in REACH-IT.

Updating a C&L notification

5. If I need to update my C&L notification, do I need to use a specific tool?

All the tools to create a C&L notification are compatible between each other. This means that you will be able to update your notification via Bulk XML tool (this bulk submission can contain different substances than the initial bulk submission), IUCLID 5, or Online REACH-IT tool; whatever the initial submission tool was.

If you want to update the C&L section from a registration dossier, you will have to update your registration dossier (according to Article 22 of the REACH Regulation). Only if you want to update the classification and labelling of your NONS registration dossier below 1 tonne, a C&L notification instead of a registration dossier update is required.

Further information on how to proceed to submit an update can be found in the *Practical Guide 7: How to notify substances to the Classification & Labelling Inventory* – chapter 3.5 at: http://echa.europa.eu/clp/inventory_notification/notification_how_en.asp -.

6. How to fill-in my C&L notification in case of update?

If you want to update a classification and labelling notification, you should clearly indicate that the notification is an update of a previous successful notification.

If you create your C&L notification update using IUCLID 5:
On top of the usual information to be submitted, do not forget to specify in your IUCLID substance data-set the following information:

- The EC number or EC list numbers of your substance in section 1.1; and
- The reference number of the notification you want to update in section 1.3.

In the dossier header of the IUCLID dossier:

- Select that the dossier is an update;
- Specify the previous submission number; and
- Give an update reason in the dossier header.

For a successful C&L notification update using IUCLID, please consult chapter 8 of *the Data Submission Manual 12 - How to prepare and submit a C&L notification using IUCLID?* available at: http://echa.europa.eu/clp/inventory_notification/notification_how_en.asp

If you create your C&L notification update using the Online REACH-IT tool:
In the Online REACH-IT tool, chose the option "Update a C&L notification successfully submitted", and enter the assigned reference number.

For a successful C&L notification update using the Online REACH-IT tool, please consult chapter 6.2.3 of the *Industry User Manual 16 - How to create and submit a C&L notification using the REACH-IT online tool* available at:
http://echa.europa.eu/clp/inventory_notification/notification_how_en.asp.

Figure 2. Update your C&L notification using the online tool

Bulk XML tool

If you want to update your C&L notification(s) using the bulk XML tool, you should also clearly indicate in your file that the notification is an update.

To do so:

- In the tab "3- Substances", specify the assigned reference number of the notification you want to update in column D "Reference number".
- In the tab "3- Substances", select a reason for update in the picklist of column E "Reason for update".

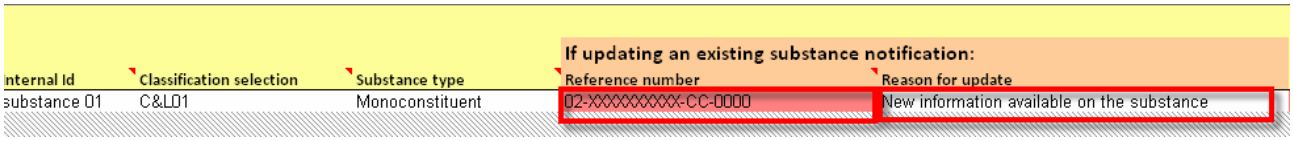


Figure 3. Update your C&L notification using the bulk XML tool

Nevertheless, if you want to update the classification and labelling provided in a registration dossier, you will have to update your registration dossier. (according to Article 22 of the REACH Regulation)

7. Is there a procedure to update the classification and labelling of a NONS registration and to submit a C&L notification?

Yes, there is. If you have already successfully claimed a registration number for a substance previously notified under Directive 67/548/EEC, you shall update your registration dossier without undue delay, rather than submit a C&L notification. Further information on how to proceed can be found in the *Questions and Answers for the registrants of previously notified substances* at: http://echa.europa.eu/reachit/nons_en.asp. Please be referred to chapter – 3.3 How to prepare my IUCLID5 substance dataset in case of NONS update? – Case 2: Other updates.

