Frequently Asked Questions about CLP

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The questions and answers presented here address general situations and are intended to assist those who do not have a detailed knowledge on CLP, to provide context information and to guide the reader to the most appropriate information sources, such as a specific guidance document or the CLP legal text itself. This information is also available on ECHA's website at http://echa.europa.eu/.

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This Frequently Asked Questions document contains information on obligations under the Regulation (EC) No. 1272/2008 (hereafter referred to as CLP Regulation or CLP) explaining how to fulfil them. This FAQ document has been agreed by and between the correspondents of the national helpdesks of the Member States, representatives of the European Commission and the European Chemicals Agency within the Helpdesk Network.

However, users are reminded that the text of the CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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Document History

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A revision of existing FAQs may be triggered by recent publication of related Commission Regulations or Guidance Documents.

CLP FAQ 1.0

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CHAPTER 1: CLP – A NEW REGULATION

1.1 What is CLP?

"CLP" or "the CLP Regulation" stands for Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH). It implements the 2nd edition of the United Nations Globally Harmonised System of classification and labelling of chemicals (GHS) into EU law.

The CLP Regulation came into force on 20 January 2009. It will replace the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD) in a stepwise approach during a transitional period.

1.2 Does CLP apply to me?

CLP applies to you if you manufacture, import, use or distribute chemical substances or mixtures. You must classify, label and package any substance or mixture, regardless of its annual tonnage, in accordance with the CLP Regulation before you place it on the EU market. Placing on the market of a substance or mixture means making it physically available to third parties, whether in return for payment or free of charge.

If you are a manufacturer or importer, you are required under CLP to classify substances that are subject to registration or to notification in line with Article 7 or 9 of REACH, even if you do not place them on the market. This includes e.g. the classification of substances that are used for product and process-orientated research and development (PPORD).

If you are a manufacturer or importer, you must notify hazardous substances that you place on the market on their own or contained in hazardous mixtures above certain applicable concentration limits, regardless of the annual tonnage manufactured or imported, as well as substances subject to registration under REACH and that you place on the market, to the Classification & Labelling Inventory established at the Agency. However, the duty to notify does not apply in case you have already submitted the information which is relevant for a notification under CLP as part of a registration.

1.3 What happens to the directives on classification and labelling of substances and preparations?

Directives 67/548/EEC (Dangerous Substances Directive, DSD) and 1999/45/EC (Dangerous Preparations Directives, DPD) on classification and labelling will be in force until 1 June 2015. Until they are repealed in their entirety on 1 June 2015, their provisions will be replaced in a stepwise approach during a transitional period which

is set out in the CLP Regulation: while substances still have to be classified in line with the DSD criteria until 1 June 2015, their CLP classifications must be provided at the latest by 1 December 2010. In the case of mixtures, they have still to be classified in line with the DPD criteria until 1 June 2015, while their CLP classifications must be provided at the latest by 1 June 2015. Further transitional rules define when the labelling and packaging of substances and mixtures according to DSD and DPD, respectively, must be replaced by labelling and packaging according to CLP.

1.4 What happened to Annex I to DSD?

Annex I to DSD, containing the list of harmonised classification and labelling of around 8,000 substances, was already repealed upon entry into force of CLP on 20 January 2009. However, the harmonised classifications included in that Annex have been transferred to Table 3.2 of Annex VI to CLP and are legally binding. This means that a supplier must continue to use them after 20 January 2009, until the end of the transitional period on 1 June 2015.

CHAPTER 2: LABELLING

2.1 What are the deadlines for using the new labels according to the CLP Regulation for substances and mixtures?

For classified substances and mixtures you must provide labels that comply with the CLP Regulation by 1 December 2010 and by 1 June 2015, respectively. Please note that in case you have already classified, labelled and packaged a substance or mixture according to CLP before the relevant deadline, only the CLP label shall appear, but not the DSD or DPD label, respectively.

Extended deadlines for re-labelling and re-packaging are granted in case substances or mixtures are already placed on the market before the relevant deadlines: the re-labelling and re-packaging of substances and mixtures, which are already in the supply chain (‘on-the-shelves’) on the mandatory compliance dates, may be postponed until 1 December 2012 and 1 June 2017 respectively. The additional two years are granted in order to facilitate the move from the existing classification, labelling and packaging system to the new one, especially for those products with a longer shelf-life.

