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The CLP Regulation: origin, scope and evolution

Paola Di Prospero Fanghella and Tiziana Catone
Centro Nazionale Sostanze Chimiche, Istituto Superiore di Sanità, Rome, Italy

Summary. The CLP Regulation implements in the EU the UN Globally Harmonised System of Classification and Labelling applying the "building block approach", that is taking on board the hazard classes and categories which are close to the existing EU system in order to maintain the level of protection of human health and environment. This Regulation applies to all substances and mixtures placed on the market and besides to classification, packaging and labelling it provides for the notification of the classification and labelling of substances to the Classification & Labelling Inventory established by ECHA. It came into force on 20 January 2009 but a transitional period is foreseen until 1 June 2015 for the full application. At the end of this period the "substance" and "preparation" Directives (respectively 67/548/EEC and 99/45/EC) will be repealed.

Key words: GHS, CLP, classification and labelling, C&L Inventory, CLP helpdesk, CLP notification.

Riassunto *(Il Regolamento CLP: origine, scopo ed evoluzione)*. Il Regolamento CLP traspone nell'Unione Europea il sistema armonizzato globale delle Nazioni Unite applicando il criterio del *building block approach* che consente di adottare alcune classi e categorie di pericolo simili a quelle preesistenti nell'attuale sistema UE per mantenere il livello attuale di protezione della salute umana e dell'ambiente. Questo Regolamento si applica a tutte le sostanze e miscele immesse sul mercato europeo e, oltre alla classificazione, imballaggio ed etichettatura, richiede la notifica della classificazione all'Inventario delle Classificazioni dell'ECHA. Il CLP è entrato in vigore il 20 gennaio 2009, ma prevede un periodo di transizione, fino al 1 giugno 2015 per la piena applicazione. Alla fine di tale periodo le Direttive sulle sostanze e sui preparati (67/548/CEE e 99/45/CE) saranno abrogate.

Parole chiave: GHS, CLP, classificazione e etichettatura, Inventario C&L, CLP helpdesk, CLP notifica.

ORIGIN

The EC Regulation 1278/2008 on classification, labelling and packaging of substances and mixtures, also called CLP [1], establishes a new system on classification and labelling of hazardous substances and mixtures by implementing in the EU the Globally Harmonised Classification and Labelling System (GHS) developed by the United Nations Economic and Social Council (UN ECOSOC) [2].

The purpose of GHS is to define the hazards of chemicals connected to the physical, toxicological and ecotoxicological properties of the substances. It is developed in order to apply agreed criteria to classify chemicals based on their hazardous effects and to communicate hazard information on labels and Safety Data Sheets (SDS).

The most relevant international organizations in the field of classification and labelling of chemicals started to be involved in the early fifties and the work was completed by technical focal points: the International Labour Organization (ILO); the Organization for Economic Cooperation and Development (OECD); and the United Nations Economic and Social Council's Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG).

The United Nations Conference on Environment and Development (UNCED), has adopted on June 1992, at Rio de Janeiro, Brazil, in the Agenda 21 (Chapter 19) regarding the environmentally sound management of toxic chemicals, the need to harmonize the classification and labelling of chemicals as one of the six action programmes to be carried on by the year 2000.

The UN Committee of Experts for the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals formally adopted the GHS in December 2002.

The first edition of the GHS was published in December 2003 and is has been revised every two years and the most updated version is the third revised edition which was published on July 2009.

The GHS document is known informally as *The purple book* and it is made of four parts: an introduction which outlines the scope, the definitions and the hazard communication elements; the classification criteria for physical chemical hazards; the classification criteria for health hazards; and the classification of environmental hazards.

The process of harmonization started looking for common elements in existing systems/recommenda-

Address for correspondence: Paola Di Prospero Fanghella, Centro Nazionale Sostanze Chimiche, Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Rome, Italy. E-mail: paola.diprospero@iss.it.

tions/legislation in force in different countries and international/intergovernmental organizations and four major systems were identified:

- the European Union (EU) Directives 67/548/EEC [3] and 99/45/EC [4] for classification an labelling respectively of substances and preparations;
- the requirements of systems in the United States of America for the workplace, consumers and pesticides;
- the requirements of Canada for the workplace, consumers and pesticides;
- the United Nations Recommendations on the transport of dangerous goods.