For substances previously notified **below 1t** under Directive 67/548/EEC, and for which no tonnage band update has been done and no update under REACH is required, a separate C&L notification has to be made if the substance fulfils the classification criteria as specified in Annex I of the CLP Regulation. This means:

- If the annual volumes of the NONS substance remain below 1 t, you shall do a C&L notification for this substance. As soon as the volume goes increases beyond this threshold; an update of the registration dossier in form of a complete registration dossier is requested.
- If the annual volume is already above 1 t, an update, in form of a spontaneous update of a registration dossier, is requested.

8. May I update any data in my C&L notification?

A notifier can update all data of his C&L notification except the submitting legal entity, the EC number or CAS number. A notifier can, among other things, add more information related to the composition of the substances, update the contact details, update the C&L or update the group of

manufacturers/importers. In case of a change of the submitting legal entity you should use the Legal Entity Change tool of REACH-IT.

9. Can I update the classification and labelling of my registration dossier by submitting a C&L notification?

No, if you have already submitted a registration dossier for your substance, you should submit a spontaneous update of your registration dossier if you want to update the classification and labelling of this substance.
If you are a member of a Joint Submission, and you submitted the C&L information of your substance jointly in both the lead registration dossier and your member registration dossier before 30th November 2010, you need to ask the Lead Registrant to submit a lead registration dossier update including the classification and labelling according to the CLP criteria.

The only exception is applicable to substances previously notified under Directive 67/548/EEC where the annual volume does not exceed 1 t. In this case a C&L notification shall be submitted.

10. Why is there a different contact name in the submission report when I update the contact details in my C&L notification?

Your contact name has been modified correctly if you have validated successfully your C&L notification update. There is no need to update again your contact details. However, the submission report will display only a contact person with the 'invoice manager' status.
If you want to modify the contact person in your C&L notification submission report, follow these steps:

1. Create a new contact person in the "Contact" tab available at Company >> View (note: REACH-IT may assign this contact in the submission report of other items, i.e., registrations, if no other contact with 'invoice manager' status has been previously defined).
2. Update your C&L notification and select the previously created contact.

Reference numbers granted to a C&L notification

11. Which number do I receive after having submitted a C&L notification?

When submitting a dossier (created by the Online REACH-IT tool, IUCLID 5, or the XML bulk) a submission number is assigned to each file submitted.

If the submission is successful (i.e., the virus check, the format check, and the Business Rules checks are passed successfully), then each substance notified receives a "Reference number", which is also called "Notification number" in the case of a C&L notification, or "Registration number" if a registration dossier was submitted. A notification number will have the following format: 02-XXXXXXXXXX-CC-0000.

The submission and reference number are available in your submission report.

You will need these submission and reference numbers if you update a dossier.

12. Which number do I receive after having submitted a C&L notification update?

If you update your C&L notification, you will receive a new submission number, but the reference number previously assigned will remain the same.

Searching for my C&L notification in REACH-IT

13. How do I verify the submission and reference numbers of my C&L notification?

You can check the classification and labelling (according to the CLP criteria) of substances you have already notified or registered by selecting <Classification and Labelling> - <View submitted C&L> in your REACH-IT account. The results can be exported either in .pdf format or .csv format.

You can also retrieve your notification number (reference number of a C&L notification) from the received submission report, or from the reference number history in REACH-IT: <Registration/Notification> - <Reference number history>.

