


# Procedure file

| Basic information   |                     |
|---|---------------------|
| <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation <a href="#">2007/0121(COD)</a></p> <p>Chemicals: classification, labelling and packaging of substances and mixtures</p> <p>Repealing Directive 1999/45/EC <a href="#">1996/0200(COD)</a><br/>Amending Regulation (EC) No 1907/2006 <a href="#">2003/0256(COD)</a><br/>See also <a href="#">2013/0062(COD)</a></p> <p>Subject<br/>3.40.01 Chemical industry, fertilizers, plastics<br/>3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport)<br/>4.60.02 Consumer information, advertising, labelling</p> | Procedure completed |

| Key players                   |   |                                       |            |
|-------------------------------|---|---------------------------------------|------------|
| European Parliament           | Committee responsible   | Rapporteur                            | Appointed  |
|                               | <b>ENVI</b> Environment, Public Health and Food Safety                          |                                       | 13/09/2007 |
|                               |   | PPE-DE <a href="#">SARTORI Amalia</a> |            |
|                               | Committee for opinion   | Rapporteur for opinion                | Appointed  |
|                               | <b>ITRE</b> Industry, Research and Energy                                       |                                       | 09/10/2007 |
|                               |   | ALDE <a href="#">LAPERROUZE Anne</a>  |            |
| Council of the European Union | <b>IMCO</b> Internal Market and Consumer Protection (Associated committee)      |                                       | 16/07/2007 |
|                               |   | PPE-DE <a href="#">SCHWAB Andreas</a> |            |
|                               | Council configuration   | Meeting                               | Date       |
|                               | <a href="#">Agriculture and Fisheries</a>                                       | <a href="#">2909</a>                  | 28/11/2008 |
|                               | <a href="#">Competitiveness (Internal Market, Industry, Research and Space)</a> | <a href="#">2832</a>                  | 22/11/2007 |
| European Commission           | Commission DG   | Commissioner                          |            |
|                               | <a href="#">Environment</a>   | DIMAS Stavros                         |            |

| Key events |   |                               |         |
|------------|---|-------------------------------|---------|
| 27/06/2007 | Legislative proposal published                            | <a href="#">COM(2007)0355</a> | Summary |
| 09/07/2007 | Committee referral announced in Parliament, 1st reading   |                               |         |
| 27/09/2007 | Referral to associated committees announced in Parliament |                               |         |
| 22/11/2007 | Debate in Council   | <a href="#">2832</a>          |         |

|            |   |   |         |
|------------|---|---|---------|
| 02/04/2008 | Vote in committee, 1st reading                        |   | Summary |
| 09/04/2008 | Committee report tabled for plenary, 1st reading      | <a href="#">A6-0140/2008</a>  |         |
| 03/09/2008 | Results of vote in Parliament                         |  |         |
| 03/09/2008 | Debate in Parliament                                  |  |         |
| 03/09/2008 | Decision by Parliament, 1st reading                   | <a href="#">T6-0392/2008</a>  | Summary |
| 28/11/2008 | Act adopted by Council after Parliament's 1st reading |   |         |
| 16/12/2008 | Final act signed                                      |   |         |
| 16/12/2008 | End of procedure in Parliament                        |   |         |
| 31/12/2008 | Final act published in Official Journal               |   |         |

### Technical information

|                            |  |
|----------------------------|--|
| Procedure reference        | 2007/0121(COD)   |
| Procedure type             | COD - Ordinary legislative procedure (ex-codecision procedure)   |
| Procedure subtype          | Legislation  |
| Legislative instrument     | Regulation   |
|                            | Repealing Directive 1999/45/EC <a href="#">1996/0200(COD)</a><br>Amending Regulation (EC) No 1907/2006 <a href="#">2003/0256(COD)</a><br>See also <a href="#">2013/0062(COD)</a> |
| Legal basis                | EC Treaty (after Amsterdam) EC 095   |
| Stage reached in procedure | Procedure completed  |
| Committee dossier          | ENVI/6/51095   |

