New rules of classifying and labelling (CLP) and changes in safety data sheets of substances and mixtures

Andrzej KRZEŚLAK, Marcela PALCZEWSKA-TULIŃSKA, Marzena WINIARSKA – REACH and CLP Centre at the Industrial Chemistry Research Institute (ICRI), REACH Consultancy Point of at the Ministry of Economy and the Polish Chamber of Chemical Industry, Warsaw

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Introduction

Regulation of the European Parliament and of the Council (EC) No. 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC (DSD - Dangerous Substances Directive) and 1999/45/EC (DPD - Dangerous Preparations Directive) and amending Regulation (EC) No. 1907/2006 was published in the Official Journal of the European Union L353 on 31.12.2008 and entered into force on the 20th day following its publication, i.e. on 20 January 2009. The obligation to comply with the provisions of the Regulation is spread over a period of time, which should enable all interested parties to make appropriate preparations in due time.

The Regulation has 1355 pages and, in addition to the main body of text, it includes the following annexes:

ANNEX I	Classification and labelling requirements for haz ardous 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	Hazard pictograms
ANNEX VI	Harmonised classification and labelling for certain hazardous substances
ANNEX VII	Translation table from classification under Directive 67/548/EEC (DSD) to classification under this Regulation

This regulation is another legal act issued by the European Union which, shortly after the implementation of the REACH regulation, imposes new duties on the manufacturers, importers and users of chemicals. In comparison to the REACH regulation, its scope is much wider, as it applies to all chemicals, irrespective of the tonnage (a reminder: REACH applies to substances manufactured or imported from outside the EU in an annual amount of 1 tonne or more).

The 1272/2008 Regulation is a system implementation consisting in the inclusion of selected GHS[1] criteria in the Community law, in accordance with the provision that **"Member States are free to determine which of the modules will be applied within the different parts of their systems".**

The GHS system (**G**lobally **H**armonised **S**ystem of Classification and Labelling of Chemicals) emerged as an aftermath of the 1992 "Earth Summit" Conference in Rio de Janeiro and it has formed basis for a new, unified hazard classification and information on chemical products at various stages of their life cycle, from raw material to recycling and disposal. The main addressees of the global harmonised system under design are chemical manufacturers, people responsible for operation and rescue plans, people engaged in the transportation of chemicals. The World Summit on Sustainable Development in Johannesburg (South Africa) in 2002 called on all countries of the world to implement GHS and to make it fully operational by 2008. Progress in this area is closely followed by the United Nations, which supervise the process and co-ordinate all actions related thereto.

Aims and benefits

Aims

The Regulation aims to ensure:

- a high level of protection of human health and the environment
- free movement of chemical substances, mixtures and certain specific articles, while enhancing competitiveness and innovation
- efficient functioning of the internal market for substances and mixtures
- achieving sustainable development in the process of approximation of legislation on classification, labelling and packaging of substances and mixtures
- harmonisation of the provisions and criteria for the classification, labelling and packaging of substances, mixtures and certain specific articles within the Community:

– impose on the **manufacturers, importers and downstream users** an obligation to classify substances and mixtures placed on the market

–– impose on the **manufacturers, producers of articles and importers** an obligation to classify substances that are not placed on the market, but are subject to registration or notification under Regulation No. 1907/2006

– impose on the **suppliers** an obligation to label and package substances and mixtures placed on the market

– impose on the **manufacturers and importers** of substances an obligation to notify the Agency of such classifications and label elements if these have not been submitted to the Agency as part of a registration under Regulation (EC) No. 1907/2006

– establish **in Part 3 of Annex VI** of the Regulation a **list of substances** with their harmonised classifications and labelling elements at Community level

– establish a **classification and labelling inventory of substances**, which is made up of all notifications, submissions, harmonised classifications and labelling elements

– determine which properties of substances and mixtures should lead to a classification as hazardous, in order for the hazards of substances and mixtures to be properly identified and communicated. Such properties should include physical hazards as well as hazards to human health and to the environment (including hazards to the ozone layer).

