



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 15 November 2007

13894/07

Interinstitutional Files:

2007/0121 (COD)

2007/0212 (COD)

2007/0213 (COD)

COMPET 283

ENV 516

CHIMIE 28

MI 240

ENT 123

CODEC 1065

NOTE

from: Presidency

to: Council (Competitiveness)

No. Cion prop.: 11497/07 COMPET 213 ENV 382 CHIMIE 17 MI 177 ENT 85 CODEC 759
14110/07 COMPET 288 ENV 532 CHIMIE 31 MI 244 ENT 132 ECO 123
CONSOM 118 CODEC 1092
14235/07 COMPET 294 ENV 547 CHIMIE 32 MI 249 ENT 134 ECO 126
CONSOM 120 CODEC 1115

Subject : 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
- Information from the Presidency on the state of play

The Council (Competitiveness) is invited to take note of the enclosed Presidency report on the state of play concerning the above proposal at its session on 22 and 23 November 2007.

Proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures
- Report from the Presidency on the state of play

I. INTRODUCTION AND BACKGROUND

1. The 2001 White Paper "Strategy for a future Chemicals Policy"¹, outlines a number of changes to the Community chemicals legislation, *inter alia* concerning registration of properties of substances, classification of chemicals and introduction of restrictions for the use of dangerous chemicals.
2. On 1 June 2007, one central element of the new chemicals policy, the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals, REACH², entered into force. A second central element of the EU Chemicals Policy is the system for classification and labelling of chemicals.
3. These two elements are closely interlinked. As an example, the classification of a substance as dangerous is a trigger in REACH as well as in other Community legislation for certain obligations applying at different stages of manufacturing or use. Already in the 2001 White Paper, the Commission drew the attention to the necessity to adapt the EU legislation on classification and labelling to the UN Globally Harmonised System for classification and labelling of substances and mixtures (GHS) at the same time as REACH would be introduced³. In June 2007 the Commission presented a corresponding proposal. (See Chapter II below.)
4. The implementation of the GHS in the Community will necessitate adaptation of downstream legislation. Two Commission proposals have been presented to this aim. (See Chapter III below.)

¹ Document 6671/01 ENT 37 ENV 101 MI 32 COM(2001) 88 final.

² Regulation (EC) 1907/2006, OJ L136, 29.5.2007, p.3.

³ Document 6671/01 ENT 37 ENV 101 MI 32 COM(2001) 88 final, Chapter 7.

5. REACH and the new Regulation on classification, labelling and packaging will gradually replace currently applicable Community legislation. For example, Council Directive 76/769/EEC⁴ will be repealed as of 1 June 2009 when the REACH system⁵ for restrictions is fully implemented. Until then, the Council and the Parliament will continue the current co-decision procedure for introducing restrictions on the use of dangerous substances. To this aim the Commission presented on 2 October 2007 a Proposal for restricting the use of four organic substances and ammonium nitrate⁶. The examination in the Council of this proposal has started and will run in parallel with the examination of the "GHS proposals".

II. PROPOSAL ON CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES (GHS)

Background and aim of the Proposal

6. Chemicals are manufactured and traded globally, and a common system for classification and labelling facilitates trade. Obviously, their hazards are the same around the world, therefore a global system for description of and information concerning hazards is also desirable in order to protect health and environment. To this aim, a system of international criteria for the classification and labelling of hazardous substances and mixtures, called the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), has been developed.

⁴ Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations, as amended by Directive 2006/122/EC (OJ L372 of 12.12.2006 p. 32) and by Commission Directive 2006/139/EC (OJ L384 of 29.12.2006 p. 94)

⁵ See Titles VII (Authorisations) and VIII (Restrictions) of REACH.

⁶ Proposal for a Decision of the European Parliament and of the Council amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate. Document 13530/07 COMPET 273 ENV 497 CHIMIE 26 MI 233 ENT 122 CODEC 1033.

7. The World Summit on Sustainable Development in Johannesburg on 4 September 2002 adopted a plan that encourages countries to implement GHS in order for the system to be fully operational by 2008. The GHS was formally adopted by the United Nation Economic and Social Council in July 2003 and revised in 2005 and in 2007.
8. The Community, through the Member States and the Commission, as well as European stakeholders, participate in the UN work to develop the GHS. The intention to implement the GHS into Community legislation has been announced on several occasions, notably in the 2001 White Paper, and in the Explanatory Memorandum to the Proposal for a Directive amending Directive 67/548/EC⁷ that was adopted and examined as an integrated part of the REACH proposal.
9. In order to fulfil the commitments in the White Paper and to honour international obligations of the Community, the Commission submitted its proposal for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures on 27 June 2007⁸. The proposal is based on Article 95 of the Treaty and builds on existing Community chemicals legislation. The current EU classification and labelling system is set out in three key instruments: the Dangerous Substances Directive (67/548/EEC)⁹, the Dangerous Preparations Directive (1999/45/EC)¹⁰ and the REACH provisions on Safety Data Sheets (Regulation (EC) 1907/2006)¹¹. During the preparation of this implementation of the GHS in the EU, experts identified the differences between the current EU system for supply and use and the GHS system. Their work has been taken into account in the proposal.

⁷ Document 15409/03 COMPET 75 ENV 651 CHIMIE 3 CODEC 1692 [COM (2003) 644 final, Interinstitutional file 2003/0257(COD)].

