CONSULTATION OF SOCIAL PARTNERS

First-stage consultation of the European social partners on amendment of certain EC directives on health and safety at work as a result of adoption of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
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1. INTRODUCTION

The purpose of this consultation is to obtain the views of the social partners on amendment of five directives on health and safety at work. These amendments are necessary to reflect new requirements laid down for classification, labelling and packaging of chemicals as a result of adoption of Regulation (EC) No 1272/2008 in order to implement, within the European Union, the United Nations Globally Harmonised System of Classification and Labelling of Chemicals.

Five EC directives on health and safety at work refer to classification and labelling requirements for chemicals. These references define either the scope or specific requirements of the directives. It is necessary to amend these five directives to ensure that the current level of worker protection is maintained.

2. THE GENERAL CONTEXT

The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is a United Nations system to identify hazardous chemicals and to inform users about the related hazards by means of standard symbols and phrases on packaging labels and of safety data sheets (SDS).

Following successful negotiations on the proposal, the European Parliament and the Council adopted Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (‘the CLP Regulation’) on 16 December 2008. This Regulation aligns the existing EC legislation with the GHS and was published in the Official Journal on 31 December 20081.

The CLP Regulation entered into force on 20 January 2009. The deadlines for classification in accordance with the new rules will be 1 December 2010 for substances and 1 June 2015 for mixtures. The CLP Regulation will ultimately replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC) after the transition period provided for in Article 61 of the same Regulation.

The CLP Regulation aims to align the EC system for classification, packaging and labelling of chemical substances and mixtures with the United Nations Globally Harmonised System

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(GHS)\(^2\). It is expected to facilitate global trade and harmonised communication of information on hazards posed by chemicals and to promote regulatory efficiency. It will complement the new ‘REACH Regulation’ (Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals\(^3\)).

Implementation of the GHS in the European Union via the CLP Regulation will require companies to classify, label and package their substances and mixtures appropriately before placing them on the market after a transition period when the two systems will be in force side by side. It aims to protect workers, consumers and the environment by means of labelling indicating possible hazardous effects of any particular chemical.

The safety data sheets provided by chemical suppliers are a major source of information for employers and workers. Transitional arrangements will also apply to the legislative requirements applicable to safety data sheets. These are summarised in Annex I.

### 3. IMPACT OF ADOPTION OF THE EC REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING OF CHEMICALS ON DIRECTIVES ON HEALTH AND SAFETY AT WORK

Classification of substances and preparations (in the GHS the term ‘mixtures’ is used) triggers other obligations in downstream EC legislation. The Commission departments concerned have assessed the potential effects of application of the GHS criteria on downstream legislation\(^4\).

They concluded that the effects are either minimal or can be minimised by appropriate changes to particular downstream legislation. The CLP Regulation itself includes such changes to the REACH Regulation. Separate amendments have been adopted to implement the CLP Regulation in other downstream European Union legislation (see Annex II).

This consultation covers one such issue: Currently five directives on health and safety at work refer to the existing European Union system for classification and labelling of chemicals (Directives 67/548/EEC on substances and 1999/45/EC on preparations) as a means of defining the scope or specific requirements of the directives.

Adoption of the CLP Regulation will result in running two classification and labelling systems for chemicals (the existing European Union system and the GHS system as implemented in the European Union by the CLP Regulation) side by side for a set period. The first transition period provided for in the CLP Regulation ends on 1 December 2010 and

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\(^2\) The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) provides a harmonised basis for globally uniform physical, environmental and health and safety information on hazardous chemical substances and mixtures. In its Plan of Implementation, adopted in Johannesburg on 4 September 2002, the World Summit on Sustainable Development encouraged countries to implement the harmonised system as soon as possible, with a view to making it fully operational by 2008.


\(^4\) Analysis of the potential effects of the proposed GHS Regulation on its downstream EU legislation (DG Enterprise) and addendum.
applies to individual substances. Thereafter a second transition period, lasting until 1 June 2015, will apply to mixtures of individual substances. The five existing directives on health and safety at work must be amended before the end of the transition periods.

It is necessary to amend the directives on health and safety at work in order to ensure that the requirements which depend on the European Union classification system for chemicals continue to apply. The amendments should align the directives with the changes made to the classification and labelling system for chemicals by the CLP Regulation.

The five directives on health and safety at work, and the relevant sections that refer to classification of chemicals, are:


Article 2 defines the scope of the directive by means of the term ‘hazardous chemical agent’, which, in turn, is defined by referring to the relevant EC directives on classification and labelling of chemicals.


Article 2 defines the scope of the directive by means of the terms ‘carcinogen’ and ‘mutagen’, which, in turn, are defined by referring to the relevant EC directives on classification and labelling of chemicals.