Benefits

The CLP Regulation should:

- contribute to the fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai
- contribute to facilitating world-wide trade due to global harmonisation of rules for classification and labelling and consistency between these rules and transport rules.

Scope of application

The Regulation should replace Council Directive 67/548/EEC (DSD) of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and Directive 1999/45/EC (DPD) of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. The final date for repealing the directives currently in force and replacing them with the CLP Regulation is 1 June 2015.

The regulations on classification of mixtures should be applied only after reclassification of all substances, which is to be completed by 1 December 2010.

Operators should be allowed to apply the classification criteria contained in the CLP Regulation earlier on a voluntary basis, but in that case to avoid confusion the labelling and packaging should comply with this Regulation instead of Directives 67/548/EEC (DSD) or 1999/45/EC (DPD).

Substances and mixtures which are already in the supply chain when the labelling provisions of this Regulation become applicable to them may continue to be placed on the market without relabeling for a period of 2 years (in order to avoid unnecessary burden on enterprises), that is until 1 December 2012 in the case of substances and until 1 June 2017 in the case of mixtures.

Subject to developments at UN level, the classification and labelling of **P**ersistent, **B**io accumulative and **T**oxic (**PBT**) and **v**ery **P**ersistent and **v**ery **B**io accumulative (**vPvB**) substances should be included in this Regulation at a later stage.

This Regulation should apply to all substances and mixtures supplied in the Community, except where other Community legislation lays down more specific rules on classification and labelling.

Exemptions

The provisions of the Regulation shall not apply to substances and mixtures in the case of their application **in finished products intended for the final user,** such as:

cosmetic products as defined in Directive 76/768/EEC of 27 July 1976, OJ L 262, 27.9.1976, p. 169

- **certain products used in animal nutrition** within the scope of Council Directive 82/471/EEC of 30 June 1982, OJ L 213, 21.7.1982, p. 8
- **flavourings** for use in foodstuffs and source materials for their production within the scope of Council Directive 88/388/EEC of 22 June 1988, OJ L 184, 15.7.1988, p. 61
- **food additives** authorised for use in foodstuffs intended for human consumption within the scope of Council Directive 89/107/EEC of 21 December 1988, OJ L 40, 11.2.1989, p. 27
- **active implantable medical devices** within the scope of Council Directive 90/385/EEC of 20 June 1990, OJ L 189, 20.7.1990, p. 17
- **medical devices** within the scope of Council Directive 93/42/EEC of 14 June 1993, OJ L 169, 12.7.1993, p. 1
- **in vitro diagnostic medical devices** within the scope of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998, OJ L 331, 7.12.1998, p. 1
- **flavouring substances used in or on foodstuffs** within the scope of Commission Decision 1999/217/EC of 23 February 1999, OJ L 84, 27.3.1999, p. 1
- **veterinary medicinal products** within the scope of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001, OJ L 311, 28.11.2001, p. 1
- **medicinal products for human use** within the scope of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, OJ L 311, 28.11.2001, p. 67
- **additives for use in animal nutrition** within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003, OJ L 268, 18.10.2003, p. 29
- the provisions of the Regulation also do not apply to issues that are within the scope of Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the **general principles and requirements of food law**, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1
- with the exception of instances where **Art. 33*** applies, the Regulation does not apply to the **transport of dangerous goods** by air, sea, road, rail or inland waterways.

The provisions of the Regulation do not apply to:

- **radioactive substances and mixtures** within the scope of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the danger arising from ionising radiation, OJ L 159, 29.6.1996, p. 1
- **substances and mixtures which are subject to customs supervision,** provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit
- **non-isolated intermediates**
- **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 environmental legislation
- **waste:**

Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste (OJ L 114, 27.4.2006, p. 9) is not a substance, mixture or article within the meaning of Art. 2 of this Regulation.

Member States may apply for exemptions from this Regulation in specific cases for certain substances or mixtures, where that is necessary in the interests of **defence**.

