

Health and Safety Executive Board					
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RESULTS OF CONSULTATION ON THE PROPOSED EUROPEAN REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES AND REPORT ON LATEST DEVELOPMENTS IN NEGOTIATIONS					

Purpose of the Paper

1. To up date the Board of developments following their (HSC's) consultation on the proposed European Regulation to adopt the Globally Harmonised System (GHS) for the classification and labelling of chemicals in the EU, and the latest developments in Member State negotiations.

Background

2. Chemicals often have harmful or hazardous properties. People and/or the environment may suffer adverse effects from exposure to these properties. As a result, many countries have developed laws that require certain controls to be in place when supplying and using chemicals that could cause harm, to ensure the protection of people and the environment. Existing laws and regulations around the world, established to identify and communicate the hazardous properties of chemicals, are similar in many respects. However, their differences are significant enough to result in different classifications, labels or safety data sheets, for the same product in different countries. This affects both the level of protection and the extensive global trade in chemicals.

3. At the Earth Summit held in Rio de Janeiro in 1992, world leaders generated an international mandate, set out in Agenda 21 of the United Nations Conference on Environment and Development, to make available "a globally harmonised hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols". This was endorsed at the World Summit in Johannesburg in 2002, with a commitment for countries to adopt the GHS in national legislation by 2008.

4. The proposed European Regulation on the Classification, Labelling and Packaging of Substances and Mixtures, represents Europe's response to that commitment. The proposed Regulation will replace the existing European classification and labelling system (the Dangerous Substances Directive – 67/548/EEC; and the Dangerous Preparations Directive – 99/45/EC). The Regulation will be directly acting on Member States without the need for transposition. However, HSE will need to prepare enforcing regulations to allow the provisions to be enforced in the UK. We will also need to amend and finally revoke the Chemicals (Hazard Information and Packaging for Supply) Regulations, to allow classification and labelling under the new system.

Argument

5. HSC/MISC/07/10 and HSC/07/08 advised on developments in the UK's response to the EC's proposed Regulation, and sought the Commission's approval of the UK negotiating strategy and agreement to the publication of the Consultative Document No 213 which invited comments on the proposed draft Regulation.

6. The UK has been, and continues to be, very active in the Council negotiations, and is following closely developments in the European Parliament (EP). The Slovenian Presidency is committed to achieving a first reading deal with the EP in June, in order to meet the internationally agreed implementation deadline of GHS of 2008. As such, negotiations are now moving rapidly.

7. This prospect has helped those, like the UK and the European Commission, who are seeking to implement the GHS while also keeping as close as possible to the existing EU system for classification and labelling which already provides a high level of protection for people and the environment.

8. Subject to any unexpected developments in the final stages of the negotiations, the UK has worked proactively with like-minded member States to secure:

- Better definition of the duties of the different actors in the supply chain, and in particular clarification that distributors do not have responsibility to classify substances and mixtures, though they do have responsibilities for labelling and packaging
- Derogations for labelling of small and awkwardly shaped packages similar to those we have written into CHIP now under discretionary powers available to Member States
- Improved provisions for companies to keep the chemical name of a substance confidential (without loss of safety) by using a generic or alternative name
- Flexible arrangements for combined transport and supply labelling.
- Numerous clarifications and improvements throughout the text of the Articles and Annexes.

9. The UK has also been at the forefront of resisting changes that would have increased the cost of adopting the GHS system. These include:

- Preventing the adoption of acute toxicity category 5, as pressed for by Sweden, Denmark, France and Poland. If adopted this would have meant that essentially all substances and mixtures would be classified for acute toxicity
- Preventing the introduction of new classifications for substances and mixtures that are persistent, bioaccumulative and toxic (PBT) and very persistent and very toxic (vPvBs) - in essence a combination of existing classifications
- Preventing the substantial extension of the classification and labelling of flammable liquids to include liquids with a flash point from 60 to 93°C that would have resulted if the GHS category Flammable Liquids category 4 would have been adopted, as advocated by certain Member States
- Maintaining the existing requirements for provision of child resisting fastenings and tactile warnings of danger on containers of certain hazardous substances and mixtures, thereby avoiding very substantial costs (estimated as at least £37m by the cleaning products sector).