### Documentation gateway

|   |             |                               |            |     |         |
|---|-------------|-------------------------------|------------|-----|---------|
| Legislative proposal  |             | <a href="#">COM(2007)0355</a> | 27/06/2007 | EC  | Summary |
| Document attached to the procedure                              |             | <a href="#">SEC(2007)0853</a> | 27/06/2007 | EC  |         |
| Document attached to the procedure                              |             | <a href="#">SEC(2007)0854</a> | 27/06/2007 | EC  |         |
| Committee draft report  |             | <a href="#">PE398.679</a>     | 11/01/2008 | EP  |         |
| Amendments tabled in committee                                  |             | <a href="#">PE402.685</a>     | 26/02/2008 | EP  |         |
| Committee opinion   | <b>ITRE</b> | <a href="#">PE400.315</a>     | 06/03/2008 | EP  |         |
| Economic and Social Committee: opinion, report                  |             | <a href="#">CES0493/2008</a>  | 12/03/2008 | ESC |         |
| Committee opinion   | <b>IMCO</b> | <a href="#">PE398.646</a>     | 27/03/2008 | EP  |         |
| Committee report tabled for plenary, 1st reading/single reading |             | <a href="#">A6-0140/2008</a>  | 09/04/2008 | EP  |         |
| Text adopted by Parliament, 1st reading/single reading          |             | <a href="#">T6-0392/2008</a>  | 03/09/2008 | EP  | Summary |
| Commission response to text adopted in plenary                  |             | <a href="#">SP(2008)6073</a>  | 17/10/2008 | EC  |         |

|                    |  |                                |            |     |         |
|--------------------|--|--------------------------------|------------|-----|---------|
| Draft final act    |  | <a href="#">03671/2008/LEX</a> | 16/12/2008 | CSL |         |
| Follow-up document |  | <a href="#">COM(2012)0630</a>  | 29/10/2012 | EC  | Summary |
| Follow-up document |  | <a href="#">COM(2013)0049</a>  | 05/02/2013 | EC  | Summary |
| Follow-up document |  | SWD(2013)0025                  | 05/02/2013 | EC  |         |

#### Additional information

|                      |                         |
|----------------------|-------------------------|
| National parliaments | <a href="#">IPEX</a>    |
| European Commission  | <a href="#">EUR-Lex</a> |

#### Final act

[Regulation 2008/1272](#)  
[OJ L 353 31.12.2008, p. 0001](#) Summary

[Corrigendum to final act 32008R1272R\(02\)](#)  
[OJ L 016 20.01.2011, p. 0001](#)

[Corrigendum to final act 32008R1272R\(11\)](#)  
[OJ L 349 21.12.2016, p. 0001](#)

[Corrigendum to final act 32008R1272R\(17\)](#)  
[OJ L 117 03.05.2019, p. 0008](#)

#### Delegated acts

|                                |                              |
|--------------------------------|------------------------------|
| <a href="#">2019/2843(DEA)</a> | Examination of delegated act |
| <a href="#">2019/2902(DEA)</a> | Examination of delegated act |
| <a href="#">2022/2555(DEA)</a> | Examination of delegated act |
| <a href="#">2020/2769(DEA)</a> | Examination of delegated act |
| <a href="#">2021/2845(DEA)</a> | Examination of delegated act |
| <a href="#">2020/2661(DEA)</a> | Examination of delegated act |
| <a href="#">2021/2593(DEA)</a> | Examination of delegated act |
| <a href="#">2021/2600(DEA)</a> | Examination of delegated act |
| <a href="#">2020/2699(DEA)</a> | Examination of delegated act |
| <a href="#">2020/2768(DEA)</a> | Examination of delegated act |
| <a href="#">2021/2547(DEA)</a> | Examination of delegated act |
| <a href="#">2023/2675(DEA)</a> | Examination of delegated act |
| <a href="#">2023/2672(DEA)</a> | Examination of delegated act |
| <a href="#">2022/3027(DEA)</a> | Examination of delegated act |
| <a href="#">2023/2929(DEA)</a> | Examination of delegated act |

## Chemicals: classification, labelling and packaging of substances and mixtures

PURPOSE: to establish a new system on classification and labelling of hazardous substances and mixtures by implementing in the EU the international criteria agreed by the United Nations. PROPOSED ACT: Regulation of the European Parliament and of the Council.

