Manual of
EUROPEAN
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POLICY

Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

The Manual was published by Earthscan/Routledge from 2010 to 2012. It was designed as an on on-line interactive reference work and annual printed versions were also produced.

This section is the text of the Manual as published in 2012. It is therefore important to note the following:

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The Manual should be cited as follows:

Farmer, A.M. (2012) (Editor). Manual of European Environmental Policy. 1043pp. Routledge, London.

Institute for European Environmental Policy

Classification, labelling and packaging of chemical substances and mixtures

Formal references	
Regulation (EC) No 1272/2008 (OJ L353/1 31.12.2008)	Regulation 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/EC
Proposed – COM(2007)355	
Legal base	Article 114 TFEU (Article 95 TEC)
Regulation (EU) No 286/2011 (OJ L83/1 30.3.2011)	Amendment for the purposes of its adaptation to technical and scientific progress
Corrigenda (OJ L138 26.5.2011)	Corrigenda to Regulation (EU) No 286/2011
Regulation will repeal Directives	
Directive 67/548/EEC (OJ L196 16.08.1967)	Directive on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
Most important amendments for Directive 67/548/EEC	
Directive 79/831/EEC (OJ L259 15.10.1979)	Sixth amendment to Directive 67/548/EEC
Directive 92/32/EEC (OJ L154 05.06.1992)	Seventh amendment to Directive 67/548/EEC
Directive 2006/121/EC (OJ L396 30.12.2006)	Amendment to adapt Directive 67/548/EEC to REACH
Directive 1999/45/EC (OJ L200 30.7.1999)	Directive on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations
Most important amendments for Directive 1999/45/EC	
Regulation (EC) No 1907/2006 (OJ L396 30.12.2006)	Deletion of provisions of safety data sheets
Legal base	Article 114 TFEU (Originally article 95 TEC)
Binding dates	
Entry into force of Regulation	20 January 2010
Classification can be based on Directives 67/548/EEC, 1999/45/EC as well as the Regulation	1 December 2010
Labelling and packaging only according to the Regulation	1 December 2010
Substances put on the market according to DSD before 1 December 2010 to be relabelled and repackaged	1 December 2012

according to CLP	
Repeals Directives 67/548/EEC and 1999/45/EC	15 June 2015
Mixtures put on the market according to DPD before 1 June 2015 to be relabelled and repackaged according to CLP	1 June 2017

Purpose of the legislation

The European Union (EU) legislation on classification, labelling and packaging (CLP) aims to ensure a high level of protection of human health and the environment and the functioning of the internal market. It does so by laying down EU-wide criteria that must be applied to determine whether a substance or mixture which is manufactured or imported into the European market has properties which could damage human health or the environment. The EU legislation on CLP consists of three acts: The Dangerous Substances Directive 67/548/EEC (DSD), the Dangerous Preparations Directive 1999/45/EC (DPD) and Regulation (EC) No 1272/2008 on CLP of substances and mixtures.

Until 1 December 2010, substances are to be classified, labelled and packaged in accordance with DSD. After that date, substances are to be classified according to DSD and CLP but labelled and packaged in accordance with the CLP only. However, a substance may also be classified, labelled and packaged in accordance with the provisions of CLP before 1 December 2010. In this case, the packaging and labelling provisions of DSD do not apply. Until 1 June 2015, mixtures are classified, labelled and packaged in accordance with DPD.

Substances classified, labelled and packaged in accordance with DSD and already placed on the market before 1 December 2010 are not required to be relabelled and repackaged in accordance with CLP until 1 December 2012. Mixtures classified, labelled and packaged in accordance with DPD and already placed on the market before 1 June 2015 are not required to be relabelled and repackaged in accordance with CLP until 1 June 2017.

Both DSD and DPD will be repealed by CLP as of 1 June 2015.

Summary of the legislation

Directive 67/548/EEC (DSD)

This Directive has been updated several times since its adoption in 1967. One of the most important amendments to this Directive was the 6th amendment in 1979 (Directive 79/831/EEC), which introduced a notification system for "new" substances which required lists of "existing" substances. The European Inventory of Existing Substances (EINECS) listed all substances that were reported to be on the market on or before 18 September 1981 and these were considered as "existing" substances whereas those substances put on the market for the first time after that date were known as "new" substances and added to the European List of Notified Chemical Substances (ELINCS).