The entire system was developed taking into account, among others, some basic agreed principles:

- the level of protection of workers, consumers, general public and the environment was not lowered;
- the classification and consequent labelling principles are based on hazards arising from the intrinsic properties of chemical substances and mixtures;
- transitional measures are foreseen in order to implement the globally harmonized new system adopting the required changes in the existing systems.

As a result the aim of GHS is to improve chemical safety and health protection giving reliable and comprehensive information on hazards and protective measures to be adopted through labelling and safety data sheets and also trade in chemicals is expected to be easier.

SCOPE

The CLP Regulation takes on board these principles applying the "building block approach". According to this principle GHS may be seen as a collection of building blocks, the various hazard classes and categories, from which to form a regulatory approach in the different countries and/or systems. For example while physical hazards are relevant in the workplace and transport sectors, consumers may not need to know some physical hazard related to different uses not intended for them.

The CLP Regulation implements hazard end points that are in the GHS in a consistent way. For instance if a substance presents reprotoxic properties the harmonized criteria and labelling should be followed. Additional hazard classes and consequent statements are provided by CLP (EUHxxx) for the end points which are not covered by GHS, but already existing in the EU Directives on classification and labelling of dangerous substances and preparations.

The objective of CLP is to give the criteria to be followed to identify and evaluate the properties of substances and mixtures which lead to a classification as hazardous and to a proper communication of these hazards.

Chemical products have to be classified and labelled by the manufacturers, importers, downstream users or distributors responsible for marketing using harmonised classifications, which are determined at Community level and/or self-classification under their responsibility.

Harmonised classifications of substances are based on Member State proposals or proposals made by manufacturers, importers or downstream users. Mixtures will always have to be self-classified.

CLP is made of seven titles and seven annexes as it is shown below:

Legal text containing principles and general rules

Title I	General issues
Title II	Hazard classification
Title III	Hazard communication in the form of labelling
Title IV	Packaging
Title V	Harmonisation of classification and labelling of substances and the classification and labelling inventory
Title VI	Competent authorities and enforcement
Title VII	Common and final provisions.

Annexes on technical details

Annex I	Classification and labelling requirements for hazardous substances and mixtures
Annex II	Special rules for labelling and packaging of certain substances and mixtures
Annex III	List of hazard statements, supplemental hazard information and supplemental label elements
Annex IV	List of precautionary statements
Annex V	Hazards pictograms
Annex VI	Harmonised classification and labelling for certain hazardous substances
Annex VII	Translation table from classification under Directive 67/548/EEC to classification under this Regulation.

FIELD OF APPLICATION

This Regulation applies to production and use of chemicals not linked to the quantities which are produced or imported per year.

CLP applies to all substances and mixtures (included plant protection product and biocides) placed on the market and to all substances subject to 1907/2008 Regulation on the registration, evaluation, authorization and restriction of chemicals (REACH), even those not placed on the market if they are subject to registration or notification under REACH.

CLP doesn't apply to the transport of dangerous goods, but ensures consistency to them, being the criteria for classification for common end-points the same in the two systems. It applies also to articles containing explosive substances which need to be classified and labelled as explosive.

The exemptions are:

- radioactive substances and mixtures;
- certain substances and mixtures which are subject to customs supervision;
- non-isolated intermediates;
- certain substances and mixtures for scientific research and development;
- waste; and
- certain substances or mixtures in the finished state,

intended for the final user: medicinal products, veterinary medicinal products, cosmetic products, medical devices, food or feeding stuffs.

TIMELINES

CLP came into force on 20 January 2009. There are some transitional provisions for substances/mixtures already placed on the market. A transitional period is foreseen, so that substances are required to be classified, labelled and packaged starting from 1 December 2010, while mixtures from 1 June 2015 according to the provisions of CLP. At the end of the transitional period both 67/548/EEC Directive on dangerous substances and 1999/45/EC Directive on dangerous preparations will be repealed *(Figure 1)*.

CLP has been adapted to the technical progress the first time by the Regulation 790/2009 [8] which entered into force on 25 September 2009.

It transfers the 30th and 31st ATPs (adaptation to technical progress) of Directive 67/548/EEC to the Regulation (EC) n. 1272/2008. The harmonised classifications set in the 1st ATP have been applied, together with related labelling and packaging provisions, since 1 December 2010.