CONTENT: Chemicals are manufactured and traded globally, and their hazards are the same around the world. Therefore the description of hazards should not differ between countries if the product is the same. If the same criteria are used to identify the hazards of chemicals and the same labelling is used to describe them, the level of protection of human health and the environment becomes more consistent, transparent and comparable throughout the world. Professional users of chemicals and consumers all over the world benefit from such a harmonisation. In addition, enterprises will save costs if they do not have to assess hazard information for their chemicals against different sets of criteria.

This proposal builds on existing chemicals legislation and establishes a new system on classification and labelling of hazardous substances and mixtures by implementing in the EU the international criteria agreed by the United Nation Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures, called the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). It addresses supply and use of chemicals and, therefore, the main target audience are workers and consumers, as is the case for the current EU system.

The aim is to ensure a level playing field for all suppliers of substances and mixtures in the internal market, as well as a high level of protection of health, safety, environment and consumers. The proposal aims to ensure that the requirements for substances and mixtures are harmonised and that substances and mixtures complying with them can move freely throughout the internal market. This rewards the efforts required from economic actors to reclassify substances and mixtures.

To this end, the proposed Regulation takes a fivefold approach based on the GHS:

- 1) it harmonises the classification, labelling and packaging rules for substances and mixtures;
- 2) it obliges enterprises to classify their substances and mixtures themselves;
- 3) it obliges enterprises to notify the classifications;
- 4) it establishes a harmonised list of substances classified at Community level in Annex VI;
- 5) it establishes a classification and labelling inventory, made up of all notifications and harmonised classifications referred to above.

The Regulation applies to substances and mixtures. However, since the physical hazards of substances or mixtures are to some extent influenced by the way in which they are released, the Regulation also covers release by aerosols through a specific hazard class. Radioactive substances are excluded from the scope, as they are covered by other rules. Substances and mixtures subject to customs supervision are also excluded, subject to certain conditions, as they are not supplied in the EU. Substances and mixtures for scientific research and development not placed on the market are also excluded when used under controlled conditions minimising exposure.

The essential terms are defined. Following the GHS, the term 'preparation' is replaced by 'mixture'.

Annex I lists the hazard classes of the GHS, as well as the relevant hazard categories and criteria. If a substance or a mixture fulfils the criteria for any hazard class, it is hazardous. The Commission is empowered to update Annex I and to include new hazard classes agreed at UN level. The concept of 'dangerous' is also laid down, in order to allow minimising effects on downstream legislation.

The label elements from the GHS are specified, i.e. the name, address and telephone number of the supplier, product identifiers, hazard pictograms, signal words, hazard statements and precautionary statements. To maintain the level of protection of current EU law, supplemental information on hazards not yet included in the GHS must also be mentioned. Furthermore, the nominal quantity in the package, as placed on the market to the general public, has to be indicated. To protect confidential business information, it is possible to apply for permission to use a name that does not reveal the substance's chemical identity. The Agency established by the REACH Regulation will decide on such applications. Principles of precedence for labelling are specified. The supplier has to update the label after changes to the classification, unless the labels are part of an approval decision concerning a biocide or a plant protection product. In the latter case, the applicable special legislation has to be complied with.

To ensure that customers notice hazard information, there are rules on the colours and format of labels and on the location of information on labels.

To reduce the burden on enterprises and to avoid the duplication of transport labels, there are provisions determining which labels to use in case of inner and outer packages.

Safety measures for containers and other packages are set out.

Certain provisions of the REACH Regulation are moved to this Regulation, with regard to the notification to the Agency and establishing the classification and labelling inventory.

Member States must appoint the authorities for the application and enforcement of this Regulation. Good cooperation between all competent authorities is essential. To bundle information on human health, as under current legislation, one body per Member State is responsible for receiving health-related information. To enhance the exchange of practical experience, the Agency's Forum established by the REACH Regulation shall also exchange enforcement information under this Regulation.

Lastly, Member States have to establish proportionate sanctions for non-compliance.

## Chemicals: classification, labelling and packaging of substances and mixtures

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The Committee on the Environment, Public Health and Food Safety adopted a report drafted by Amalia SARTORI (EPP-ED, IT) and made some amendments to the proposal for a regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006. The committee attempted, where possible, to align the text with GHS texts.

