COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

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IMPLEMENTATION OF THE GHS

Reports from Governments or organizations

<u>Transmitted by the representatives of the European Commission</u> (DG ENTERPRISE and DG ENVIRONMENT)

BACKGROUND

1. In its Plan of Implementation, adopted in Johannesburg on 4 September 2002, the **World Summit on Sustainable Development** encouraged countries to implement the new GHS as soon as possible with a view to having the system fully operational by 2008.

The current EU system

- 2. The current EU classification and labelling system for chemicals is set out in three key instruments:
 - (a) the Dangerous Substances Directive (67/548/EEC);
 - (b) the Dangerous Preparations (i.e. mixtures of chemicals) Directive (1999/45/EC);
 - (c) Annex II of the REACH Regulation (EC) 1907/2006; originally the Safety Data Sheet Directive (91/155/EEC).
- 3. These Directives and the Regulation are very closely linked. They have Internal Market (Article 95 of the EU Treaty) objectives (i.e. the approximation of laws aiming at the establishment of an Internal Market, in this case in the trade of chemicals in the EU, taking as a basis a high level of protection of health, safety, consumers and environment).
- 4. For international transport purposes, classification and labelling systems mirror the international transport regulations for all modes of transport. For national transport purposes Directives 94/55/EC (road) and 96/49/EC (rail), as amended, apply the provisions of ADR and RID respectively.

THE EU CONTEXT

5. The recommendation of the World Summit on Sustainable Development has been taken up by all EU Member States. In several instances Member States called upon the Commission to adopt the GHS. Accordingly, the Commission services have indicated in various for that the GHS will be incorporated into Community legislation.

IMPLEMENTATION UPDATE

Supply and use

- 6. On 27th of June 2007, the European Commission adopted 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" (COM(2007) 355 final). The proposed Regulation would align the EU system of classification, labelling and packaging substances and mixtures with the United Nations Globally Harmonised System (GHS). It included a transitional period which proposed that the deadline for substance reclassification and relabelling would be 1 December 2010, and for mixtures 1 June 2015.
- 7. The proposal has been notified to the TBT and was published by WTO in September 2007 under the reference number G/TBT/N/EEC/163. One comment has been received from China relating to that notification.
- 8. A more detailed summary of the aim, scope and provisions of the proposed Regulation was provided in the Information document UN/SCEGHS/14/INF.18 presented by the Commission experts at the meeting in December 2007.
- 9. Since the Commission's proposal was published, it has been subject to the legislative co-decision procedure. Both the European Council and the European Parliament consider the Regulation implementing the GHS as a high priority, and are working with a tight agenda to secure final adoption in the autumn 2008. A milestone on the way to adoption within this timescale was reached at the end of June 2008 under the Slovenian Presidency, when the Council Working Party (WP) and the representative of the European Parliament agreed on a text of the Regulation. Formal adoption by the Council and Parliament in the autumn would allow publication and entry into force of the Regulation by end of 2008, allowing the European Union to honour its international commitments to have the system operational by 2008. The transitional dates for substance and mixture reclassification and relabelling remain as in paragraph 5 above.
- 10. The Recitals and Articles in the Commission's proposal include issues such as the aim and scope of the Regulation as well as procedural arrangements. Many of the changes agreed by the Council and the Parliament on the Recitals and the Articles clarify procedural issues, and so are only of limited relevance within the global context.
- 11. However, some of the issues addressed are relevant in the global context. These include several issues where the UN GHS does not yet provide answers, for example:
 - Provisions applying to small packaging
 - Labelling of inner/outer packaging to avoid contradictions with transport requirements
 - How to limit the information on the label to keep it digestible for the user without loosing necessary information
- 12. The Annexes to the Commission proposal include the technical provisions; in particular Annex I mirrors the provisions and criteria in Parts 2 to 4 of the "Purple Book".

