

Frequently Asked Questions about CLP

Version 1.0.1, March 2010

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/.

LEGAL NOTICE

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.

Frequently Asked Questions about CLP (version 1.0.1)

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Note to FAQ (version 1.0.1):

New chapters have been introduced:

- Chapter 2: Industry roles under CLP (NEW)
- Chapter 3: Scope and exemptions under CLP (NEW)

Re-numbered and renamed:

 Chapter 4: (previously Chapter 3) – Notification/Classification and Labelling (C&L) Inventory

Re-numbered:

- Chapter 5 = previously Chapter 2
- Chapter 6 = previously Chapter 4
- Chapter 7 = previously Chapter 5

Publication of related Commission Regulations or Guidance Documents may trigger a revision of existing FAQs. Please therefore check regularly the ECHA website for updates of this document.

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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.

1.5. Is there any change in the existing EU transport legislation resulting from the new CLP Regulation? (New)

Directive 2008/68/EC on the inland transport of dangerous goods which shall have been transposed by Member States into national law by 30 June 2009 includes neither references to CLP nor to the previous legislation on classification and labelling. CLP Article 1(6) states "Save where Article 33 applies this Regulation shall not apply to the transport of dangerous goods by air, sea, road, rail or inland waterways." Accordingly, CLP does not change the transport legislation. However, CLP lays down in Article 33 specific rules for labelling of outer packaging and single packaging which are transported.

CHAPTER 2: INDUSTRY ROLES UNDER CLP

2.1. What roles and obligations do re-fillers have under CLP?

Re-fillers are downstream users of substances or mixtures whose use is limited to transferring substances or mixtures supplied to them from one container (or packaging) into another. Re-fillers are therefore not obliged to classify in accordance with Title II of CLP, but may also take over the classification derived in accordance with Title II already by another actor in the supply chain provided the re-filler does not change the composition of the substance or mixture that is being refilled. In any case the re-filler has to ensure that the labelling and packaging is in accordance with CLP. This can mean that the original label must be replaced by another one. For example, when the contents of a 200 I drum is decanted into 25 ml bottles, the new label should be in line with the small packaging exemptions, unlike the original bigger one which required full labelling.

Note that re-fillers established within the EU who are supplied with substances or mixtures by an actor outside the EU are considered to be importers under CLP, unless they can benefit from the provisions foreseen for re-importers, see FAQ 2.2. This means that they have the obligation to classify these substances and mixtures and to notify relevant substance information to the Classification and Labelling (C&L) Inventory.

2.2. What roles and obligations do re-importers have under CLP? (New)

According to CLP Article 2(19), a re-importer is considered a downstream user. Re-importers are therefore not obliged to notify to the C&L Inventory nor to classify in accordance with Title II of CLP, but may also take over the classification derived in accordance with Title II already by another actor in the supply chain. In any case the re-importer has to ensure that the labelling and packaging is in accordance with CLP.

Note that for a re-importer to be considered a downstream user certain conditions have to be fulfilled. First, the re-imported substance must have been registered or notified before it was exported from the EU. In addition, the substance must have been re-imported within the same supply chain. Third, a re-importer should be able to show that the re-imported substance is the same as the one that was originally exported. Finally, the re-importer should also be able to show that he has been provided with the respective information in accordance with REACH Article 31 or 32.

When any of the conditions mentioned above is not fulfilled, the re-importer is considered an importer. This means that he has the obligation to classify these substances or mixtures and to notify relevant substance information to the C&L Inventory.

2.3. Will distributors have to classify under CLP? (New)

A distributor is a natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or contained in a mixture, for third parties. Distributors are not obliged to classify themselves. In contrast to other suppliers, a distributor (including a retailer) does not

have to classify substances and mixtures himself, but may take over the classification that was derived in accordance with Title II of CLP by another actor in the supply chain. Typically, the respective classification is made available on a Safety Data Sheet.

The same derogation is also granted to a downstream user as long as he does not change the composition of the substance or mixture supplied to him.