Another important amendment was the seventh amendment. It repeats in an expanded form the provisions of the parent Directive of 1967, dealing only with CLP of dangerous

substances and also repeats, with modifications, the provisions introduced by the sixth amendment of 1979 covering notification of new substances involving testing and assessment.

The amendment to adapt this Directive to the REACH Regulation (EC) No 1970/2006 introduces the same registration requirements for new chemicals as for existing substances, which means that the rules for notification of new chemicals will be replaced by those of REACH. In addition, the amendment will repeal requirements on testing and assessment and confidentiality of data. However, since REACH does not include rules on the CLP of dangerous substances, the requirements set by this Directive regarding these matters will continue to apply.

The notification procedures applied to new substances only, that is those not on the market by 18 September 1981. The European inventory of existing commercial chemical substances (EINECS) contains the definitive list drawn up in accordance with Decision 81/437/EEC of all substances (over 100,000) deemed to have been on the market on 18 September 1981. The European list of notified chemical substances (ELINCS) drawn up in accordance with Decision 85/71/EEC) lists all substances notified since 18 September 1981 and was updated annually. Annex I of the Directive lists the substances classified as dangerous under the 15 danger categories set out in the Directive. New substances were added to Annex I as they were classified following notification. The amendment to adapt this Directive to REACH deletes the requirements to notify substances (Article 1(a)), the exchange of information on notified substances (Article 1(b)) and the potential risk to man and the environment of notified substances. It also deletes Articles 7–15 dealing with notifications. All these provisions have been replaced by REACH. The amendment to adapt this Directive to REACH repeals also the requirements of Article 3 on testing and assessment of the properties of substances. These tests are replaced by Article 13 of REACH.

The DSD classifies substances on the basis of their intrinsic properties according to 15 danger categories, one of which is ‘dangerous for the environment’. The general principles of the classification requirements are set out in Annex VI. Annex I contains the list of dangerous substances. The substances in Annex I are to be characterized by concentration limits or any other parameter enabling an assessment to be made of the health or environmental hazard of preparations containing the dangerous substances. Article 115 of REACH requires that from 1 June 2007, harmonized classification will be added to Annex I of this Directive for classification of a substance as carcinogenic, mutagenic or toxic for reproduction (category 1, 2 or 3), or as a respiratory sensitizer. Harmonized classification and labelling for other effects may also be added to Annex I on a case-by-case basis if justification is provided.

Substances are not to be placed on the market unless they are packaged and labelled according to the quite specific requirements laid down. The general principles of the classification and labelling are applied according to the criteria in Annex VI and in accordance with the results of tests set out in Annexes VII and VIII. To enable professional users to take the necessary protection measures before the first delivery of a dangerous substance, the manufacturer is to provide a safety data sheet.

Directive 1999/45/EEC (DPD)

Dangerous preparations that are mixtures or solutions of two or more substances (including paints, solvents, alloys and pesticides), are to be assessed for their hazards to health and the

environment and classified, packaged and labelled accordingly. The double purpose is served of removing barriers to trade and protecting people and the environment. The Directive complements the 'seventh amendment', which applies to substances and not to preparations.

The Directive applies to preparations which (a) contain at least one substance which is dangerous as defined in Article 2 (2) and (b) are considered dangerous according to the evaluations set out in Article 5 (physico-chemical properties), Article 6 (health hazards) and Article 7 (environmental hazards). Some provisions of the Directive apply to preparations which are not considered dangerous according to Articles 5, 6 and 7 but which may nevertheless present a specific hazard. A number of preparations are excluded, for example medicines, cosmetics, waste, foodstuffs, animal feeding stuffs and preparations containing radioactive substances.

Dangerous preparations are classified according to the following categories: explosive; oxidizing; extremely flammable; highly flammable; flammable; very toxic; toxic; harmful; corrosive; irritant; sensitizing; carcinogenic; mutagenic; toxic for reproduction and dangerous for the environment.

Member States must ensure that preparations covered by the Directive are not placed on the market unless they comply with the Directive and cannot restrict marketing if its provisions are satisfied. Unlike 'the seventh amendment', this Directive does not require pre-notification to the authorities before a product is placed on the market, but the authorities may request information on composition and other pertinent information. Those placing preparations on the market must also hold available the data used for the classification and labelling and for establishing the safety data sheet.

Preparations must be packaged and labelled in accordance with detailed requirements, which must include trade name; name of person placing the preparation on the market; chemical name of the relevant substance or substances present; danger symbol; risk phrases and safety advice. In certain circumstances, some information may be kept confidential. Persons placing a preparation on the market must provide a safety data sheet, principally for professional users, to enable them to take the necessary measures. Details of safety data sheets are set out in Directive 91/155/EEC.