On 30 March 2011 the 2nd adaptation to the technical progress of the CLP Regulation has been published in the EU Official Journal [9]. It entered into force on 19 April 2011 and mainly adapts the CLP to the 3rd revision of the GHS and will apply to substances from 1 December 2012 and to mixtures from 1 June 2015.

NOTIFICATION

CLP provides for the notification of the classification and labelling of substances to the Classification & Labelling Inventory (C&L) established by European Chemicals Agency (ECHA). Manufacturers or importers of substances subject to registration, under Article 6 of the REACH Regulation, or classified as hazardous, irrespective of the quantity, need to be notified to the inventory both whether they are put on the market as such or in a mixture which is classified as hazardous due to the presence of this substance. Also substances in articles which are subject to registration under Article 7 of the REACH Regulation are required to be notified to the ECHA Inventory.

This Inventory will be maintained by ECHA and a non-confidential version of it will be published on the ECHA website.

CRITERIA

Translation tables

CLP classification criteria for substances are very similar to the pre-existing EU Directives criteria. Translation of existing classifications into CLP classifications is made easier by means of a translation table in Annex VII to this Regulation according to the CLP Article 61 [5]. These CLP classifications are to be considered as minimal classifications and needs to be used with care as there are limitations to the applicability for some types of hazards.

This table was also used as a basis for the semi-automatic transposition of existing Annex I entries (updated to the 29th ATP) to the table 3.1 of Annex VI of the CLP Regulation.

For physical chemical properties experts were consulted when the classification according to CLP criteria and that according to transport Regulation were not the same.

When a substance is not present in Annex VI to CLP with the harmonized classification, it has to be self-classified by the responsible for marketing. In addition, also substances which are in Annex VI have to be self classified by the manufacturer/importer for the end points which are non classified for.

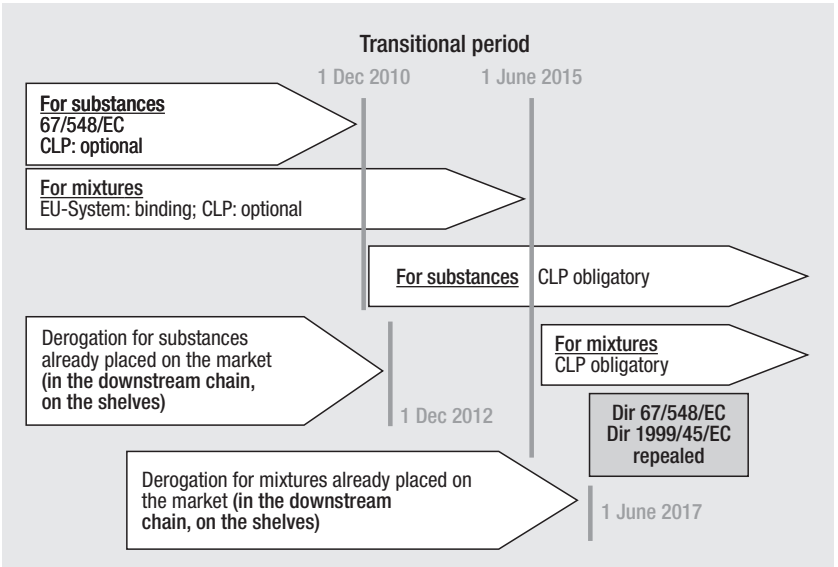

Fig. 1 | *Timelines for the application of the CLP Regulation*

As the entire Annex I to DSD list of substances, as amended by the 29th ATP, was transposed into the CLP Annex VI, the chance was taken to remove all the specific concentration limits which were identical to the generic concentration limits.

A number of errors in the translation of Annex VI has also been identified, and will be addressed in future updates to CLP. In the meantime, the list of known errors can be found on the ECHA website.

Information requirements

If the information available is not sufficient to conclude on the hazardous properties of the substance, new testing must be performed to determine the physical hazards of a substance if required in CLP Annex I, part 2, while new tests can be performed for the determination of the health and environmental hazards of the substance, but they are not obligatory under CLP.

On the other side REACH requires for filling data gaps for substances under registration, so that these new data can be used to classify under CLP.

Registrants have the obligations to avoid unnecessary new animal studies sharing test data each other or using alternative and non-test methods to assess the properties of chemical substances [5].

Information that has been used for the classification and labelling of substances or mixtures must be kept available for at least 10 years after the last supplying in order to be checked, if necessary, by competent authorities.

