

EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies Chemicals

Archives - Impact assessment and introduction of the draft CLP Regulation in 2008

On 27 June 2007, the European Commission adopted a proposal (COM(2007) 355 final) 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. This proposal takes account of the comments received during public stakeholder consultation in autumn 2006. Together with the proposal, the Commission presented an impact assessment to the European Parliament and to the Council.

Further background and state of play [41 KB]

Stakeholder Consultation

The Commission launched a public stakeholder consultation on the internet from 21 August to 21 October 2006. All stakeholder replies were published on the internet. Some 370 contributions were received. 82% were sent by industry - associations or companies; of the 254 company responses, 45% came from enterprises with less than 250 employees. 10 NGOs and one trade union responded.

18 Member State governments and/or public authorities sent comments. Non-EU public authorities (Iceland, Norway, Switzerland; Romania was not yet a Member State at that time) gave input as well. No international organisation sent comments. 97% of the responses supported the implementation of the GHS in the EU and 96% of these by means of a Regulation.

Based on the replies and comments, the Commission Services drafted an <u>evaluation of the stakeholder replies</u> [46 KB]. The points raised by the various stakeholders were considered and widely taken up in the revised proposal.

See the stakeholder consultation on the GHS draft Regulation

Commission proposal

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 - legislative text as adopted on 27 June 2007 by the European Commission (COM(2007) 355 final) is available below in English. All other languages are available in the Consilium register of documents

• Explanatory Memorandum and Enacting terms

• Annex I - Classification and Labelling Criteria of hazardous substances and mixtures

- Annex II Special rules for labelling and packaging
- Annex III List of hazard statements
- Annex IV List of precautionary statements
- Annex V Pictograms
- Annex VI Harmonised list of hazardous substances
- Annex VII Conversion table for reclassification

 Entries of Annex I to Council Directive 67/548/EEC, including the adaptations to the GHS criteria

• Entries of Annex I to Council Directive 67/548/EEC

Impact Assessment

The impact assessment made use of the impact assessment reports prepared by RPA and London Economics as well as the responses to the Internet Consultation. The responses from companies on costs led to further efforts to quantify significant cost items. Although the change from the existing to the future classification and labelling system will have significant one-off costs, these costs are expected to be offset by trade benefits in the longer term.

- Note on the optimal length of the transitional period (Annex I of Impact Assessment)
- Commission Impact Assessment
- Commission Impact Assessment Executive Summary

Risk & Policy Analysts / London Economics:

- Impact Assessment of Implementing the GHS Study Summary (Risk & Policy Analysts / London Economics) [92 KB]
- Impact Assessment of Implementing the GHS Work Package 1 (Risk & Policy Analysts / London Economics) [2 MB]
- Impact Assessment of Implementing the GHS Work Package 2 (Risk & Policy Analysts / London Economics) [391 KB]]

Criteria on Human Health and the Environment

Comparison between the current EU and the GHS Criteria (Dec 2007) [[74 KB]

Downstream legislation

Classification of substances and preparations (GHS: "mixtures") triggers **other obligations in EU legislation**, referred to as downstream legislation.

The Commission services have assessed the potential effects of the implementation of the GHS criteria on downstream legislation.

Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation (DG Enterprise) and Addendum [2023 KB]

The analysis concludes that effects are either minimal or can be minimised by appropriate changes to particular downstream acts. The CLP Regulation itself includes such changes to REACH. For Council Directive 1996/82/EC on the control of major-accident hazards involving dangerous substances (Seveso II Directive), the implementation of GHS is expected to have a more substantial impact. Therefore, this Directive needs to be amended separately. Separate amendments implementing the CLP in other EU downstream acts were part of further Commission proposals. On 16 and 17 October 2007, the Commission adopted two proposals (COM(2007)611 final and COM(2007)613 final) implementing the GHS for seven pieces of EU downstream legislation.

Based on these proposals the European Parliament and the Council adopted <u>Directive</u> 2008/112/EC, OJ L 345 and <u>Regulation (EC) 1336/2008</u>, OJ L 354 on 16 December 2008.

Related Commission proposals

Proposal for a Decision of the European Parliament and of the Council amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC in order to adapt them to Regulation (EC) ... on classification, labelling and packaging of substances and mixtures (COM(2007)611 final of 16 October 2007)

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 648/2004 in order to adapt it to Regulation (EC) ... on classification, labelling and packaging of substances and mixtures ($\underline{COM(2007)613}$ final of 17 October $\underline{2007}$)

Technical Assistance to the European Commission on the Implementation of the GHS

```
Final report (Ökopol study) [ [267 KB]
```

Annex 1: [45 KB] List of documents

Annex 2: [409 KB] Synopsis - Section I - Structural elements

Annex 3: [535 KB] Synopsis - Section II - Classification

Annex 4: [27 KB] Synopsis - Section II - Hazard communication

Annex 5: [41 KB] Issues beyond scope

Annex 6: [19 KB] Additional guidance on the GHS

Annex 7: [84 KB] Cut-off values

Annex 8: [36 KB] Classification of preparations - methodological elements

Annex 9: [23 KB] List of documents on changes in GHS

Preparation of the Annexes

Technical Support for the Preparation of the Annexes for the EU Legislation Implementing the GHS (Milieu) [597 KB]

CLP-Regulation (EC) No 1272/2008

```
Enacting terms [318 KB]

Annex I [3 MB]

Annex III [106 KB]

Annex III [3 MB]

Annex IV, Part 1 [720 KB]

Annex IV, Part 2 [4 MB]

Annex V [143 KB]

Annex VI, without tables [150 KB]

Annex VI, Table 3-1 Part 1 [1 MB] Part 2 [1 MB] Part 3 [2 MB]

Annex VI, Table 3-2 Part 1 [1 MB] Part 2 [8 MB]

Annex VII [178 KB]
```

N.B. The content of this document is copied from the archived website of the European Commission/DG Enterprise and Industry, and has not been updated.