⁸ Document 11497/07 COMPET 213 ENV 382 CHIMIE 17 MI 177 ENT 85 CODEC 759.

⁹ Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, as amended [OJ 196, 16.8.1967, p. 1]

¹⁰ Council Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations, as amended OJ L200, 30.7.1999, p.1

¹¹ As of 1 June 2007, Council Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations and dangerous substances was repealed and replaced by REACH.

10. Since the proposal aims to meet the Community commitment to implement GHS in accordance with the “Johannesburg timetable” it should be examined with high priority in order to reach an agreement as early as possible, preferably during the first half of 2008. In addition, the ongoing implementation of the REACH obligations requires early adoption of the GHS regulation so that it can be implemented in parallel with the various steps of REACH. The only means to achieve this is to reach a first reading agreement¹² between the Institutions.

Procedure

11. Under the Portuguese Presidency, the Working Party on Technical Harmonisation (Dangerous substances) has started a detailed examination of the proposal. A first reading of all articles has been achieved and an informal network of experts has been established to examine the contents of the Annexes *inter alia* to check their conformity with the UN GHS and with existing Community legislation. The findings of the informal network will be examined by the Working Party.
12. At this stage, all delegations have a general scrutiny reservation on the entire proposal, several delegations have specific scrutiny reservations on certain articles and almost all delegations have linguistic reservations. The Danish, French, Maltese and United Kingdom delegations have parliamentary scrutiny reservations.
13. The Presidency has established first contacts with the European Parliament. The Parliament has indicated its intention to start the examination in the ENVI Committee during November and to give its first-reading opinion in May or June 2008.

¹² An agreement at first reading must be concluded before the European Parliament votes in Plenary on the amendments contained in the draft EP Report at first reading.

State of play in the Working Party

14. In general, delegations have welcomed the proposal and confirmed that they are prepared to contribute to a swift adoption of this legal act. In order to facilitate an understanding of the effects of the Proposal, the Impact Assessment prepared by the Commission has been thoroughly discussed.
15. Following the first reading, the Presidency notes that the following important issues need further consideration:
 - a) Although most delegations agree that the proposed regulation shall, in principle, only apply to substances and mixtures already within the scope of the EU legislation on classification and labelling, many requests for clarification of the scope have been made.
 - b) The exact obligations for the different actors in the supply chain (manufacturers, importers, distributors and downstream users) have been discussed *inter alia* against the background that they do not have the same access to information relevant for classification and labelling.
 - c) The confidentiality provisions of the proposal have been in put in question by delegations that believe they could lead to a decreased level of protection of consumers and other users of chemicals, in particular as concerns occupational health.
 - d) The proposal contains special rules for labelling of and information concerning chemicals distributed in small or otherwise awkward packages. Here, it has been questioned whether the information provided to users will be as complete as under the current EU system.

- e) In this proposal, a clear distinction is made between the concepts "hazardous" and "dangerous". This distinction is important for downstream legislation. In most Community languages one single word is used for both concepts. Various attempts to resolve this problem have been suggested, but none of them has so far been sufficiently developed.

- f) Many delegations stress the need for adequate information to be available in the language of the end users and therefore see a need to further scrutinize the provisions on language-use on labels.

- g) The Working Party has also directed its interest towards the provisions allowing changes to various elements of the Regulation through Comitology. In accordance with the new Comitology Decision¹³, the regulatory procedure with scrutiny must be applied when measures of general scope designed to amend non-essential elements of the Regulation are adopted through Comitology. It has been noted that in this case an agreement between the legal services requires an exact description following a prescribed wording of which implementing powers are conferred on the Commission.

¹³ Council Decision 2006/512/EC amending Council Decision 1999/468/EC. OJ L200 of 22.7.2006 p. 11-13.

III. PROPOSALS AMENDING CERTAIN DOWNSTREAM LEGISLATIVE ACTS IN ORDER TO ADAPT THEM TO THE GHS PROPOSAL

16. Classification of substances and preparations under the currently applicable Directives 67/548/EEC and 1999/45/EC triggers obligations in other pieces of EU legislation, normally referred to as downstream legislation. Since the Regulation on classification, labelling and packaging of substances and mixtures is intended to replace these Directives, amendments to the downstream legislation must also be introduced. To this aim, the Commission has presented two Proposals^{14,15} covering a number of downstream acts. These proposals will be examined by the Working Party with the aim of reaching an agreement between the Institutions thereon at the same time as an agreement is reached on the present Proposal. There are other downstream requirements, including the Seveso II Directive¹⁶, where the implementation of GHS is expected to have a substantial impact, and for which the necessary measures will have to be introduced in further separate amendments.

IV. CONCLUSION

The Council is invited to take note of this report and of the Presidency's intention to actively pursue the examination of the proposal with a view to preparing the ground for an agreement at first reading.

¹⁴ 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 the GHS Proposal. Document 14110/07 COMPET 288 ENV 532 CHIMIE 31 MI 244 ENT 132 ECO 123 CONSOM 118 CODEC 1092.

¹⁵ Proposal for a Regulation of the European Parliament and the Council amending Regulation (EC) 648/2004 in order to adapt it to the GHS proposal. Document 14235/07 COMPET 294 ENV 547 CHIMIE 32 MI 249 ENT 134 ECO 126 CONSOM 120 CODEC 1115.

¹⁶ Council Directive 1996/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances, as amended [OJ L 10, 14.1.1997, p. 13]