

## Questions & Answers

Changes in requirements for  
registration dossiers submitted from  
1 December 2010



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#### Document history

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[http://echa.europa.eu/help/echahelp\\_en.asp](http://echa.europa.eu/help/echahelp_en.asp)

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## 1 Introduction

On 1 December 2010 Regulation (EC) 1907/2006 (the REACH Regulation) will be amended by Article 58 of Regulation (EC) 1272/2008 (the CLP Regulation).

This amendment of the REACH Regulation will have an impact on registration dossiers submitted to ECHA from 1 December 2010 onwards. More specifically, registration dossiers will be affected in the following way:

Registration dossiers will have to include the information on classification and labelling according to the criteria specified in the CLP Regulation (Article 58(11) of CLP);

The dissemination of information contained in registration dossiers will take into account the hazard criteria established by the CLP Regulation (Article 58(7) of CLP);

The content of the chemical safety report will also be impacted by the hazard criteria established in the CLP Regulation (Article 58(1) of CLP).

ECHA is committed to help registrants comply with these regulatory provisions. To this end, ECHA released updated versions of the following manuals and tools on 1 December 2010:

“Data Submission Manual 5 - How to complete a technical dossier for registrations and PPOD notifications” ([http://echa.europa.eu/reachit/dsm\\_en.asp](http://echa.europa.eu/reachit/dsm_en.asp));

Technical completeness check plug-in (TCC plug-in). Released on the IUCLID website (<http://iuclid.echa.europa.eu/>);

Fee calculation plug-in. Released on the IUCLID website (<http://iuclid.echa.europa.eu/>).

The present document aims at describing the most relevant modifications introduced by the CLP Regulation that affect registration dossiers. This is done by a selection of questions and answers pairs grouped under the following topics:

Changes affecting the technical completeness check of dossiers (TCC);

Changes affecting the fee to be paid;

Changes affecting the dissemination of the information contained in the dossier.

Further information on the CLP Regulation is available in our dedicated webpage at [http://echa.europa.eu/clp\\_en.asp](http://echa.europa.eu/clp_en.asp)

## 2 Changes affecting the technical completeness check of dossiers (TCC)

### 2.1 What information do I need to provide on classification and labelling to comply with the new criteria established by the CLP Regulation?

Registration dossiers submitted from 1 December 2010 onwards must include the information on the classification and labelling according to the CLP criteria. This is achieved by filling in section 2.1 of your IUCLID dossier ("2.1 – GHS").

This section will be considered complete if all the hazard classes and differentiations related to 'Physical hazards', 'Health hazards', and 'Environmental hazards' resulting from the CLP Regulation are filled in. For each one of them a 'Hazard category' and a 'Hazard statement', or a 'Reason for no classification' has to be indicated.

In addition, the following information must also be included:

- If a 'Hazard category' and a 'Hazard statement' are indicated in the hazard differentiation 'Specific target organ toxicity – single' and/or 'Specific target organ toxicity – repeated', then information needs to be provided in the field 'Affected organs'.
- If a 'Concentration range' is specified for 'Specific concentration limits', i.e. if at least one of the two 'range' fields is completed, then at least one 'Hazard category' has to be given, and vice-versa.
- If at least one hazard class/hazard differentiation contains a 'Hazard statement' in the block 'Classification', then a 'Hazard statement' or a 'Supplemental hazard statement' must also be included in the block 'Labelling'.
- Furthermore, a selection must be done in the field 'Signal word'.

Detailed information on how to fill in this IUCLID section is available in "Data Submission Manual 5 - How to complete a technical dossier for registrations and PPORD notifications". This manual will be updated on 1 December 2010 with clear information on what has to be provided as a consequence of the CLP Regulation. You can find that manual following this link: [http://echa.europa.eu/reachit/dsm\\_en.asp](http://echa.europa.eu/reachit/dsm_en.asp)

### 2.2 I have already submitted a C&L notification; do I need to include the same information again in my registration dossier?

Yes, you have to include the information on classification and labelling according to the CLP criteria in section “2.1 – GHS” of your IUCLID registration dossier.

However, please note that in case of a joint submission, the information on classification and labelling is provided in principle by the lead registrant. In this case, if you have already submitted your member dossier, you need to confirm with the lead registrant that the classification and labelling was provided in the joint submission according to the CLP criteria. See also FAQ 2.5 below for more information.

### **2.3 How can I verify that my registration dossier is complete according to the modification introduced by the CLP Regulation from 1 December 2010?**

A new version of the TCC plug-in will be available on 1 December 2010 on the IUCLID website (<http://iuclid.echa.europa.eu/>). This new release of the TCC plug-in will be adapted to include the requirements introduced by the CLP Regulation. This means that the TCC plug-in will check that information on classification and labelling is provided at least in IUCLID section 2.1 (“2.1 – GHS”). In addition, the TCC plug-in will check that every classification and labelling block provided in section 2.1 is complete. If the classification and labelling information is also provided in section 2.2 (“2.2 DSD – DPD”), the TCC plug-in will also check the completeness of this information.

### **2.4 I submitted an initial registration dossier before 1 December 2010 which failed the technical completeness check at ECHA. I will only be able to submit the requested update after 1 December 2010; do I need to include the information on classification and labelling according to the CLP Regulation?**

All registrants need to include the information on classification and labelling according to the CLP Regulation without undue delay from 1 December 2010 if not already done. Therefore, you are strongly advised to include that information in the requested update. This will avoid you having to update your registration dossier without undue delay.