The main amendments are as follows :

Scope: The Regulation will not apply to substances and mixtures for scientific research and development or for process oriented research and development, which are not placed on the market or are placed on the market at an annual volume below 1 tonne per supplier. The

Commission had excluded from the scope substances and mixtures for scientific research and development, which are not placed on the market, provided they are used under such controlled conditions minimising exposure as if they were classified as carcinogenic, germ cell mutagenic or toxic to reproduction (CMR) category 1A or 1B according to Annex I, but the Committee did not accept this. The latter added that the list of the substances with their harmonised classifications and labelling should be available for the public.

Definition: preparation means a mixture or solution composed of two or more substances; mixture and preparation are synonyms.

Minimum threshold value for notification to the Agency: Members stated that the obligation, starting from 1 December 2010, to notify the Agency for the purposes of the classification inventory should not apply to every case in which a substance subject to registration is to be placed on the market, but only to substances classified as hazardous, including where REACH is concerned. For a substance classified as hazardous on its own or in a mixture, a threshold of 1 tonne a year is laid down.

PBT labelling: the Agency shall, in accordance with Article 123 of Regulation (EC) No 1907/2006, provide as a matter of high priority, and in consultation with the Commission, competent authorities and stakeholders, guidance and/or recommendations for any supplemental information on the label that is considered necessary for the protection of human health or the environment when a mixture contains substances with persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties in excess of 0.1%. In addition, Members stipulated that the Commission shall promote the harmonisation of the labelling of PBT and vPvB at the level of the United Nations and shall, as appropriate, subsequently adjust and adapt sections 1.1 and 1.2 of Annex II and part 2 of Annex III referred to in Article 27(1) and/or part 2 of Annex II and part 3 of Annex III referred to in Article 24.

Labelling: in the case of natural materials, a designation such as 'essential oil from ...' or '... extract' may be used instead of the names of the components of this essential oil or extract.

Deadline for labelling update: the supplier of a substance or a mixture shall take all appropriate measures to update the label following any change to the classification and labelling of the substance or mixture, without delay and in any case not later than twelve months after the change of classification.

Tests on humans: tests on humans for the sole purpose of this Regulation are generally not acceptable and shall only be undertaken when no other alternatives are possible to ensure the best protection of human health and the classification of a substance or mixture according to its actual effects on human health. Tests on non-human primates shall not be performed for the purposes of this Regulation. The Commission proposal contained a prohibition on testing on humans and animals.

Animal testing: where new tests are carried out for the purposes of this Regulation, tests on animals shall be undertaken only where no other alternatives, which provide the same level of reliability and quality of data, are possible. Testing methods shall be regularly reviewed with a view to reducing testing on vertebrate animals and the number of animals involved. The committee added that validation studies to assess non-animal tests, or methods that reduce the number of animals used or the suffering experienced by test animals, shall be designed to ensure that new test methods take account of the requirements of the Regulation and similar legislation implementing the Globally Harmonised System of Classification and Labelling of Chemicals in other jurisdictions so that classification and labelling requirements do not become a barrier to the replacement, reduction and refinement of animal testing.

Evaluation of data: when evaluating the data the manufacturer or importer shall consider additional information such as the form and/or physical state in which the substance or mixture is used after it is placed on the market and may refine the classification accordingly. Normal handling and use should be taken into consideration in the classification of a substance or mixture. Where a specific product sector group has established a Hazard and Classification Centre, which brings together expertise in the evaluation of information, test data, weight of evidence determinations, and bridging principles, any supplier within the product sector may rely on an evaluation from that centre for the establishment of the hazards associated with, and the corresponding classification of, the mixture.

Packaging: the committee added several clauses amending the provisions on packaging relating to, inter alia, packaging containing 125 ml or less, if the substance or mixture is classified as Chronically Aquatic Hazardous of category 3 or 4; hazard and precautionary statements regarding substances or mixtures in small or unsuitable packaging; packaging for single use; packaging of substances and mixtures destined for the general public and fulfilling the criteria for Hazard Class 2.16. An additional Article was added on the labelling of detergents.

Guidance by the Agency: the supplier of a substance or a mixture intended for use by the general public shall label the product in accordance with the guidance provided by the Agency for the communication of information to the general public on the risks and safe use of chemical substances and mixtures, as provided for in Regulation (EC) No 1907/2006.