SOME CHANGES IN THE CRITERIA

Hazard classes and categories

Classification criteria for physical hazards, health and environmental effects are reported in Annex I and some changes have occurred implementing the new system: for physical hazards five hazard classes under Directive 67/548/EEC are extended to sixteen hazard classes under CLP Regulation; for health hazards two new classes were adopted, the single exposure specific target organ toxicity (STOT-SE) and the repeated exposure specific target organ toxicity (STOT-RE).

Environmental hazards

Classification criteria for environmental effects are slightly different from the existing ones: BCF cut-offs ≥ 500 instead of currently ≥ 100 and log Kow ≥ 4 instead of currently ≥ 3.

As a consequence some substances currently classified as R 50/53 ("Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment") or R 51/53 ("Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment") would fall into a lower category or would not be classified at all, so that substances to which the currently applied R53 ("May cause long-term adverse effects in the aquatic environment") is based on a BCF between 100 and 500 and/or a log Kow between 3 and 4 need to be re-evaluated as classification could change.

Classification of mixtures

The innovative tiered approach for the classification of mixtures in the case of health acute toxicity is based on three steps: classification based on testing of the mixture, on bridging principles, on the concentrations and toxicities of the ingredients (ATE values using ATEmix calculations).

Some changes in the classification of mixtures are due to the generic concentration limits for reprotoxicants which are lowered to 0.3% for reprotoxicity category one and two and to 3.0% for category three, while in the existing system the values were 0.5% and 5.0% respectively.