Member States may permit some limited derogations from the labelling requirements, in which case the Commission must be informed.

Member States may provisionally prohibit marketing where there is detailed evidence that a preparation constitutes a hazard for man or the environment. The Member States must inform the Commission and the other Member States of this as well as give reasons for the prohibition. The Commission must then consult the other Member States and take a decision.

Regulation (EC) No 1272/2008 (CLP)

While the main features of classification and labelling are similar under DSD/DPD and CLP, there are some differences which are due to the integration of the terminology, classification criteria and labelling elements of the UN GHS and to procedures taken over from REACH.

Notification under the CLP Regulation means that manufacturers and importers submit certain classification and labelling information of substances they are placing on the market

to the Classification & Labelling Inventory held by ECHA. The Inventory is a new database which did not exist under DSD or DPD. Notification under the CLP Regulation applies to all hazardous substances of all tonnages and also to all non-hazardous substances subject to registration under REACH whenever they are placed on the market in the EU. ECHA published a guidance document1 on how to notify substances.

CLP does not require new testing for the purpose of classification for health or environmental hazards but testing for physical hazards is required unless adequate and reliable information is already available (such as through the application of REACH). The supplier may decide to fill data gaps by conducting new testing. In this case, testing on animals must be avoided wherever possible and alternative methods must always be considered first.

The hazard classes and categories under CLP are comparable with those under DSD. However, the number of hazard classes has been increased under CLP, particularly for physical hazards, where the number of hazard classes has increased from 5 to 16.

Annex VII of CLP provides a table for suppliers to translate existing classifications into classifications according to CLP. This allows the supplier to assign classifications according to CLP, instead of classifying them from scratch in accordance with Title II and the criteria set out in Annex I to CLP. This procedure is intended for cases where a supplier has already classified a substance according to DSD before 1 December 2010 or for cases where a supplier has already classified a mixture according to DPD before 1 June 2015. The translation table covers only those hazards where there is a reasonable correlation between DSD/DPD and CLP.

The Regulation replaces risk phrases, safety phrases and symbols with mostly equivalent hazard statements, precautionary statements and pictograms. It also introduces ‘Danger’ and ‘Warning’ symbols from the GHS to indicate the severity of a hazard as a new feature in EU legislation.

An overview of the most important differences introduced by CLP is included in the Table below[2].

DSD/DPD	**CLP**
DSD terminology, e.g. preparation, dangerous, category of danger, risk phrase, safety phrase	UN GHS terminology, i.e. mixture, hazardous, hazard class, hazard statement, precautionary statement
DSD categories of danger for physical, health and environmental hazards	UN GHS hazard classes including those differentiations which best reflect the DSD categories of danger; total number of hazard classes higher under CLP than the total number of categories of danger under DSD
DPD calculation rules (“conventional method”) for the classification of preparations	UN GHS calculation methods (additivity, summation) deviating from the DPD calculation rules
Testing, human experience or calculation for mixture classification	Similar to DPD; in addition bridging principles that allow the classification of mixtures on the basis of data on similar tested mixtures and information on individual hazardous ingredient substances
DSD categories of danger plus	UN GHS hazard classes plus supplemental labelling

additional labelling elements, e.g. R1 (“Explosive when dry”)	elements taken over from DSD e.g. EUH001 (“Explosive when dry”)
If harmonised classification then normally for all categories of danger	If harmonised classification then for substances which are carcinogenic, mutagenic, toxic to reproduction or respiratory sensitisers; other effects on a case-by-case basis
Harmonised classification based on a Member State proposal	Harmonised classification based on a Member State proposal (provisions previously contained in REACH) or a proposal by a manufacturer, importer or downstream user
No notification procedure foreseen	Notification of the classification and labelling of substances to the Classification & Labelling Inventory established by ECHA (provisions previously contained in REACH)

Development of the legislation

The first action programme on the environment of 1973, specifically asked the Commission ‘to investigate the measures still required to harmonize and strengthen control by public authorities over chemicals before they are marketed’. This had become an issue in several Member States and in the United States and indeed the development of the Directive would have been quite different if it had not been for the legislative activity in the United States and international discussions within the OECD.