- 13. The comments received on the Annexes during the negotiations highlight again the need to clarify and improve the wording in the "Purple Book". In general the problems identified mirror the observations already addressed to the UN SCEGHS in the past, which are now being taken up, for example in the informal document forwarded by the implementation correspondence group, in the proposals suggested by the pilot trial group, or outlined in the submissions by members of the UN SCEGHS.
- 14. We expect that these "observations" will be considered by the UN SCEGHS in the near future.
- 15. Other areas where further work is needed to improve the workability of the GHS and to strive for global harmonisation are:
 - The provisions for labelling exemptions on small packaging; and
 - The use and selection of Precautionary Statements.
- 16. We recognise that the responsible correspondence groups have already devoted much effort to progress these topics and we expect that this work will continue into the next biennium.
- 17. As short term solutions to secure a workable system the EU has tried to find or develop "interim" solutions to tackle these deficiencies of the GHS. In general these are included in the Annexes to the EU Regulation or in guidance, as these are easier to adapt or change when the GHS is amended in the future. This approach, therefore, helps to avoid inconsistencies in the application of the GHS in the longer term.
- 18. Although we completely understand that careful consideration is needed with regard to the development of "new elements" to the UN GHS during the implementation stage, we are convinced that the issues identified by the various correspondence groups will improve workability and address the deficiencies of the "Purple Book". This work must continue, and should have priority in the work plan for the next biennium.

NEXT STEPS

Safety Data Sheets

19. One of the next tasks of the Commission services will be to adapt Annex II of the REACH Regulation which includes the provisions on Safety Data Sheets, to align them fully with the UN GHS provisions.

Guidance documents

- 20. The preparation of detailed guidance for the application of the GHS criteria is under development in the framework of REACH Implementation Project 3.6 (RIP 3.6), taking account of the expertise of EU Member State experts, cf. http://ecb.jrc.it/reach/ (first click on 'documents / restricted access' on top of the page, then enter user name (segr) and password (segr07)). It is expected that the guidance will be finalised in early 2009.
- 21. In parallel to specific guidance, general guidance is also being developed, focussing on basic features and procedures related to classification and labelling in the EU context. The guidance is addressed to those who want to have a quick overview of the new legal requirements for classification and labelling in the EU, i.e. suppliers of chemicals and non-EU target groups. This guidance document will be made available by the time the EU legislation enters into force.

LINKS TO THE LEGISLATIVE PROPOSAL

Supply and use

22. The Regulation proposed by the Commission, the executive summary of the Commission's impact assessment and the full Commission impact assessment are available via the following website:

http://ec.europa.eu/enterprise/reach/ghs_more_on_com_proposal_en.htm

23. All 23 language versions of the Regulation proposed by the Commission and the executive summary of the Commission's impact assessment are available in Eur-Lex:

http://europa.eu.int/eur-lex/lex/RECH_naturel.do Click: Com final, enter year: 2007, enter number: 355

However, please, be aware that the Commission proposal on its web site does **NOT** include the changes based on the outcome of the discussions in Council and Parliament.

24. However, the Council has made available on their web site the latest text of the Regulation, including the changes agreed by the Council Working Party (WP) and the representatives of the European Parliament. Please, note that the text is NOT yet adopted by the European Parliament and the Council.

To access the documents:

- 1. Go to the Council website http://www.consilium.europa.eu/cms3%5Ffo/
- 2. Choose language, e.g. English
- 3. At the top of the homepage, click on the 6th button from left "Documents"
- 4. Click on "Access to Council documents".
- 5. Click on the top button on the left side "Search in the register"
- 6. Click on the button "Advanced search" also to the left
- 7. Enter "7388/08" or "11206/08" ibn the field "Document number".

Document 11206/08 contains recitals and articles.

Document 7388/08 with 9 addenda contains the Annexes.

Please note that the texts are NOT yet adopted by the European Parliament and the Council, further on they will be subject to legal-linguistics finalisation!

25. The Commission will provide soon a link to this text on its web site.

Transport

- 26. The Commission Services responsible for transport have already introduced the GHS in Directives on the Transport of Dangerous Goods, based on the "Recommendations on the Transport of Dangerous Goods, Model Regulations" itself amended to reflect the current GHS.
 - ADR/RID 2005: directives 94/55 and 96/49 (amendments 2004/111 and 2004/110) included most elements;

- ADR/RID 2007: directives 94/55 and 96/49 (amendments 2006/89 and 2006/90) added some further categories;
- Proposed Directive, COM(2006)852, published 22 Dec.2006 and to be adopted summer 2008, to be implemented by MS by 30 June 2009, amalgamating the road and rail provisions and extending the scope to inland waterways, hence applying the GHS amendments included in the 2009 transport revisions, as reflected in the international agreements, to the transport sector.
- 27. The consolidated versions of the Directives including the above-mentioned amendments can be found on the following websites:

http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1994L0055:20061124:EN:PDF http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0049:20061124:EN:PDF

28. We will keep the SCEGHS informed about further progress.