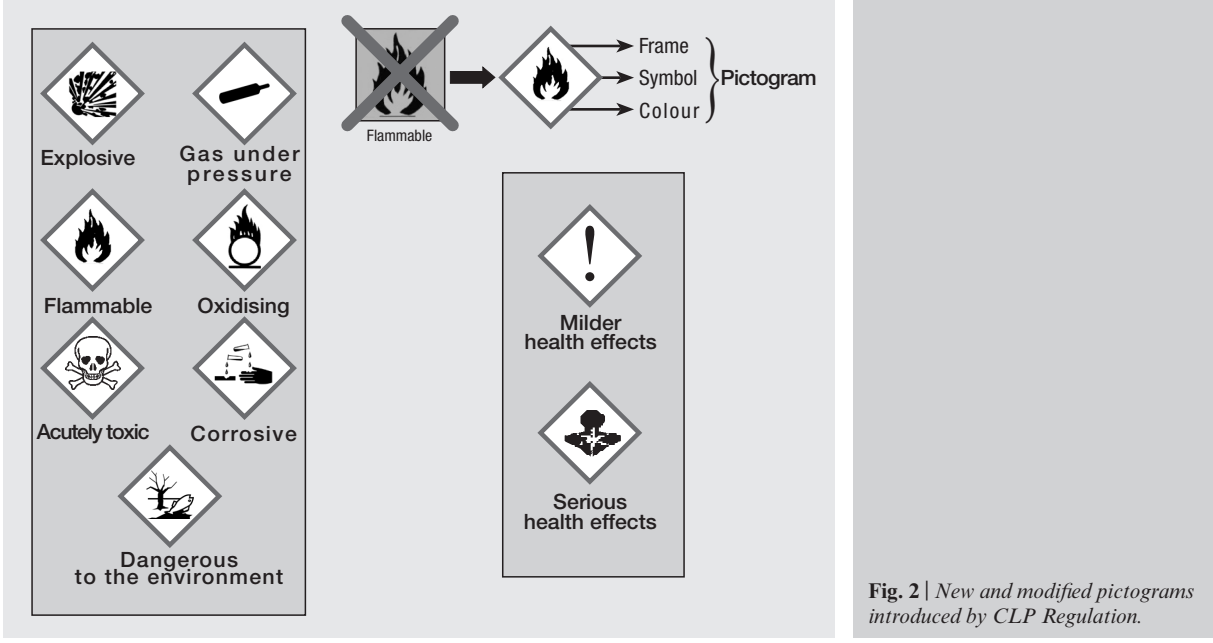

Fig. 2 | *New and modified pictograms introduced by CLP Regulation.*

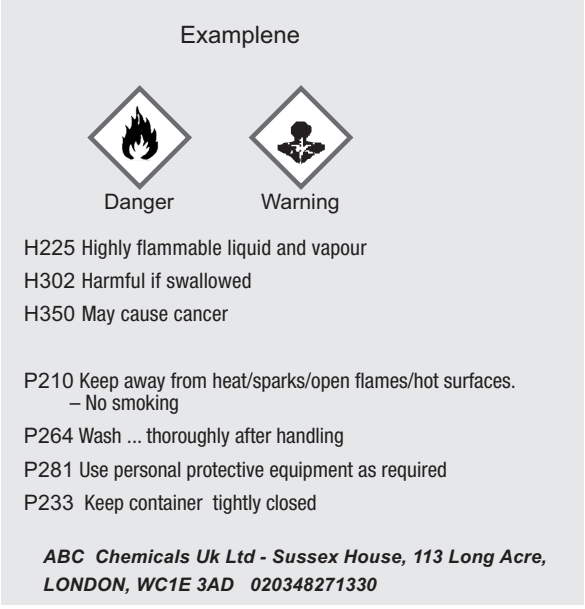

Fig. 3 | *Labelling elements: an example of label.*

Also for skin irritants the concentration limits are lowered from 10% to 5%.

As a consequence, a certain number of mixtures which are not classified according to the existing system need to be classified according to CLP.

Labelling

According to CLP hazard pictograms (symbols) are diamond shaped, white and black with a red border, mostly similar to the existing EU system, but two new symbols are also adopted, the damaged person for some severe effects and the exclamation mark for some less severe effects *(Figure 2)*.

In addition the indications of danger such as flammable, or irritant are replaced by two new signal words, "danger" and "warning" while risk and safety phrases are replaced by hazard statements respectively. No more than six P statements should appear on the label while hazard statements are selected following some priority criteria in the case of a resulting too high number of statements.

New phrases for the different hazards are introduced too. Hazard statements replace R-phrases, while Precautionary statements replace S-phrases.

According to CLP Article 17, a substance or mixture classified as hazardous shall bear a label including the following elements:

- name, address and telephone number of the supplier(s);
- the nominal quantity of the substance or mixture in the package where this is being made available to the general public, unless this quantity is specified elsewhere on the package;
- product identifiers;
- hazard pictograms;
- the relevant signal word;
- hazard statements;
- appropriate precautionary statements;
- a section for supplemental information.

An example of label is shown in *Figure 3*.

INFORMATION RELATING TO EMERGENCY HEALTH RESPONSE

The provisions in CLP Article 45 are similar to the provisions of the dangerous preparation directive (Article 17) asking to the Member States to appoint body(s) responsible for receiving information on mixtures classified as hazardous on the basis of their health or physical effects to be used for medical purposes, in particular in event of emergency. Information must be kept confidential.

In addition to that, "by January 2012, the Commission shall carry out a review to assess the possibility of harmonising the information..., including establishing a format for the submission of information by importers and downstream users to appointed bodies". As a consequence Member States and Commission are evaluating the possibilities to establish a harmonised format for submission of information.

HELPDESK

CLP provides for the establishment of national helpdesks in order to provide advice to companies on the CLP obligations. All the helpdesks are connected in the joint network of REACH and CLP helpdesks settled at ECHA. The Italian CLP helpdesk is located at the Istituto Superiore di Sanità which is the technical support to the national Competent Authority.

DOWNSTREAM LEGISLATIONS

There are a lot of obligations in Community legislation referring to C&L, so that EU and national legislation need updating to adopt CLP, *e.g.* workers safety and consumer products Directives, Seveso Directive and others. Some updating has been already made for detergents Regulation, toys and cosmetics Directives and some others are in progress.

EVOLUTION

The simultaneous application of CLP and REACH Regulations is in a certain way a revolution in the management and control of chemicals. The aim is to know as much as possible the properties and the risks related to substances and mixtures to which humans and environment can be exposed. The adoption of adequate measures to minimize risks is the natural consequence of this new policy.

In addition to many guidance on REACH application also some guidance for CLP application were published by ECHA: the Introductory guidance on CLP Regulation and Guidance on the application of the CLP criteria [6, 7].

The CLP Regulation is going to be adapted to the technical progress the third time by end 2011 in order to include harmonized classifications for substances evaluated by the RAC Committee by end 2010.

In the meantime the UN GHS is being revised for the fourth time in the next biennium and ClP will be adapted again.

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Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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