Within the Commission, debate centred on whether to amend yet again the existing Directive 67/548/EEC on packaging and labelling or to develop an entirely new draft. At times, two independent draft proposals appear to have existed prepared by different departments with a power struggle between them.

In November 1974, the OECD adopted a Recommendation on the assessment of the potential environmental effects of chemicals and the preparation of this Recommendation and subsequent work on it provided a forum for technical discussion involving representatives from the United States and Canada as well as all Member States.

In June 1975, the draft of the French legislation on a scheme of pre-market testing for new chemicals was communicated to the Commission and served to provide impetus and focus to these discussions. The fact that this draft law was notified by the French environmental authorities to the Commission's environment service may have helped ultimately to strike a distribution of roles rather more favourable to environmental concerns than might otherwise have been achieved in the Community. A working group was established by the Commission and this had the immediate effect of linking discussions which were going on in several Member States at a time when these had reached tentative conclusions only in France. Development of the sixth amendment can thus be considered as an example of the ideal situation where an issue requiring Community action can be taken up at Community level before sometimes conflicting legal constraints have been created in several Member States. Clearly, the absence of any prior legislation on pre-market testing of chemicals was an important factor in facilitating agreement on a very complex and potentially divisive topic.

In 1976, the Toxic Substances Control Act was passed in the United States but the full effect of this began to emerge only in 1977 following publication of implementation rules by the US Environmental Protection Agency (EPA). Thereafter, the US legislation became an

increasingly important factor in the negotiations in Brussels mainly as a precedent for some of the problems that arose during negotiations and as an argument for strengthening environmental aspects of the Directive.

The basic structure of the sixth amendment as adopted can already be discerned in the proposal. But if one considers the very numerous changes of detail including the requirement for an inventory of existing substances, the ultimately adopted Directive must be considered as having been fundamentally changed. The Economic and Social Committee was favourably inclined to the proposal. The European Parliament was concerned only about a technical issue of labelling and wanted to see the use of national languages on labels an absolute requirement. The point was not taken up in Council. In general, it must be said that both the Economic and Social Committee and the European Parliament failed to appreciate the significance of the draft Directive or even to reflect what were to become the major issues of subsequent concern.

The most important change made to the sixth amendment after it was proposed was the introduction of step sequence testing at the initiative of the German government which was being prodded by its chemical industry. In actual fact, no public allusion to step sequence testing – let alone any text setting out its principles and provisions – can be found in any official document prior to publication of the Directive 79/831/EEC in the *Official Journal*. But quite apart from this major omission, by late 1977 it was already increasingly evident that the Directive as finally adopted would differ significantly from the Proposal, making the sixth amendment one of the most obvious cases where lack of intermediate public information makes the Community legislative process so difficult to reconstruct.

The 'seventh amendment' which entirely replaced the sixth amendment was intended to clarify it and has also introduced the following new elements:

- the period between notification and marketing is increased from 45 to 60 days;
- in order to reduce the amount of testing on animals suppliers are to cooperate in sharing data if more than one of them needs to notify the same substance;
- extra information is required for low-volume chemicals;
- less information is required for substances used only for research and development;
- a new definition of polymer; and
- safety data sheets.

The DPD was made necessary by the new category 'dangerous for the environment' introduced into DSD. The opportunity was therefore taken to consolidate in one Directive the existing requirements for CLP of dangerous preparations and pesticides and to include also other substances such as explosives.

A report published by VROM, the Netherlands Environment Ministry, in 1996 showed that many new dyestuffs had been placed on the market without having been notified in accordance with the Directive. A second collaborative project involving several Member States called SENSE (Solid Enforcement of Substances in Europe) covering selected companies and substances (not just dyestuffs) found that 5 per cent of new substances had not been notified compared to 37 per cent in the earlier project. It also found many unidentified substances and widespread misclassification and labelling[3].

In early 1999, a team of five Member States (United Kingdom, Portugal, Netherlands, France and Denmark) together with representatives from industry, workers, consumers and environmental protection was set up to review the Directive under the SLIM (Simpler Legislation for the Internal Market) programme. The intention was to simplify procedures for industry and perhaps reduce animal testing. In 1998 the Commission began a review of chemicals policy and in February 2001 issued a White Paper (COM(2001)88) dealing with future chemicals policy which would alter the regime for new chemicals. Eventually, this led to the REACH Regulation (EC) No 1907/2006. This Regulation repeals some of the Articles of this Directive and builds upon others. Hence, there is a degree of interplay between the REACH Regulation and this Directive.