2.2 Is it allowed to use label elements according to Directive 67/548/EEC or 1999/45/EC together with elements according to the CLP Regulation on the same label?

No, this is not allowed as this would lead to confusion on the market and hamper the transition to the CLP classification and labelling system. In other words, only one labelling system shall be applied on any label; which one to choose will depend on the timing in relation to the transitional deadlines of 1 December 2010 and 1 June

2015 (see question 2.1). In case you decide to already classify, label and package a substance according to the CLP rules before 1 December 2010 or a mixture before 1 June 2015, you must not use any labelling elements in accordance with DSD or DPD, respectively.

2.3 Is the number of hazard statements on the label limited?

The number of hazard statements on the label is in principle not limited as they will normally have to reflect all hazard classifications of a substance or mixture. The only exemption is for evident duplication or redundancy.

2.4 Is the number of precautionary statements on the label limited?

In contrast to the number of hazard statements, the number of precautionary statements is limited on the label. The general rule is that no more than six precautionary statements shall appear on the label **unless** they are necessary to reflect the nature and the severity of the hazards. Guidance on the selection from more than 100 different precautionary statements will be provided by the Agency.

2.5 Is a label which is designed according to legislation of non-EU countries implementing the GHS accepted in the EU?

In the EU, only those labels which comply with the CLP rules will be accepted. This means that those provisions that are laid down in Title III of the CLP Regulation and the details regulated in its Annexes II – V must be respected. However, many aspects in relation to the arrangement of labelling elements and in relation to supplemental labelling information are at the discretion of the supplier of the hazardous substance or mixture.

CHAPTER 3: NOTIFICATION TO THE CLASSIFICATION & LABELLING INVENTORY

3.1 What are the deadlines for notification to the Classification and Labelling Inventory?

For substances which are placed on the market on or after 1 December 2010, the deadline for notification to the inventory is one month after they have been placed on the market.

For substances placed on the market on 1 December 2010 itself, the notification is in practice due on 3 January 2011, because 1 January 2011 will be a Saturday and 2

January a Sunday. It is of course possible to voluntarily notify before 1 December 2010.

For substances placed on the market after 1 December 2010, the one month period has to be calculated from the date they are placed on the market after 1 December 2010. This will also apply to substances which have been placed on the market before 1 December 2010, but which are not placed on the market on 1 December 2010 itself, but only again afterwards.

For example, you as manufacturer or importer place a substance on the market on 8 November 2010, then you stop doing so for a while, and then you place it on the market again on 1 February 2011. You will then have to calculate the obligatory one month notification deadline from 1 February 2011, and therefore your notification is due on 1 March 2011. You can, of course, already voluntarily notify before 1 December 2010.

Prospective notifiers should bear in mind that the period from 24 December 2010 to 2 January 2011 will be an official holiday for the Agency. Accordingly, it is recommended that, where possible, a notification is submitted before 24 December 2010, as this would allow for any technical problems with the submission tool to be resolved in a timely manner, thus reducing the risks of difficulties in making a successful notification.

3.2 Do I have to notify the DSD or the CLP classifications to the Inventory? And which classifications are needed for the registration dossier?

A notification to the Classification & Labelling Inventory requires substance classifications according to the CLP criteria.

Whether to include the classifications according to CLP or to DSD in the REACH registration dossier will depend on the timing of submission of the registration: in case you submit a registration before 1 December 2010, the dossier shall contain the DSD classification. It is advisable that you also include the classification in accordance with CLP in that registration dossier because this will make the submission of a separate notification by you unnecessary. In case you submit a registration after 1 December 2010, you must include the CLP classification. Nevertheless, you may choose to also include the DSD classification in the registration dossier. After 1 June 2015, a registration should include only the classification according to CLP.

3.3 Would only substances manufactured or imported in quantities of 1 tonne or more per year be subject to notification?

No, according to Article 39(b) of the CLP Regulation, the requirement for notification to the Inventory includes *all* hazardous substances within the scope of CLP, either on their own or contained in a mixture above legally defined concentration limits, and which are imported or manufactured and placed on the market within the EU. In other words: the requirement for notification goes beyond substances manufactured or

imported in quantities of 1 tonne or more per year.

3.4 Do I have to notify explosive articles to the Classification & Labelling Inventory?

If you are a manufacturer or importer of an explosive substance (explosive according to the CLP criteria) that will be incorporated into an article at a later stage you do need to notify that substance. However, you do not have to notify explosive articles.