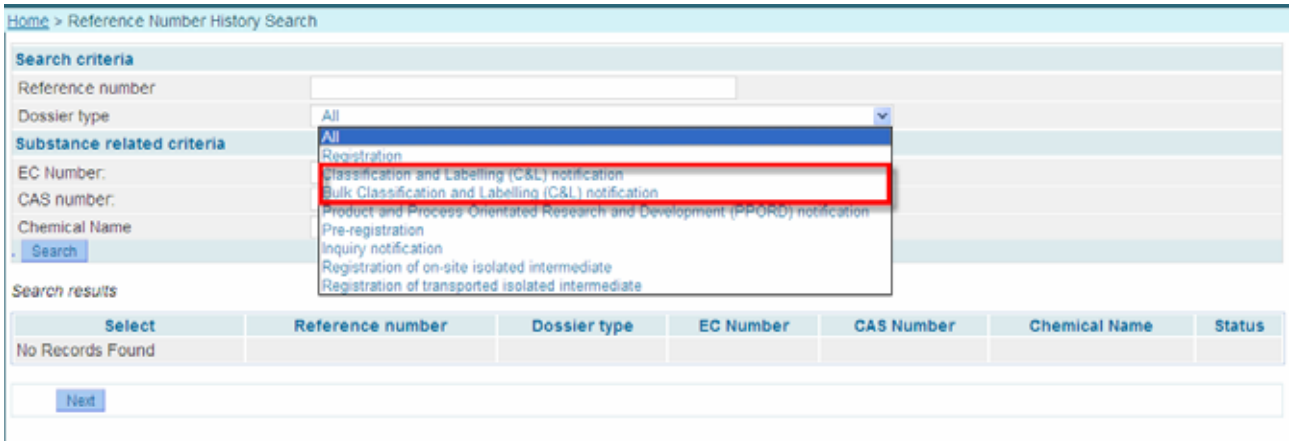


Figure 4. Search for your submission and reference numbers

14. How can I check in REACH-IT all the C&L notifications I have already submitted?

You have the possibility to search in the internal classification and labeling (C&L) inventory for all the C&L notifications you have submitted as part of:

- A bulk file;
- A IUCLID notification;
- An Online REACH-IT notification; and
- A registration dossier (after a successful registration, i.e. after you have received the registration number).

Only the classification and labelling notifications made according to the CLP criteria are searchable, and you can search only for the C&L notification(s) you have submitted.

To do so, use the <View submitted C&L> functionality available in the C&L menu of REACH-IT: <Classification and Labelling> - <View submitted C&L>.

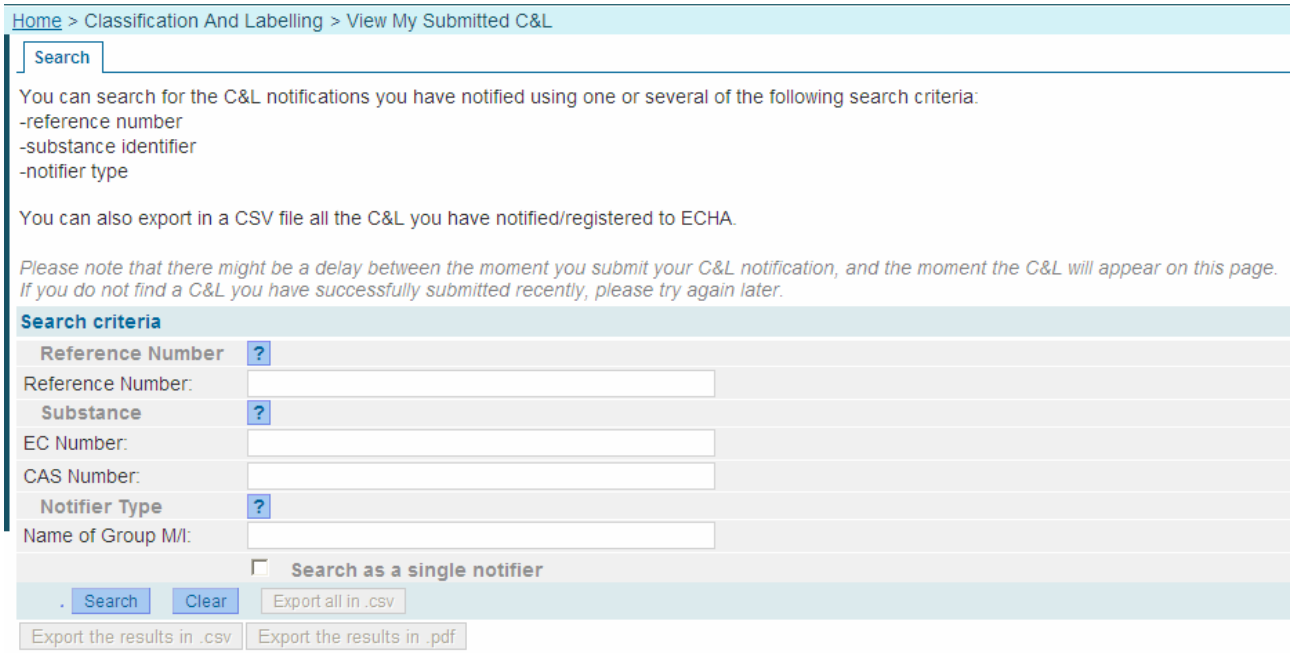


Figure 5. View your submitted C&L

There are different search options: by reference number (notification or registration number), EC number, CAS number or Name of the group of manufacturers/importers.
The search results can also be exported in .csv format or .pdf file format.