Annex III, item 1 refers to the relevant EC directives on classification and labelling of chemicals.

(4) **Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding** (tenth individual Directive within the meaning of Framework Directive 89/391/EEC).

Annex I, item 3 on chemical agents refers to risk phrases in the relevant EC directives on classification and labelling of chemicals.

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(5) Council Directive 94/33/EC on the protection of young people at work. This is an independent directive (i.e. it is not an individual Directive within the meaning of Directive 89/391/EEC).

Item 3 in section I of the Annex on chemical agents refers to the relevant EC directives on classification and labelling of chemicals.

4. CLASSIFICATION AND LABELLING OF CHEMICALS

Classification of chemicals is a standardised way to define the inherent hazardous properties of a chemical. A distinction is drawn between three kinds of hazard: physical-chemical hazards, hazards to human health and hazards to the environment. In the case of hazards to human health, the pathways (oral, inhalation or dermal uptake) by which the chemical could cause an adverse effect are specified. Most hazards are defined on the basis of the level of severity of the effect (e.g. very toxic, toxic or harmful).

The classification of substances is determined by comparing test data and other information with the criteria for the relevant hazard class. The classification of mixtures can be determined either by testing the mixture as a whole, which is necessary for most physico-chemical properties, or by other methods such as assessing the hazardous properties of the substances in the mixture and applying calculation rules to decide the classification. A third approach is to use epidemiological data.

Classification and labelling of chemicals are strictly hazard-based. They do not take into consideration any exposure of humans or the environment. This means that the classification describes the potential of a chemical to cause damage. Whether or not, and in which dose, a chemical comes into contact with humans or the environment determines which, if any, damage is actually caused. If a substance or mixture is classified for any of the hazardous properties defined in the CLP Regulation, it is called ‘hazardous’.

The CLP Regulation will make some changes to the current rules on classification and labelling of chemicals. It is similar to the Dangerous Substances Directive (67/548/EC) and the Dangerous Preparations Directive (1999/45/EC) in some ways, e.g.:

- It provides a single system for hazard classification and labelling.
- It covers approximately the same hazards.
- It often uses similar or the same classification criteria.
- It sets up an equivalent system for communication of hazards.

On the other hand, the CLP Regulation is different from the current directives in that:

- It defines further hazard classes and categories.
- It partly uses other criteria and other cut-offs.

• It takes a different approach for mixtures.
• It changes some of the rules on labelling.

The CLP Regulation does not include categories which are not in the current European Union system, namely:
• Flammable liquids category 4;
• Acute toxicity category 5;
• Skin corrosion/irritation category 3;
• Aspiration hazard category 2;
• Acute aquatic toxicity category 2;
• Acute aquatic toxicity category 3.

It incorporates the current Annex I to the Dangerous Substances Directive (67/548/EC) and Title XI (classification and labelling inventory) of the REACH Regulation. The CLP Regulation maintains the current level of protection by including EU ‘left-overs’ not yet covered by the GHS:
• Ozone depletion (Annex I, part 5);
• Additional labelling requirements in Annex II, e.g.:
  • EUH014 [R14] ‘reacts violently with water’;
  • EUH066 [R66] ‘repeated exposure may cause skin dryness or cracking’.

The main general changes introduced by the CLP Regulation to the existing rules on classification and labelling regard the methods and criteria for determining physico-chemical hazards, some human health end-points and application of rules for using non-test data.

5. Communication on dangerous properties

The classification of a substance or mixture is to be communicated on the label (and packaging) and via the safety data sheet.

The classification on the label is abbreviated and accompanied by a hazard symbol, alerting users to the specific hazard. The label is intended to ensure that the person handling the chemical is informed of any hazard in a concise way. There are several rules on how much information should be supplied and in which order and format.

The safety data sheet is required for any substance or mixture placed on the market that is classified as hazardous or as a substance of very high concern or that contains significant amounts of such substances (in accordance with Article 31 of the REACH Regulation). Apart from details of the classification, the safety data sheet contains other information necessary for appropriate protection of workers and the environment, such as specific advice on safe
handling and storage or on risk management measures, along with further legal information. If an exposure scenario is attached to the safety data sheet, more specific information on how to use the substance or mixture is included.

6. **ACTION PROPOSED AT EU LEVEL**

The Commission has to consider the need for amending the five directives on health and safety at work to take account of adoption of the CLP Regulation.

These five directives are based on Article 137 of the EC Treaty. Article 138 of the EC Treaty requires a two-stage consultation of the social partners at European level before the Commission submits any new proposals in the social policy field.