New Article 40(a): a new article entitled classification and labelling of hazardous substances under Directive 67/548/EEC for hazard categories other than those specified in Article 38(1) is inserted. It states that the classifications and forms of labelling set out in the new part 4 of Annex VI may be applied by suppliers. Where a supplier decides not to apply those classifications and forms of labelling, he shall be required to re-evaluate the substance in question on the basis of the criteria laid down in parts 2 to 5 of Annex I.

The committee noted that in the Commission proposal, Annex VI, part 3, has binding force. It proposed adding a part 4 setting out classifications and forms of labelling for hazardous substances which have already been the subject of Community harmonisation under Directive 67/548/EEC in connection with hazard categories other than those specified in Article 38. Part 4 on Annex VI is to be considered a non-binding reference tool for the use of the authorities and industry.

Accidents: every year Member States shall submit to the European accident database set up under the EHLASS programme (European Home and Leisure Accident Surveillance System) data detailing the number of accidents, and the mixtures involved, in respect of which appointed bodies have received requests for medical information concerning treatment and curative measures.

Comitology: the Commission must adopt Annex VIIa and may adjust and adapt Annexes I to VIIa to technical and scientific progress in accordance with the regulatory procedure with scrutiny. The Commission shall take due account of the further development of the GHS within the United Nations, developments in international chemical programmes and conventions, data from accident databases, such as poison information units and the European Home and Leisure Accident Surveillance System (EHLASS), and the validation of alternative tests by ECVAM.

## Chemicals: classification, labelling and packaging of substances and mixtures

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The European Parliament adopted, by 604 votes to 9 with 13 abstentions, a legislative resolution amending the proposal for a regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006. The report had been tabled for consideration in plenary by Amalia SARTORI (EPP-ED, IT) on behalf of the Committee on the Environment, Public Health and Food Safety. The amendments were the result of a compromise between Parliament and Council.

The main amendments were as follows :

Purpose of the Regulation: the Regulation aims to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures by:

- harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;
- providing an obligation for manufacturers, importers and downstream users to classify substances and mixtures placed on the market;
- enabling suppliers to label and package substances and mixtures placed on the market;
- enabling manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under the REACH Regulation;
- providing an obligation for manufacturers and importers of substances to notify the Agency, of such classifications and labelling elements if these have not been submitted to the Agency as part of a registration under REACH;
- establishing a list of substances with their harmonised classifications and labelling elements at Community level;
- establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements.

Scope: Parliament did not accept the Environment Committee's amendment relating to exclusion from the scope for substances and mixtures for scientific research which are placed on the market at an annual volume below 1 tonne per supplier. The text now states that the Regulation does not apply to substances and mixtures for scientific research and development, which are not placed on the market, provided they are used under controlled conditions in accordance with Community workplace and environment legislation. Furthermore, Member States may allow for exemptions from this Regulation in specific cases for certain substances or mixtures, where necessary in the interests of defence.

Definitions: the term "mixture" as defined in this Regulation has the same meaning as the term "preparation" previously used in Community legislation. In addition, Parliament inserted several new terms into the text.

Labelling: the label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide otherwise. The product identifier for a mixture shall consist of both the trade name or the designation of the mixture and the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard. Statements such as "non-toxic?", "non-harmful?", "non-polluting?", "ecological?" or other statements indicating that the substance or mixture is not hazardous or any other statements that are inconsistent with its classification should not appear on the labels or packaging of hazardous substances or mixtures.

Deadline for labelling update: the supplier must ensure that the label is updated, without undue delay, following any change to the classification and labelling of that substance or mixture, where the new hazard is more severe or where new supplemental labelling elements are required. Where labelling changes are required other than those referred to above, the supplier shall ensure that the label is updated within 18 months.

SMEs: when there is a request for use of an alternative chemical name, SMEs shall pay a reduced fee. The Agency should study the possibilities for further simplification of the notification procedure in particular taking the needs of SMEs into account.

Bodies responsible for information: Member States shall appoint a body or bodies responsible for receiving information for formulating preventative and curative measures, in particular in case of emergency health response. Three years after entry into force the Commission shall assess possibility to harmonise information.

Information to the public: within three years from the entry into force of the Regulation, the Agency shall carry out a study on the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on labels.