Time schedule for enforcement of the provisions of the Regulation

1. On the date of this Regulation taking effect, the Annex I to Directive 67/548/EEC (DSD) becomes ineffective (in Poland: Annex to the Ordinance of the Minister of Health of 28 September 2005 on the list of hazardous substances and on the classification and labelling thereof (Dz. U. No. 201, item 1674 of 14 October 2005)): instead Table 3.2 of Annex VI to the CLP Regulation is in force (unfortunately the names of substances in the table mentioned are in English only, therefore the annex to the Ordinance of the Minister of Health mentioned above may be useful with regard to the Polish nomenclature of substances).
2. Until 1 December 2010 **substances** should be classified, labelled and packaged in accordance with the current regulations (using Annex VI to the CLP Regulation instead of Annex I to Directive 67/548/EEC (DSD); in Poland – in accordance with the Ordinance of the Minister of Health of 2 September 2003 on the criteria and manner of classifying chemical substances and preparations (Dz. U. No. 171, item 1666, 2003, as amended) and with the Ordinance of the Minister of Health of 5 March 2009 on the labelling of packaging of hazardous substances and hazardous preparations and of certain chemical preparations (Dz. U. No. 53, item 439, 2009)).

However, the CLP Regulation allows for the classification, labelling and packaging of substances in accordance with its provisions before 1 December 2010. In such case the provisions on labelling and packaging of Directives 67/548/EEC (DSD) and 1999/45/EC (DPD) are not applied. In view of this:

- the **safety data sheet of the substance** should include both classifications: according to the old and the new regulations
- the packaging of the substance should be **labelled in accordance with the CLP Regulation**

- **packaging** provisions of the CLP Regulation should be complied with.

3. From 1 December 2010 until 1 June 2015, substances are classified according to both the CLP Regulation and Directive 67/548/EEC (DSD) (two classifications in the safety data sheet). Labelling and packaging is done in accordance with the CLP Regulation only.
4. Until 1 June 2015 mixtures should be classified, labelled and packaged in accordance with the current regulations (using Annex VI to the CLP Regulation). However, the CLP Regulation allows for the classification, labelling and packaging of mixtures in accordance with its provisions before 1 June 2015. In such case the provisions on labelling and packaging of Directives 67/548/EEC (DSD) and 1999/45/EC (DPD) are not applied. In view of this:

- the **safety data sheet of the mixture** should include both classifications: according to the old and the new regulations
- the packaging of the mixture should be **labelled in accordance with the CLP Regulation**
- **packaging** provisions of the CLP Regulation should be complied with.

5. From 1 June 2015 only the provisions of the CLP Regulation will be applied with regard to both substances and mixtures.

Important immediate issues and recommendations

The Regulation imposes on the manufacturers, importers and downstream users the obligation to classify substances or mixtures prior to placing them on the market (subject to transitional provisions).

The obligation to classify in some cases also rests on manufacturers and importers of articles (substances intended to be released, substances of very high concern).

The obligation to classify applies to substances irrespective of their tonnage and whether these are phase-in substances or not; therefore, from 1 December 2010 subject to classification are all substances that pose a risk, and not only those which according to REACH must be registered until that date.

If a substance or mixture will be (or is) classified as hazardous – the supplier must ensure that it is labelled and packaged in accordance with the requirements of the CLP Regulation prior to being placed on the market (subject to transitional provisions).

Every manufacturer or importer, or group of manufacturers or importers, who places on the market a hazardous substance, either on its own or in a mixture, is obliged to notify the Agency, which maintains a classification and labelling inventory (in the form of a database). Information submitted as part of registrations under REACH will be included in the inventory.

Information in the inventory **is publicly accessible**.

Distributors can use the classification of a substance or mixture determined by one of the actors in the supply chain.

Downstream users can also use the classification of a substance or mixture determined by one of the actors in the supply chain, provided that they do not change its chemical composition.