Note that distributors established within the EU who are supplied with substances or mixtures by an actor outside the EU are considered importers under CLP. This means that they have the obligation to classify these substances and mixtures and to notify relevant substance information to the C&L Inventory.

2.4. Is an establishment which is recovering a substance obliged to classify and notify it to the Classification and Labelling Inventory? (New)

Under CLP, recovered substances and mixtures will normally have to be treated in the same way as other substances and mixtures under CLP. This means that they have to be classified according to Title II of CLP and the substances have to be notified to the C&L Inventory, unless the establishment undertaking the recovery (manufacturer of the recovered substance) has already submitted a registration under REACH and included the information necessary for a notification. In case the establishment undertaking the recovery can rely on the exemption from the REACH registration provisions for recovered substances pursuant to REACH Article 2(7)(d), it would still have to notify the recovered substances to the C&L Inventory, in accordance with CLP Article 39(b) and 40.

When classifying under the CLP Regulation, the establishment undertaking the recovery may take over the classification derived in accordance with Title II of CLP already by the registrant of the same substance, if this is appropriate. When notifying in such cases to ECHA, it is recommended to retrieve the classification and labelling information provided earlier by the registrant of the original substance from ECHA's Classification & Labelling Inventory and agree to it.

CHAPTER 3: SCOPE AND EXEMPTIONS UNDER CLP

3.1. Will radioactive substances and mixtures have to be classified or notified under CLP? (New)

No, they will not.

Radioactive substances and mixtures within the scope of Directive 96/29/Euratom are exempted from the scope of CLP. The reason for the exemption is that this legislation already lays down provisions for the protection of workers and the general public arising from ionising radiation, so there is no need to apply CLP in addition.

3.2. Will substances and mixtures under customs supervision have to be classified and notified under CLP? (New)

No, they will not, provided the following conditions are met: if substances or mixtures are in temporary storage, in transit, in a free zone or in a free warehouse on the EU territory and are only transiting through the EU and remain under customs supervision while waiting to leave the EU, they are not subject to the provisions of the CLP Regulation.

Importers of substances or mixtures which are destined to leave the EU again, who wish to rely on the exemption from CLP, need to ensure that such substances and mixtures, while on the EU territory, meet all the following conditions:

- they are put in a free zone or free warehouse as defined under customs legislation or placed under another relevant customs procedure (transit procedure, temporary storage),
- they are kept under supervision of the customs authorities, and
- they do not undergo any form of treatment or processing during their stay in the EU. For this purpose a free zone or a free warehouse on the EU territory is regarded as being part of the EU.

In case of doubt, it is recommended to contact the customs authorities who can clarify applicable customs rules established by Regulation (EEC) No 2913/92 on the Community Customs Code which may be applied to substances and mixtures merely passing through the EU.

3.3. Will a non-isolated intermediate have to be classified and notified under CLP? (New)

No, they will not: As long as an intermediate falls under the definition of REACH Article 3(15)(a) concerning non-isolated intermediates, it is exempted from any obligations under CLP.

It must be noted, however, that quantities of the same substance may be used in other operations or under other conditions than mentioned in this definition, which would imply that those quantities cannot be regarded as "non-isolated intermediate", but rather as a substance that may be placed on the market. Only the quantities of the substance used under the conditions qualifying it as a "non-isolated intermediate"

are exempted from CLP. For the remaining quantities, the relevant requirements under CLP must be fulfilled.

3.4. Will new substances that were notified under Directive 67/548/EEC have to be classified and notified to the Classification and Labelling Inventory? (New)

Yes, they will. Substances notified under Directive 67/548/EEC are deemed to be registered under the REACH Regulation. As the respective dossiers currently only contain the DSD classifications, these would have to be updated with the CLP classifications without undue delay, in accordance with REACH Article 22. The timely update of such a dossier with the CLP classifications will make a separate notification to the C&L Inventory by the same manufacturer or importer unnecessary. ECHA recommends industry to submit such updates as soon as practicable.