15. I have successfully submitted my C&L notification, I received my reference number, but I do not find my classification and labelling in the 'View submitted C&L' REACH-IT functionality. Why?

There may be different reasons to that:

- There is a time delay between the moment a C&L notification is assigned a reference number, and the moment the C&L is stored in the internal C&L inventory. Please try again later.
- You are a member of a group, but you are not the one who has submitted the C&L notification on behalf of the group. So, you cannot see the C&L; only the company who has submitted the file can see it. The same applies to joint submission members.
- The C&L information cannot be transferred automatically to the C&L inventory because you have specified more than one composition, and more than one classification and labelling, without linking them together in your IUCLID dossier. Your C&L notification is valid if you have received a reference number, nevertheless it will be transferred later to the C&L inventory.

C&L notification using IUCLID

16. The hazard category picklist associated to the Specific Concentration Limits contains the values “STOT Single Exp. 3a" and "STOT Single Exp. 3b". What does it mean?

“STOT single Exp. 3a” and “STOT single Exp 3b” do not exist in the CLP Regulation, and are currently used in the picklist to identify the hazard statement associated to a Specific Concentration Limit.

This distinction between 3a and 3b is made, in the Specific Concentration Limit only, to reflect that STOT single 3 in Annex I to the CLP Regulation is associated to two different Hazard Statements (H335 or H336). But 3a and 3b do not exist in the CLP Regulation.

Therefore:

- “STOT single Exp. 3a” stands for “STOT single Exp. 3 / H335”.
- “STOT single Exp. 3b” stands for “STOT single Exp. 3 / H336”.

17. I am failing BR 77. Why?

You need to specify a “hazard category” and a “hazard statement” or “reason for no classification” for every hazard classes and differentiations related to ‘Physical hazards’, ‘Health hazards’, and ‘Environmental hazards’.

When creating C&L notifications using IUCLID5, you may have forgotten to extend some blocks by clicking the “green cross” in order to confirm the existence in section 2.1 of the following repeatable blocks:

- “Germ cell mutagenicity”.
- “Carcinogenicity”.
- “Specific target organ toxicity – single (STOR-SE).
- “Specific target organ toxicity – repeated (STOT-RE)”.

Online C&L notification in REACH-IT

18. What are the limitations of the online C&L notification tool?

The online tool cannot be used if:

- Your substance has multiple compositions or multiple classification and labellings;
- You want to claim confidentiality on the IUPAC name.

If you are in such a case, IUCLID shall be used to create your C&L notification.

19. I know that there is an option where I can agree to a previous C&L. Where?

If you use the Online REACH-IT tool, it will be displayed at the bottom of your webpage in the C&L tab of the REACH-IT online C&L notification module. The "I agree" option will be displayed on your screen once you have entered relevant information regarding the substance identity and optical information of the C&L notification created via REACH-IT (<Classification and Labelling> - <Notify a C&L online>). The system will automatically display a substance already included in the C&L inventory that matches your substance, if applicable, and it will give you the possibility to select the "I agree" option. Within the C&L inventory, two groups of substances should be differentiated:

- Substances with an already harmonised C&L in Annex VI of CLP. The harmonized C&L is legally binding;
- Substances that have already been registered under REACH Regulation including a C&L notification or that have already been notified under CLP Regulation. In this case you can select between one of the classification and labelling notifications provided or propose a different C&L.

However, you, as a notifier, should know that the responsibility to provide a valid classification and labelling for your substance is your responsibility. REACH-IT only provides you the means to minimise the administrative work and agree with previous entries.

If your substance has not been previously harmonised, registered or notified, the "I agree" option will not be enabled.