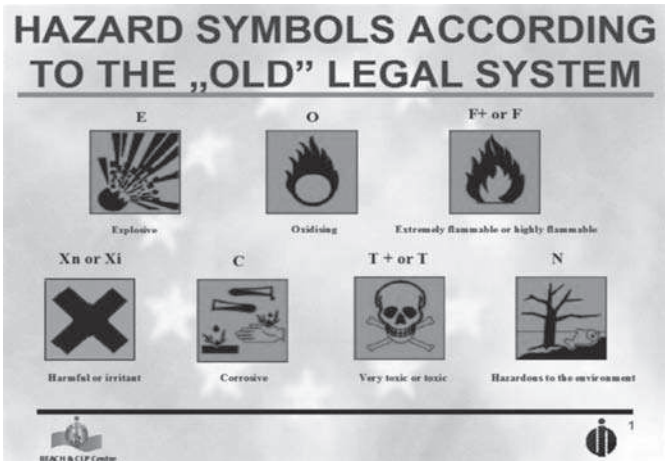
This will have a strong impact not only on manufacturers of small quantities of substances and on importers of substances and mixtures, but also on large companies, which are at present focused on preparatory work for full registration.

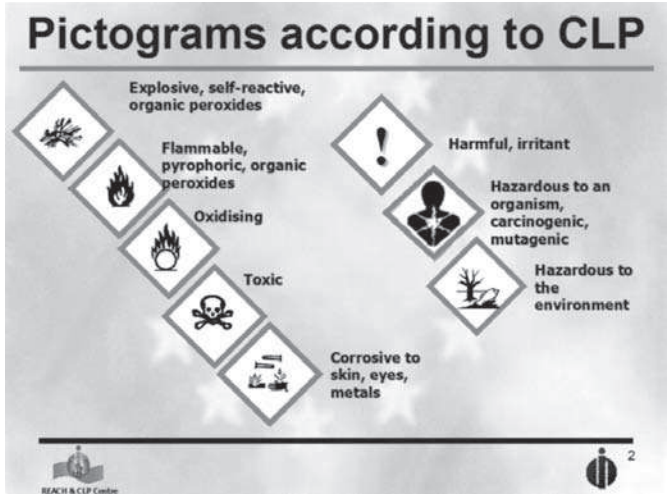
Importers of mixtures are likely to face the most serious problems. They frequently have insufficient information on the composition of articles imported into the European Union. If such information cannot be obtained, the only solution is to carry out analysis or to rely on the manufacturer's declaration.

There are cases when the harmonised classification and labelling specified in Annex VI to the CLP Regulation are not consistent with those applied up to date. In these cases the safety data sheets and labels for substances and mixtures have to be amended appropriately taking into account the changes. It is not allowed to follow national regulations which were repealed when the Regulation of the European Parliament and of the Council (EC) No. 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP), amending and repealing Directives 67/548/EEC (DSD) and 1999/45/EC (DPD) and amending Regulation (EC) No. 1907/2006 (REACH) came into force.

Annex VI to the Regulation and Tables 3.1 and 3.2 thereof do not include changes introduced by the 30th and 31st Adaptations to Technical Progress (ATPs). A Commission Regulation (EC) No. 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No. 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures has been published. This Regulation will remain in force until 1 December 2010 as the 1st ATP to the CLP Regulation.

The figures show hazard pictograms used in accordance with the legislation based on DSD and DPD Directives, followed by hazard pictograms compliant with the new system provided by the CLP Regulation:





M.Sc. (Eng) Marzena WINIARSKA works at the REACH & CLP Centre, which is REACH Consultancy Point on behalf of the Polish Ministry of Economy (ICRI). The main task of the Point is conducting training, advisory and consulting activity for the companies interested in the REACH & CLP provisions' implementation.

M.Sc. (Eng) Andrzej KRZEŚLAK works at the REACH & CLP Centre, which is REACH Consultancy Point on behalf of the Polish Ministry of Economy (ICRI). The main task of the Point is conducting training, advisory and consulting activity for the companies interested in the REACH & CLP provisions' implementation.

M.Sc. Marcela PALCZEWSKA-TULIŃSKA is head of the Group in the Department for Separation Processes and the Substances Purification (ICRI), working out the safety data sheets. She conducts training & advisory activity for the companies implementing the REACH & CLP provisions at the structure of the Consultancy Point.