The Commission is considering to propose amendments that would introduce technical changes to the classification-based provisions that define certain aspects of their scope, without affecting the objectives to be achieved by these directives. An option could be to put forward a single amending directive on health and safety at work containing all the changes needed to realign the relevant parts of the five existing directives, moving from the current to the new European Union classification system for chemicals. This approach looks the most appropriate as it would be in line with the principle of better regulation, simplifying the regulatory environment and avoiding unnecessary administrative costs. An alternative approach could be to amend each of the directives individually. However, it is difficult to see the benefit of such an approach.

At the same time, the Commission could take this opportunity to make a number of minor amendments to the Annex to Directive 94/33 on young people at work. These amendments would clarify changes to certain EC legislation mentioned in this Annex. For example, references to the current directives on biological agents and on carcinogens and mutagens need to be updated.

7. **MATTERS FOR CONSULTATION**

In the light of the foregoing, the social partners are invited to answer the following questions:

1. Do you consider that the five existing directives on health and safety at work should be amended to reflect adoption of the Regulation on classification, labelling and packaging that implements the UN Globally Harmonised System within the EU?

2. In particular, do you agree with the approach of amending the five existing directives by adopting a single amending directive under Article 137 of the Treaty?

3. Should this amendment be designed to have a neutral effect on the requirements of the existing directives, i.e. should its overall objective be to maintain the level of worker protection provided by the five directives?

4. Do you agree that the Annex to Directive 94/33 on young people at work should be updated to reflect the changes to a number of pieces of EC legislation referred to in the Annex to the directive?
ANNEX I

The CLP Regulation entered into force on 20 January 2009. However, not all the provisions of the CLP Regulation will be obligatory immediately: transitional provisions in Article 61 set two target dates that affect classification, hazard communication and packaging of hazardous substances and mixtures, namely 1 December 2010 and 1 June 2015.

Details of the dates from which the new rules will apply are given below.

1. **The CLP Regulation came into force on 20 January 2009.**

From 20 January 2009 the following rules apply:

- until 1 December 2010, substances *must* continue to be classified, labelled and packaged in accordance with the Dangerous Substances Directive (DSD). However, substances *may* also be classified, labelled and packaged in accordance with the CLP Regulation before this date. When this is done, the labelling and packaging provisions of the DSD will no longer apply to the substance. This means that labelling and packaging *must* comply with the rules in the CLP Regulation;

- until 1 June 2015, mixtures *must* continue to be classified, labelled and packaged in accordance with the Dangerous Preparations Directive (DPD). However, mixtures *may* also be classified, labelled and packaged in accordance with the CLP Regulation before this date. When this is done, the labelling and packaging provisions of the DPD will no longer apply to the mixture. This means that labelling and packaging *must* comply with the rules in the CLP Regulation;

- until 1 June 2015, the classification of a substance under the DSD *must* be indicated on the safety data sheet. This will apply to safety data sheets both for substances on their own and for mixtures of substances;

- until 1 December 2010, if a substance is classified, labelled and packaged in accordance with the CLP Regulation, the classification under the CLP Regulation *must* appear on the safety data sheet, alongside the classification based on the DSD. However, suppliers may choose to identify the classification of a substance under the CLP Regulation before fully applying the CLP Regulation to it. When this is done, the supplier may include this information on the accompanying safety data sheet, under the heading ‘other information’;

- until 1 June 2015, the classification of a mixture in accordance with the DPD *must* be indicated on the safety data sheet;

- until 1 June 2015, if a mixture is classified, labelled and packaged in accordance with the CLP Regulation, the classification under the CLP Regulation *must* appear on the safety data sheet, alongside the classification based on the DPD. However, suppliers may choose to identify the classification of a mixture under the CLP Regulation before fully applying the CLP Regulation to it. When this is done, the supplier may include this information on the accompanying safety data sheet, under the heading ‘other information’;

- from 20 January 2009, Title V started to apply. **Manufacturers, importers and downstream users** can therefore submit proposals for harmonised classification to the European Chemicals Agency (*Article 37(2) of the CLP Regulation*) and must submit a
proposal to the competent authority in one of the Member States if they have new information which may lead to a change in the harmonised classification and labelling (Article 37(6) of the CLP Regulation; see also section 22 of the guidance document).