20. The hazard category picklist associated to the Specific Concentration Limits contains the values “STOT Single Exp. 3a" and "STOT Single Exp. 3b". What does it mean?

“STOT single Exp. 3a” and “STOT single Exp 3b” do not exist in the CLP Regulation, and are currently used in the pick-list to identify the hazard statement associated to a Specific Concentration Limit.

This distinction between 3a and 3b is made, in the Specific Concentration Limit only, to reflect that STOT single 3 in Annex I to the CLP Regulation is associated to 2 different Hazard Statements (H335 or H336). But 3a and 3b do not exist in the CLP Regulation.

Therefore:

- “STOT single Exp. 3a” stands for “STOT single Exp. 3 / H335”;
- “STOT single Exp. 3b” stands for “STOT single Exp. 3 / H336”.

XML bulk C&L

21. Is there a manual for the bulk XML tool?

No, unfortunately there is no specific manual, but you are kindly referred to guidance already available at http://echa.europa.eu/clp/inventory_notification/notification_how_en.asp. You should observe the following steps to submit successfully your C&L bulk notification:

- Read the *Practical guide 7: How to notify substance in the Classification and Labelling Inventory* (refer to the website mentioned above).
- Read the *Introductory Guidance on the CLP Regulation* or the *Guidance on the Application of the CLP criteria* for specific questions related to the C&L applicable to your substance;
- Download the Bulk XML tool available in the previously mentioned website and extract the contents of the CLnotification.zip file to any folder in your computer.
- Remember to enable macros as described in the release_notes.txt in the CLnotification.zip file.
- Read carefully the instructions in the "About" tab of your downloaded CL notification file.
- Check the C&L notification examples available in your downloaded CLnotification zip file.
- If you need further explanation on the meaning of a specific field, place your mouse over commented fields (with a red triangle on the right-hand corner).
- Save your data using the "Validate data and create XML" button rather than "Save as" option. The tool will save your data without any inconsistent format.

When you submit your bulk XML file via REACH-IT, make sure that you select <Classification and Labelling> - <Notify a bulk C&L> and follow the instructions provided in the submission wizard until you confirm your notification submission.

22. What are the limitations of the bulk XML tool?

The Bulk XML tool cannot be used if:

- Your substances are not identified by CAS or EC number;
- Your substances have multiple compositions or multiple C&L;
- You want to claim the confidentiality on the IUPAC name;
- You want to set a new M-Factor or specific concentration limit (SCL).

If you are in such a case, IUCLID shall be used to create your C&L notification.

23. Can I specify a M-factor or a SCL in the bulk file?

You can specify a Specific Concentration Limit, if it is already mentioned in Annex VI to CLP for example. Nevertheless, if you want to set a Specific Concentration Limit upon the strict conditions of Article 10 to CLP, you shall provide a scientific justification (cf. Article 40(1e)). A document cannot be attached in a xml bulk file; therefore the only way to set a Specific Concentration Limit under Article 10 to CLP and to attach the requested scientific justification, is to submit a C&L notification using IUCLID or the Online REACH-IT tool.

24. The Bulk XML tool is requesting a password. How can I get it?

The tab "Substance" and "Classifications" of the Bulk XML tool is password protected to remind users that the classification of your substances should follow a specific format. Please follow these steps to avoid the use of the password:

- Make sure that your macros are enabled when you open the tool. If you cannot have your macros enabled, once you open your Excel sheet select Tools >> Macro >> Security and select Medium or low. If you change your macro security, close and reopen the Bulk XML tool;
- If you need to enter data into a password protected area, the Bulk XML tool should not be used to create your notification (i.e., more than one composition or more than one classification for a specific substance);
- If you are going to copy and paste data to your Bulk XML tool, we strongly recommend that you use the tabs named after "Personal sheet 1", "Personal sheet 2" to check whether your data format is compliant with Excel;
- When you save your file, do not use the “Save as” option, but rather the “Validate data and create XML” button so you can submit your file to ECHA via REACH-IT. However, if you want to include more substances at a later stage, we recommend that you also save your file in xls format.