Consultation

10. The timing of the Consultative Document (CD No 213) was determined by the publication on 27 June 2007 of the EC's formal proposed Regulation on the Classification, Labelling and Packaging of Substances and Mixtures, and the immediate start thereafter of Member State negotiations and consideration in the European Parliament. The HSC

consultation ran from 14 August – 2 November 2007. A copy of HSC/07/08 can be found at: <http://www.hse.gov.uk/aboutus/hsc/meetings/2007/170707/c58.pdf>

11. Written for as wide an audience as possible, both those well-versed in classification and labelling matters and those with a far more limited knowledge, the CD asked 24 questions. The CD focused on key issues that had been highlighted in earlier consultations with stakeholders and in the development of the UK's initial response to the EC's draft proposals in 2006, or which emerged from early Member State negotiations.

12. The CD included an initial Regulatory Impact Assessment (RIA). The RIA invited respondents to comment on the assumptions made about the estimated costs and potential benefits of implementing the proposed Regulation in the UK. Where respondents challenged these assumptions, they were further invited to provide evidence and/or justification for any proposed amendments based on, for example, their experience of current classification, labelling and packaging activities and the anticipated changes.

13. Overall, the proposed Regulation was supported, and relatively few consultees commented in any detail. In some cases respondents offered alternative costs for the RIA and these have been included, where they were supported by evidence, experience of re-classifications or how the new Regulation would incur costs in addition to those already assigned to existing classification, labelling and packaging processes. However, the assumptions originally made have largely held. A report on the results of the formal consultation appears at Annex A.

14. Consultation with Government colleagues and industry/business representatives continues, at UK and European level. HSE hosted a second, well-supported and successful Stakeholder Workshop on 19 February 2008.

Presentation

15. Once the Regulation is adopted, we will make an announcement on the HSE web site, as well as alerting the inter-governmental GHS sub-group, the industry stakeholder group specialising in classification and labelling, and other stakeholders, who have been consulted and involved throughout.

Costs and Benefits

16. The final Regulatory Impact Assessment appears at Annex B. The implementation of the GHS criteria will be staged over a 7 ½ year period. The total, quantified costs of implementation in the UK have been estimated as between **£95,680,000** and **£215,680,000**, as against the estimated £57.2 billion annual UK chemical industry turnover. These are largely one-off costs, which reflect the migration from the existing to the new system.

17. Consultation responses supported the conclusion of both the EC's Impact Assessment (dated 2006) and the UK initial RIA that the introduction of the new Regulation is likely to have a disproportionate impact on SMEs, from both practical implementation costs and/or the 'buying in' of necessary expertise. Efforts continue to push the new Regulation onto the small firms' agenda through meetings with relevant trade associations, federations and individual small firms through the stakeholder network established following the Workshops. HSE continues to work with BERR to highlight the need for effective

communication with small firms. Stakeholders have indicated that early preparation should allow sufficient time for small firms to adapt to the new Regulation and mitigate implementation costs.

18. HSE will continue to ensure that the European Commission continues to work to assist small businesses in complying with the new regime by developing guidance and supporting packages for duty holders.

Financial/Resource Implications for HSE

19. The main costs arising from the implementation of the GHS will be the need to provide advice and guidance, and the need for enforcing officers to be trained on the GHS Regulation. These costs are estimated at **£220,000** for HSE inspectors. More detail can be found on page 46 of the final RIA. There is however no expected increase in the level or costs of enforcement required due to the implementation of the GHS, compared to the current situation.

20. EU Member States are required to appoint a Competent Authority with the expertise and resources to carry out the tasks assigned to it. Some of the functions of the Competent Authority will be to provide advice and guidance to industry on the GHS requirements. The decision on the UK GHS Competent Authority has yet to be made. Were HSE asked to take on the role of the CA for GHS alongside that for REACH, we would estimate the costs of operating as Competent Authority as part of our discussions with Government.

21. Costs associated with the negotiation of this Regulation, and related stakeholder engagement has been met from existing resources.

Environmental Implications

22. As with the existing EU system, the proposed legislation integrates the protection of people and the environment. HSE continues to work with Defra; the EA; SEPA and the Department for Environment and Heritage Northern Ireland to ensure all environmental implications are identified and responded to.

Other Implications

23. As indicated above, the small businesses are expected to bear a disproportionate cost in complying with the proposed Regulation. The UK raised this in negotiations. HSE continues to consult with small business representative bodies, through the Small Business Trade Associations Forum for example, and also directly.

Paper clearance

24. This paper was produced by Jan Harris and Robin Foster, and was cleared by the SMT.

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