Animal and human testing: where new tests are carried out for the purposes of this Regulation, tests on animals within the meaning of Directive 86/609/EEC shall be undertaken only where no other alternatives, which provide an adequate reliability and quality of data, are possible. Tests on non-human primates are prohibited. Tests on humans must not be performed. Data obtained from other sources, such as clinical studies, can however be used for the purposes of the Regulation.

PBT labelling: Member States and the Commission shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of PBT or vPvB at the level of the UN.

Lastly, it should be recalled that the reclassification and labelling of most substances must be completed by 1.12.2010 for substances and 1.6.2015 for mixtures. The current Directives on classification, labelling and packaging will be repealed on 1 June 2015. During a transitory period both systems will be applied.

## Chemicals: classification, labelling and packaging of substances and mixtures

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**PURPOSE:** to establish a new system on classification and labelling of hazardous substances and mixtures by implementing in the EU the international criteria agreed by the United Nations.

**LEGISLATIVE ACT:** Regulation (EC) No 1272/2008 of the European Parliament and of the Council 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.

**CONTENT:** by adopting this Regulation, the EU confirms its intention to contribute to the general harmonisation of the criteria for the classification and labelling of chemicals at international level by incorporating into Community law the international criteria agreed by the

United Nation Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures, called the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

The objective of the Regulation is to determine which properties of substances and mixtures should lead to classification in order that the hazards of certain substances and mixtures can be correctly identified and communicated. To ensure that customers receive information on hazards to human health and the environment, suppliers of substances and mixtures will have to ensure that they are labelled and packaged in accordance with the Regulation before placing them on the market, depending on how they have been classified.

The provisions of the Regulation will, as a general principle, apply to all substances and mixtures supplied in the EU, except where other Community legislation lays down more specific rules on classification and labelling.

Trade in substances and mixtures is an issue relating not only to the internal market, but also to the global market. Harmonised criteria for classification and labelling have been developed over a period of 12 years within the United Nations (UN) structure with a view to facilitating worldwide trade.

The label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

In addition, the product identifier for a mixture shall consist of both of the following: (a) the trade name or the designation of the mixture; (b) the identity of all substances in the mixture that contribute to the classification of the mixture as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.

The classification and labelling of most of the chemical products must be completed by 1 December 2010 for substances and 1 June 2015 for mixtures. The current Directive shall be repealed with effect from 1 June 2015. Throughout a transitory period, the two systems shall be applied.

This new Regulation replaces Directives 67/548/EEC and 1999/45/EC and supplements Regulation (EC) No 1907/2006 concerning the Registration, Evaluation and Authorisation of Chemicals (the REACH Regulation). At the same time, the Council also adopted:

- [Directive 2008/112/EC](#) amending six existing Directives to adapt them to the classification and labelling criteria of the new Regulation.
- [Regulation \(EC\) No 1336/2008](#) to align Regulation (EC) No 648/2004 with the new provisions.

ENTRY INTO FORCE: 20/01/2009.

APPLICATION: Titles II, III and IV shall apply in respect of substances from 01/12/2010 and in respect of mixtures from 1/06/2015.

## Chemicals: classification, labelling and packaging of substances and mixtures

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The Commission presented a report on the safe use of chemicals.

1) Framework in force and purpose of the report: Regulation (EC) No 1272/2008 (CLP Regulation) is the European Union's regulation regarding the classification, labelling and packaging of chemical substances and mixtures. It aligns previous EU legislation on classification, labelling and packaging of chemicals to the GHS (Globally Harmonised System of Classification and Labelling of Chemicals). The first version of the GHS was approved in 2002 and is updated every two years. GHS is a United Nations system to identify the hazards of chemicals and to inform users about these hazards through standard symbols (pictograms) and phrases on the packaging labels and through safety data sheets (SDS).

According to the CLP Regulation, communication of hazards of chemicals in the form of labelling is the main way to inform the general public on the safe use of chemicals. In particular, the CLP hazard label encompasses the following elements:

- the hazard pictogram, intended as a graphical composition that includes a symbol plus other graphic element in order to convey specific information on the hazard concerned;
- the signal word that indicates the relative level of severity of hazards to alert the reader to a potential hazard (i.e. Warning, Danger);
- the precautionary statement that describes recommended measures to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use or disposal;
- the hazard statement that defines the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard.