2. The CLP Regulation will replace the DSD for classification, labelling and packaging of substances on 1 December 2010.

From 1 December 2010 the following rules will apply:

- substances must be classified in accordance with both the DSD and the CLP Regulation;

- substances *must* be labelled and packaged in accordance with the CLP Regulation only, but substances already classified, labelled and packaged in accordance with the DSD and placed on the market (i.e. ‘on the shelves’) before 1 December 2010 will only have to be re-labelled and re-packaged by 1 December 2012;

- until 1 June 2015, mixtures *must* continue to be classified, labelled and packaged in accordance with the DPD. However, mixtures *may* also be classified, labelled and packaged in accordance with the CLP Regulation before this date. When this is done, the labelling and packaging rules in the DPD will no longer apply to the mixture. This means that labelling and packaging *must* comply with the rules in the CLP Regulation;

- until 1 June 2015, the classification of a substance in accordance with the DSD *must* be indicated on the safety data sheet, in addition to the classification under the CLP Regulation. This will apply to safety data sheets both for substances on their own and for mixtures of substances;

- until 1 June 2015, the classification of a mixture in accordance with the DPD *must* be indicated on the safety data sheet;

- until 1 June 2015, if a mixture is classified, labelled and packaged in accordance with the CLP Regulation, the classification under the CLP Regulation *must* appear on the safety data sheet, alongside the classification based on the DPD. However, suppliers may choose to identify the classification of a mixture under the CLP Regulation before fully applying the CLP Regulation to it. When this is done, the supplier may include this information on the accompanying safety data sheet, under the heading ‘other information’;

- on 1 June 2015, the CLP Regulation will replace the DPD for classification, labelling and packaging of mixtures.

From 1 June 2015 the following rules will apply:

- substances must be classified, labelled and packaged in accordance with the CLP Regulation only;

- mixtures must be classified, labelled and packaged in accordance with the CLP Regulation only, but mixtures already classified, labelled and packaged in accordance with the DPD and placed on the market (i.e. ‘on the shelves’) before 1 June 2015 will only have to be re-labelled and re-packaged by 1 June 2017; and
- Substance and mixture classifications in accordance with the CLP Regulation must be indicated on the safety data sheet.

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<thead>
<tr>
<th><strong>Registration Dates</strong></th>
<th><strong>Classification Requirements</strong></th>
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<tbody>
<tr>
<td>Registrations submitted before 1 December 2010</td>
<td>Must indicate the classification and labelling in accordance with the DSD. It is advisable also to include the classification and labelling in accordance with the CLP Regulation in the registration dossier. In that case, there is no need to submit a notification.</td>
</tr>
<tr>
<td>Registrations submitted between 1 December 2010 and 1 June 2015</td>
<td>Must indicate the classification in accordance with the CLP Regulation. The registration dossier may also indicate the classification in accordance with the DSD.</td>
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<tr>
<td>Registrations submitted after 1 June 2015</td>
<td>Must contain only the classification in accordance with the CLP alone.</td>
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ANNEX II

Examples of adaptation of EC legislation to the criteria laid down in the CLP Regulation

The CLP Regulation was adopted as part of a package of legislation also comprising:

- Regulation (EC) No 1336/2008 amending Regulation (EC) No 648/2004 of 31 March 2004 on detergents. The following changes were made: ‘preparation’ was replaced by ‘mixture’ and references to the DSD and DPD were replaced by references to the CLP Regulation;

and

- Directive 2008/112/EC amending six Community directives:

  Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products: ‘preparation’ was replaced by ‘mixture’ and references to the DSD were replaced by references to the CLP Regulation. A general reference to the Test Method Regulation (Regulation (EC) No 440/2008) and a reference to the CMR criteria under the CLP Regulation were inserted and the concept of ‘dangerous’ was translated into hazard classifications under the CLP Regulation;

  Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys: ‘preparation’ was replaced by ‘mixture’ and the concept of ‘dangerous’ was translated into hazard classifications under the CLP Regulation;

  Council Directive 1999/13/EC of 11 March 1999 (‘the VOCD’) and Directive 2004/42/EC of 21 April 2004 on the limitation of emissions of volatile organic compounds: ‘preparation’ was replaced by ‘mixture’ (in both directives). A reference to the CLP Regulation was inserted in Article 5(6) of the VOCD for substances (from 1 December 2010) and for mixtures (from 1 June 2015). Also, a reference to the CMR criteria under the CLP Regulation and hazard statements was inserted in Article 5(6), (8), (9) and (13) of the VOCD for substances (from 1 December 2010) and for mixtures (from 1 June 2015);

  Directive 2000/53/EC of 18 September 2000 on end-of-life vehicles: the concept of ‘dangerous’ was translated into hazard classifications under the CLP Regulation;

  and

  Directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment (WEEE) ‘preparation’ was replaced by ‘mixture’ and references to the DSD were replaced by references to the CLP Regulation; the concept of ‘dangerous’ was translated into hazard classifications under the CLP Regulation.

The changes resulting from Regulation (EC) No 1336/2008 and Directive 2008/112/EC are to come into force in line with the dates set for implementation of the CLP Regulation, i.e. upon the entry into force of the CLP Regulation or on 1 December 2010 or on 1 June 2015, as appropriate.