If you are in this scenario, you will also need to ensure that Section 2.2 of IUCLID (C&L under the Dangerous Substances Directive) is complete, in addition to Section 2.1 for the CLP format.

When doing so, you should mark the submission as a requested update, providing information on the last submission number as well as the communication number. Please take care to ensure that your dossier is complete by using the latest version of the TCC plug-in.

## **2.5 I am a member of a joint submission. The lead registrant did not provide the classification and labelling according to the CLP Regulation. How should I proceed?**

In principle, the lead registrant of the joint submission has to update the lead dossier to include the classification and labelling in accordance with the CLP criteria. In that case you do not need to take any further action.

A member registrant has also the option of updating individually its member dossier by including the information on classification and labelling. However, please be aware that this will be treated as an opt-out according to Article 11(3) of the REACH Regulation. Any opt out must be justified by concerns relating to disproportionate costs, confidentiality of the information submitted or disagreement with the information selected for the lead dossier. For your information, opting-out not only triggers a higher invoice but would also result in your dossier being prioritised for compliance check.

### 3 Changes affecting the fee to be paid

#### 3.1 Has the CLP Regulation an impact on the registration fees for registration dossiers submitted after 30 November 2010?

The CLP Regulation introduces amendments to Article 119 of the REACH Regulation concerning electronic public access to the IUPAC name of the substance. Therefore, this has a direct impact on the claims for confidentiality on the IUPAC name made as of 1 December 2010.

Before 1 December 2010, according to REACH a fee has to be paid for confidentiality requests on the IUPAC name for non-phase in dangerous substances, and for phase-in dangerous substances used as intermediates or in research and development.

With the changes this no longer applies to all dangerous substances. From 1 December 2010 onwards, this only applies to specific hazard classes (listed in Article 58.7 of the CLP Regulation amending article 119 of the REACH Regulation). Therefore, the circumstances under which a fee will be charged for those confidentiality requests differ from 1 December 2010.

#### 3.2 How can I check if a confidentiality claim on the IUPAC name included in my registration dossier will trigger a fee after 30 November 2010?

A new version of the Fee Calculation plug-in will be available on 1 December 2010 on the IUCLID website (<http://iuclid.echa.europa.eu/>). This new release of the plug-in takes into consideration the new classification criteria introduced by the CLP Regulation as of 1 December 2010 (see FAQ 3.1 above). ECHA strongly advises registrants to use the latest version of the plug-in before submitting any registration dossier.

## 4 Changes affecting the dissemination of the information contained in the dossier

### 4.1 What will change concerning dissemination on 1 December 2010?

For dossiers submitted as of 1 December 2010, ECHA will automatically make certain information from the dossier publicly available over the Internet, without further communication with the registrant, as explained in the related news alert at:

[http://echa.europa.eu/news/na/201010/na\\_10\\_59\\_dissemination\\_20101018\\_en.asp](http://echa.europa.eu/news/na/201010/na_10_59_dissemination_20101018_en.asp).

Registrants are advised – before submitting their registration dossier – to use the IUCLID dissemination plug-in, which enables companies to verify which information from their IUCLID dossier will be published. This plug-in is available from the IUCLID 5 website at:

<http://iuclid.echa.europa.eu/index.php?fuseaction=home.news&type=public&id=37>.

Further information about the principles of dissemination can be found in the Dissemination manual (DSM 15), available at:

[http://echa.europa.eu/help/help\\_docs\\_en.asp?view=dissemination](http://echa.europa.eu/help/help_docs_en.asp?view=dissemination).

The technical annexes to this manual show with screenshots of the IUCLID dossier which information will be made public on the ECHA website.

Although the CLP Regulation introduces amendments to Article 119 of the REACH Regulation on electronic public access, the filter rules and the dissemination plug-in will remain unchanged by this. However, the conditions under which the IUPAC name can be claimed confidential is affected by the amendments introduced by CLP, as explained in the next question.

### 4.2 What will change concerning confidentiality claims on 1 December 2010?

The CLP Regulation introduces amendments to Article 119 of the REACH Regulation concerning electronic public access to the IUPAC name of the substance, which has taken effect on 1 December 2010. Before this date the IUPAC name was disseminated for dangerous substances, unless claimed confidential. Since 1 December 2010, the IUPAC name is disseminated for substances in specific hazard classes, unless claimed confidential. This change implies that – whereas before only confidentiality claims for dangerous substances as indicated in IUCLID section 2.2 were invoiced and assessed – as of 1 December 2010, the determination of whether or not a confidentiality claim triggers a fee and

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will be assessed by ECHA will be based on the specific hazard classes indicated in section 2.1 of the IUCLID dossier.

Please note that also IUPAC name for non-dangerous substances (before 1 December 2010) or for substances without the specific hazards mentioned in CLP (as of 1 December) will be published, unless the registrant claimed it confidential. However, in this case the confidentiality claim is not subject to a fee and will be automatically accepted by ECHA. For further information about confidentiality claims, please consult the manual (DSM 16) at:

[http://echa.europa.eu/help/help\\_docs\\_en.asp?view=dissemination](http://echa.europa.eu/help/help_docs_en.asp?view=dissemination).

Registrants are reminded that, when claiming confidentiality of the IUPAC name, a public name for publication of certain information from their dossier over the Internet shall be provided. ECHA will make further instructions on how to derive such a public name available at a later stage.