25. How can I enter a harmonised entry using the Bulk XML tool?

Enter the “index number” of the classification already harmonised in Annex VI to CLP under the field “Classification name” within the tab “2-classifications” of your Bulk XML tool. The Annex VI on the Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Dangerous Substances can be found at http://ecb.jrc.ec.europa.eu/classification-labelling/clp/.

Once you have filled in the classification name, the C&L information will be automatically populated in the tab “2-classifications” of your Bulk XML tool.

Check the classification and labelling displayed.

Then in the tab “3-Substances”, enter the substance identity of your substance, and select the index number to this substance in the “classification selection” column.

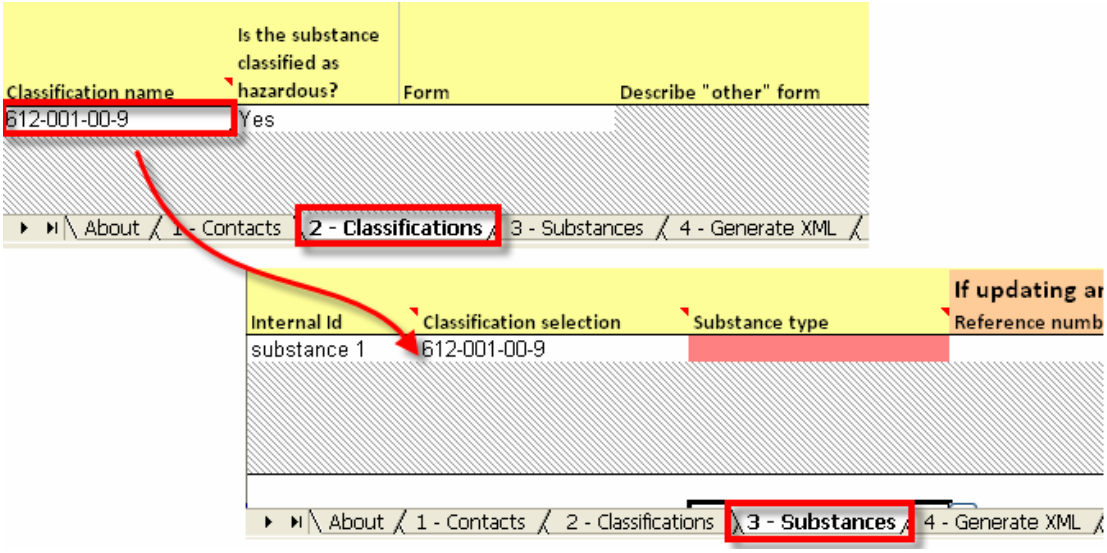


Figure 6. Harmonised C&L in the bulk XML tool

Known issue with XML bulk C&L

26. I have created a xml bulk file with the Bulk XML tool, and the file is not accepted by REACH-IT because of a validation problem. Why?

Your XML files might have been created with the Bulk XML tool version 1.0 or 1.1.

The reason for the XML validation failure is that incomplete XML files may have been generated by these previous versions of the Bulk XML Tool in the German, French and possibly other language versions of Excel, resulting in the creation of non valid XML files.

We would therefore recommend you to **download the new version** of the bulk XML tool (version 1.2.1) which is now available from the ECHA website.

This new version solves the issues encountered with the different language versions of Excel (the one you may have encountered).

All information previously entered in the former version of the Bulk XML tool are not lost, they can be not only copied / pasted to the new bulk XML Tool version 1.2.1; but also imported using the import XML button located on the "about" page.

We therefore advise you to download the new Bulk XML tool:

- Download the complete zip file from:
- http://echa.europa.eu/clp/inventory_notification/tools_download_en.asp; and
- Perform the 4-steps procedure explained in question 27 in order to check your different files that have not been accepted by REACH-IT at the XML validation step.

27. How to check your different xml files that have been not accepted by REACH-IT at the XML validation step?

Step 1: download the new version of the Bulk XML tool:

1.1- Download the zip file containing the "C&L Bulk XML creator tool for Excel 2003 and 2007" from the following webpage: http://echa.europa.eu/clp/inventory_notification/tools_download_en.asp .

1.2- Extract all the files contained in the zip. All files shall be extracted in the same folder on your computer.