3.5. Will waste have to be classified and notified to the Classification and Labelling Inventory? (New)

No, it will not. Waste as defined in the Waste Framework Directive 2006/12/EC is outside the scope of CLP. Waste is any substance or object which the waste holder discards, or intends or is required to discard. This may be waste from households (e.g. newspapers or clothes, food, cans or bottles) or from professionals or industry (e.g. tyres, slag, window frames that are discarded).

As waste is not considered to be a substance, mixture or article under CLP, waste treatment operators are not considered as downstream users. At the same time waste treatment operators will not receive Safety Data Sheets on how to handle a substance or mixture during the waste phase. As long as residues from waste treatment operations are waste, i.e. they are disposed of (e.g. land-filled), they do not fall under the scope of CLP. However, residues which are recovered as substances or mixtures do fall under the scope of CLP.

3.6. Will medicinal products need to be classified and notified to the Classification and Labelling Inventory? (New)

Substances and mixtures which are in the finished state and intended for the final user and which are medicinal products within the scope of Directive 2001/83/EC on the Community code for medicinal products for human use, or veterinary medicinal products within the scope of Directive 2001/82/EC on the Community code relating to veterinary medicinal products are on the whole exempted from the provisions of the CLP Regulation, i.e. they do not have to be classified, packaged, labelled and notified to the C&L Inventory.

However, in cases where a manufacturer or importer supplies substances and mixtures, e.g. active pharmaceutical ingredients (APIs) or excipients, that are not yet in the finished state, this manufacturer or importer will have to classify, package and label these substances and mixtures in accordance with CLP. In addition, if these substances are placed on the market, they will also have to be notified to the C&L Inventory.

This exemption from the provisions of the CLP Regulation does not distinguish between active and non-active pharmaceutical ingredients: it applies to any

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substance or mixture used in medicinal products, e.g. excipients, which is in the finished state and intended for pharmaceutical use.

3.7. Will medical devices need to be classified and notified to the Classification and Labelling Inventory? (New)

Substances and mixtures which are medical devices as defined in Directives 90/385/EEC and 93/42/EEC and which are invasive or used in direct physical contact with the human body, as well as those covered by Directive 98/79/EC, are exempted from the provisions of CLP on the whole if they are in the finished state and intended for the final user:

- Substances and mixtures covered by Directive 90/385/EEC that are invasive or used in direct physical contact with the human body would include cochlear implants, implantable cardiac pacemakers, implantable defibrillators and implantable nerve stimulators,
- Substances and mixtures covered by Directive 93/42/EEC that are invasive or used in direct physical contact with the human body would include sutures, catheters, stents, balloon catheters and wound dressings and
- Substances and mixtures covered by Directive 98/79/EEC would include reagents for diagnostic of Hepatitis C and HIV, self-diagnosis devices for the measurement of blood sugar and IVD Analysers.

As the substances and mixtures mentioned above are exempted from the provisions of CLP, they do not need to be classified, packaged, labelled and notified to the C&L Inventory. However, for substances that are manufactured or imported in volumes of at least 1 tonne per year, either on their own or contained in a mixture, the obligation to classify (but not label, package and notify) may still arise from REACH because such substances would have to be registered.

3.8. Will cosmetic products have to be classified and notified to the Classification and Labelling Inventory? (New)

Similarly to other exempted substances and mixtures referred to in CLP Article 1.5 which are in the finished state and intended for the final user, substances and mixtures in the form of cosmetic products as defined in Directive 76/758/EEC on the whole are exempted from the provisions of CLP. However, for substances that are manufactured or imported in volumes of at least 1 tonne per year, either on their own or contained in a mixture, the obligation to classify (but not label, package and notify) may still arise from REACH because such substances would have to be registered.

Note that a manufacturer or importer who supplies a substance or mixture which is not yet in the finished state is obliged to classify, package and label the ingredient substance or mixture in accordance with CLP, and also to notify that substance or mixture in line with the provisions on notification to the C&L Inventory.