In June 2007, the European Chemicals Agency published a guidance document[4] for the preparation of an Annex XV dossier on harmonized classification and labelling. The guidance document is written on the basis of the requirements of the REACH Regulation in relation to Annex I of the Directive 67/548/EEC.

The same month, the Commission issued a proposal (COM(2007)355) to align Directive 67/548/EEC with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), developed at the level of the United Nations. The current EU system and the GHS system are conceptually similar and cover the same structural elements: classification, packaging and hazard communication including labelling and safety data sheets. The proposed Regulation was published in the *Official Journal* on 31 December 2008. Guidance on how to apply the provisions of Regulation (EC) No 1272/2008 was published in August 2009. This guidance is divided into guidance for suppliers[5] and guidance on detailed technical and scientific applications[6].

Implementation of the legislation

Industry had initially expressed fears about the cost of testing and that innovation might be inhibited. Fears were also expressed about unfair competition with new products appearing in the United States and Japan which did not require disclosure of chemical identities. Some of the fears appeared to have been borne out by the rather few notifications made in the early years. However, a more likely explanation is that industrialists made a point of putting substances that were under development on the market before September 1981 so that they would not count as ‘new’ substances and this depressed the number of notifications in the early years. The number of notifications has since been increasing steadily. By 1988 the total number was 550 and by 1997 was over 3,800. The proportion of all notifications by country by 1997 was as follows:

United Kingdom	26 per cent
Germany	24 per cent
France	12 per cent
Netherlands	10 per cent
Italy	8 per cent
Rest	20 per cent

Figures and further information are provided in the Commission's three-yearly report on the implementation of the Directive (COM(1999)178).

All companies manufacturing or importing hazardous substances were required to classify them by 1 December 2010 and notify ECHA by 3 January 2011. By the deadline ECHA received more than three million notifications covering 24,529 substances[7, 8, 9].

In February 2012 the ECHA published its first EU Classification and Labelling Inventory (available at this link). It lists the classification of all the chemical substances used in the EU and allows the identification of those that are potentially hazardous and may damage health and the environment. This Inventory provides hazard information on more than 100,000 substances based on over 3 million notifications submitted by manufacturers and importers. The aim is to provide easy access to information on the hazardousness of a given substance, facilitating the task to correctly classify and label substances and mixtures, as well as encourage substitution of hazardous substances with less damaging alternatives where feasible. [10]

Enforcement and court cases

A number of cases have been submitted to the European Court of Justice (ECJ) by chemical companies arguing, unsuccessfully, for declassification of dangerous substances (such as rosin (Case *C*-150/06*P*) or *p*-propyl-bromide (*T*-291/04*R*)).

By the end of 2010 a number of Member States received reasoned opinions for failing to notify the Commission by 1 April 2010 on how the CLP Regulation had been transposed in their national legislation.

Related legislation

The following legislations interact with CLP:

- Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the CLP of dangerous substances (DSD).
- Directive 1999/45/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the CLP of dangerous preparations (DPD).
- Regulation (EC) No 689/2008 concerning the export and import of certain dangerous chemicals.
- Directive 98/8/EC on placing of biocidal products on the market.
- Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

References

1 ECHA (2010) *Practical Guide 7: How to notify Substances in the Classification and Labelling Inventory*, 2010, European Chemicals Agency [link]

2 ECHA (2009) *Questions and Answers on Regulation 1272/2008 on classification, labelling and packaging of Substances and Mixtures*, 27.5.2009.

3 ENDS Report 279, April 1998.

4 ECHA (2007) *Guidance for the Preparation of an Annex XV Dossier on harmonized classification and labelling*, June 2007. [link]

5 ECHA (2009) *Introductory Guidance on the CLP Regulation*, August 2009, [link]

6 ECHA (2009) *Guidance on the Application of CLP Criteria*, August 2009, [link]

7 EC Press Release (2010), *Chemicals: Commission asks three Member States to adopt Measures to implement EU Legislation*, 30 September 2010, European Commission webpage [link]

8 EC Press Release (2010), *Environment: Commission asks four Member States to implement EU chemicals legislation*, 28 October 2010, European Commission webpage [link]

9 EC Press Release (2010), *Environment: Commission asks four Member States to implement EU chemicals legislation*, 24 November 2010, European Commission webpage [link]

10 EC Press Release (2012), *New Classification and Labelling Inventory opens way to safer use of hazardous substances*, 13 February 2012, European Commission, webpage [link]