In accordance with the CLP Regulation, the European Chemicals Agency (ECHA) carried out a study to evaluate the communication of information to the general public on the safe use of substances and mixtures and the potential need for additional information on the label. The study was based on two main elements:

- a Eurobarometer opinion poll conducted in 2010, which surveyed the perceptions of European citizens towards the label comprehension and understanding of related hazard pictograms;
- an additional qualitative study conducted in 2011 - by a team of European academics with expertise in risk perception, research and analysis - in order to provide further elements on public perceptions and individual behavioural patterns.

On 20 January 2012, ECHA has transmitted the report on the "Study on the Communication on Safe Use of Chemicals to the General Public" to the Commission<sup>5</sup>. This Report summarises the main findings of the study, compares them to other similar reports provided by internationally recognized organisations (UN, UNITAR, etc.) and draws conclusions on whether an amendment of the CLP Regulation is justified or not.

2) The Commission's recommendations: in the light of the findings of ECHA's study, changes to the CLP pictograms themselves are not recommended. The Commission considers that it is more beneficial to allow the public to get used to the new global system, steadily improving the overall understanding of the hazards posed by chemicals and encouraging a safer use of household chemicals in particular.

As the Commission considers that, at this point in time a legislative proposal to amend the CLP Regulation is not justified, it recommends that:

- awareness raising activities should be prepared and conducted to enhance safe use of chemicals by EU citizens coordinated/promoted by the ECHA's risk communication and helpdesk networks preferably in the run-up to the deadline as of which the CLP labelling obligations will apply to chemical mixtures (1 June 2015);
- manufacturers and importers could be encouraged to bring product appearance and packaging more in line with the hazard information on labels;
- contents simplification and layout improvement on substance and mixture labels should be promoted (for instance, providing further guidance on omitting certain information elements and on precedence rules);
- a further analysis of the understanding of the safe use of substances and mixtures is conducted some time after 1 June 2015 (also, hazard and precautionary statements should be considered).

## Chemicals: classification, labelling and packaging of substances and mixtures

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In accordance with the requirements of Regulation (EC) No 1907/2006 (REACH), the Commission presents a [report](#) on the operation of the Regulation. The report also contains information on the functioning of Regulation (EC) No 1272/2008 (CLP Regulation).

Human health and the environment: whilst it is still too early to quantify the benefits, the Commission states that overall, progress towards meeting the human health and environment objective of REACH is materialising, and will accelerate as the remaining key benefit drivers become fully operational. However, the Commission notes some key shortcomings which may hinder achievement of the benefits:

- many registration dossiers have been found to be non-compliant, including with regard to substance identity;
- insufficient assessments by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent, and very bioaccumulative (vPvB) properties;
- problems with regard to the content and format of the extended safety data sheet.

ECHA identified three broad areas for improvement in the operation of REACH and the CLP Regulation:

- industry needs to work on the quality of registration dossiers;
- effective communication through the supply chain of information on substances and how to use them safely needs further attention;
- limited resources demand effective prioritisation of substances for further consideration in the REACH and CLP processes. Further use of registration information should be facilitated in order to best focus authorities resources towards safe use of substances.

Enforcement: enforcement is the sole responsibility of the Member States and all of them have nominated enforcement authorities. The Commission wants Member States to maximise the effectiveness of available resources through better coordination and knowledge sharing. It will develop enforcement indicators and calls on Member States to monitor the effectiveness of enforcement.

The enforcement of CLP is closely related to the enforcement of REACH, both facing similar challenges. The total number of inspections concerning particular products and individual duty holders has steadily increased over the last three years. In terms of issues identified where further improvements are necessary;

- compliance with the legal requirements could be substantially improved, since generally the compliance rates amounted to 70% ;  
and
- reporting by Member States needs further harmonisation.

Compared with situation before the CLP Regulation was adopted, the Commission and all Member States are now regularly updated on enforcement activities and compliance rates. This will allow enforcement activities to focus on problematic areas and the development of joint enforcement strategies.

Scope of REACH: overall, the Commission is of the view that the scope of REACH was set well and no major overlaps with other EU legislation have been identified. Nonetheless, it discusses the minor overlaps which were identified and adds that it has also identified certain areas where information generated under REACH processes could be used in the context of EU sector-specific legislation requirement.

Amendments: some needs for adjustments have been identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission concludes that changes to the enacting terms of REACH will not be proposed.