Step 2: open the Bulk XML tool and enable the macros:

Enable macros before creating a C&L notification to ensure that the application works as designed. Follow these steps to confirm the availability of macros in your program:

2.1- Open the Bulk XML tool: open the file CLNotification1.2.xls;

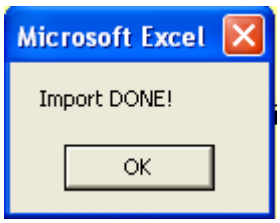
2.2- You should confirm that your macros are enabled. Follow these steps to confirm the macro security level in your computer:

- 2.2-1. Select the Tools >> Options from your menu bar;
- 2.2-2. Select security and click on macro security;
- 2.2-3. Set the security level to medium or low. If you already have it set to medium or low, go to step 3;
- 2.2-4. Close your CLNotification1.2.xlsb and open it again;
- 2.2-5. Click on the button "Enable macros" (only when security level = medium).

Step 3: check former XML files not accepted:

3.1- In the tab <About>, click on <Import data from XML>

3.2- Select the XML file that you want to check (the one created with the old Bulk XML tool, and that failed the XML validation in REACH-IT), and click on <open>
3.3- After successful import of the file in the Bulk XML tool v1.2.1, the following message is displayed:



3.4- Click on <OK>
3.5- Go to the tab <1- Contacts> and check it
3.6- Go to the tab <2- Classifications> and check it
3.7- Go to the tab <3- Substances> and check it
3.8- Go to the tab <4- Generate XML> and click on <Validate data and create XML>

3.9- In case of remaining mistakes you will get directed to the error page.
3.10- Correct the remaining mistakes and perform again step 3.8.

Step 4: Import the generated XML file in REACH-IT.

28. How should I re-submit a bulk C&L notification when certain substances show status "Failed"?

The C&L notification submission report will indicate those substances of your bulk notification that have been successfully submitted. When the notification for some substances fails, it is recommended to exclude the successfully submitted notifications before you submit again your bulk C&L notification.

You can check in the submission report of the bulk submission which notifications have failed and the reason of the failure.

You can also use the <View submitted C&L> module to confirm successful C&L notifications. Select <Classification and Labelling> - < View submitted C&L > and search for your substance using one of the search criteria. If your substance does not appear in the <View notified C&L> table, then it means that the notification has not been successful.

Group of manufacturers/importers in REACH-IT

29. I need to include one/several members in my Group of manufacturers/importers. Shall I submit a new C&L notification for the same substance?

If you have already submitted one or several C&L notifications on behalf of a group of manufacturers/importers, in order to update the composition of the group, you just need to add the new member(s) into your already created group of manufacturers/importers (MI) associated to your C&L notification(s). You can proceed as follows:

- In REACH-IT: Go to <Classification and Labelling> - <Manage the Group(s) of Manufacturer(s)/Importer(s)>;
- Select the group you want to modify;
- Click on the 'View/update group' button;
- Update your group composition.

While doing that, all the notifications and submission reports associated to this group of manufacturers and importers will be updated with the new group composition.

Thanks to this group management in REACH-IT, it is not necessary to submit an update of the notification every time there is a new member in the group that has submitted this notification.

Note that all the changes in the group definition will be kept and tracked in the REACH-IT database, which means that ECHA and the enforcement authorities will know when a company has joined a group.

Example:
LE submits one or several notifications on behalf of a group composed of LE A and LE B. If he updates the group definition in REACH-IT by adding LE X to the group, then automatically LE X will be considered as having submitted the notification too. LE, LE A, LE B and LE X will be considered as notifiers.

30. Will the members of a C&L notification(s) submitted by a group of manufacturers/importers receive a submission report?

The members of a group of manufacturers and importers will not receive a submission report. They will have to contact the original notifier to receive the reference number (or a copy of the submission report).

The company submitting the notification will be responsible for informing the group members after successful (or unsuccessful) notification to ECHA and for sharing the submission report received with the members.

31. Can I update a C&L notification as a member of a group of manufacturers/importers?

Only the company who has submitted the C&L notification file will be able to update the C&L notification. This means that a member of a group is considered as "co-notifier" of a C&L notification, but cannot update a notification.