3.9. Will food and feeding stuffs have to be classified and notified to the Classification and Labelling Inventory? (New)

According to CLP Article 1(5(e), substances and mixtures which are used in food for humans or feeding stuffs for animals in accordance with the Food Safety Regulation

(EC) No 178/2002 are on the whole exempted from the provisions of CLP, i.e. they do not have to be classified, packaged, labelled or notified to the C&L Inventory. The exemption also includes the use of a substance or mixture when they are used:

- as food additive in foodstuffs within the scope of Directive 89/107/EEC,
- as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC,
- as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003 or
- in animal nutrition within the scope of Directive 82/471/EEC.

In cases where a manufacturer or importer supplies the denoted substances or mixtures (also) in a form where no such exemptions apply, he would have to classify, package and label them label in accordance with the provisions of CLP and notify the relevant substances to the C&L Inventory.

3.10. 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.

3.11. 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.

CHAPTER 4: NOTIFICATION/CLASSIFICATION & LABELLING (C&L) INVENTORY

4.1. Which substances have to be notified to the Classification and Labelling Inventory? (New)

The following substances will have to be notified to the C&L Inventory, irrespective of their quantities:

- Substances which are subject to registration under REACH (≥ 1 tonne/year) and placed on the market. This will also include certain substances contained in articles where REACH Article 7 provides for their registration. Notification of these substances is not necessary where a manufacturer, importer or Only Representative (OR) has already registered the substance with the classification and labelling according to CLP when its notification in line with CLP Article 40(1) is due;
- Substances classified as hazardous under CLP and placed on the market irrespective of the tonnage. This includes substances which are classified as hazardous under CLP, but which are exempted from registration, e.g. polymers referred to in REACH Article 6(3); and
- Substances classified as hazardous under CLP and present in a mixture above the concentration limits specified in Annex I of CLP or as specified in Directive 1999/45/EC, where relevant, which results in the classification of the mixture as hazardous, and where the mixture is placed on the market. In practice, only substances contained in imported mixtures would have to be notified (by the importer).

4.2. 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.

4.3. 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.

4.4. 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.

4.5. Is notification according to CLP Article 39(b) applicable to the physical hazards of substances contained in mixtures? (New)

Yes, it is. CLP Article 39(b) refers to all hazards. This includes notification of a substance classified for a particular physical hazard and contained in a mixture whenever the mixture is placed on the market and needs to be classified for a physical hazard due to the presence of that substance. It should be noted that the physical hazard class to which the mixture belongs could be different from that of the substance(s) causing the hazard. Expert judgment should be sought in case of doubt.

4.6. In view of the obligation to notify according to CLP Article 39(b): How should an importer proceed in case he has only information on the DSD classifications of the substances contained in the mixtures he imports? (New)

If a mixture that is classified as dangerous (according to DPD - until 01/06/2015) or as hazardous (according to CLP) is imported, CLP Article 39(b) requires that the substances in the mixture which led to this classification be notified to the C&L Inventory. According to CLP Article 40(1), the notified classifications of substances must be the CLP classifications. It may happen that importers are only provided with the DSD classifications of the substances contained in the mixtures, e.g. by means of a Safety Data Sheet, while further data on the substances are not available to them. At the same time the mixture has to be classified as dangerous according to the DPD criteria, due to the presence of these substances. In these situations importers should use the translation table in Annex VII to the CLP and notify the relevant CLP classifications of the substances in the mixture. Further explanation on the use of the Annex VII translation tables is provided in chapter 1.7. of the "Guidance on the application of the CLP criteria" as published on the Agency's (ECHA's) website under http://guidance.echa.europa.eu/guidance en.htm

4.7. 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 5: LABELLING

5.1. 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 relabelling 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.

5.2. 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.

5.3. 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.

5.4. 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.

5.5. 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 I-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 6: REQUEST FOR USE OF AN ALTERNATIVE CHEMICAL NAME

6.1. 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.

6.2. 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.

6.3. 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.

6.4. 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 7: ANNEX VI TO CLP

7.1. 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: $C \ge 20$ %, C; R34: 5 % $\le C < 20$ %, Footnote: O; R8: $C \ge 70$ %.

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.

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