3.5 Must the classification and labelling of polymers be notified to the Inventory?

A polymer is a substance and must be notified on the basis of Article 39(b) and 40(1) of the CLP Regulation if it fulfils the criteria for classification as hazardous and it is placed on the market.

3.6 CLP refers in its Article 40(1) to a "group of manufacturers or importers". Is this the same as a SIEF?

No, it is not. The term "group" is not defined under the CLP Regulation, in particular it does not equate to a Substance Information Exchange Forum as defined under REACH. Nevertheless, SIEF members can decide to notify to the C&L Inventory as a group. In this case the identity of each member should be specified in the notification.

CHAPTER 4: REQUEST FOR USE OF AN ALTERNATIVE CHEMICAL NAME

4.1 What is the process to request the use of an alternative chemical name for a substance contained in a mixture?

Before 1 June 2015, where a mixture has not yet been classified, labelled and packaged according to the CLP Regulation, any request for use of an alternative chemical name which refers to a substance contained in the mixture should be submitted to a Member State Competent Authority under Article 15 of, and Annex VI to, Directive 1999/45/EC (Dangerous Preparations Directive; DPD). Should the request be approved before 1 June 2015, the use of the approved alternative chemical name can also continue after 1 June 2015. Please note that an approved request to a Member State Competent Authority under Article 15 of, and Annex VI to, Directive 1999/45/EC (the Dangerous Preparations Directive; DPD) is in the first place valid only in the Member State that took the decision. In case a company wants to place the mixture also in other Member States on the market it shall forward a

copy of this decision to the respective Member States that are, as a rule, required to treat the approved confidential name as secret.

In case a mixture is classified, labelled and packaged in accordance with the CLP Regulation before 1 June 2015, the corresponding request should be done in line with the provisions under Article 24 of the CLP Regulation, and not in accordance with the provisions of DPD. This includes the submission of the request to the Agency, and not to the Member State Competent Authority. Any request approved by the Agency will be applicable in all EU Member States.

4.2 Can Annex VI to Directive 1999/45/EC still be used for such requests?

Yes, it can still be used, namely in case a mixture is still classified, labelled and packaged in line with the DPD rules, but not yet in accordance with CLP, and where the request has to be made to the Member State Competent Authority.

4.3 Is there a form available for an application to request the use of an alternative chemical name for a substance contained in a mixture?

The Agency is currently developing formats applicable to requests for use of an alternative name under Article 24 of the CLP Regulation. They will be made available by the Agency in due course.

4.4 What about the fees?

As laid down in Article 24, the European Commission will determine the level of fees for requests for use of an alternative name under the CLP Regulation. This will be done via a Commission Regulation which will be adopted through the so-called comitology procedure (currently ongoing).

CHAPTER 5: ANNEX VI TO CLP

5.1 What is the meaning of the “Footnote” mentioned in particular substance entries in the column displaying the specific concentration limits in Table 3.2 of Annex VI to CLP?

Table 3.2 of Annex VI to the CLP Regulation took over the harmonised classifications previously contained in Annex I to Directive 67/548/EEC. The "Footnote" in the Specific Concentration Limits column of Table 3.2 contained in Annex VI to CLP reflects, for a number of substances, the "Footnote" appearing for those substances in Annex I to Directive 67/548/EEC where differing concentrations resulted in differing classifications for the flammable, explosive and oxidizing hazards. In other words, these specific concentration limits have been retained in Table 3.2 of Annex VI to CLP with mention of the related differing classification.

For example, the entry 007-004-00-1 relating to nitric acid is displayed with the following specific concentration limits: C; R35: C ≥ 20 %, C; R34: 5 % ≤ C < 20 %, Footnote: O; R8: C ≥ 70 %.

The Footnote refers to the classification as O; R8 (oxidising) of the substance; a mixture containing that substance, e.g. a water-based solution of nitric acid, will only have to be classified as oxidising if it contains nitric acid in concentrations at or above 70%.

Using the term “Footnote” helps those familiar with Directive 67/548/EEC to see the parallel to the system under that Directive. The term "Footnote" does not mean that there is an explanation for the term to be found in Part 1 of Annex VI, which is in contrast to the explanations provided in that Part for the Notes appearing in the Notes column of Table 3.2, e.g. Note B, C or H.