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HEALTH AND SAFETY COMMISSION

Update the proposed European Regulation on Classification and Labelling of Substances and Mixtures based on the United Nations' Globally Harmonised System

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Issue

1. Developments in the European Union's implementation of the UN's Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Timing

2. Routine.

Recommendation

3. To note that:
- the European Commission is expected to publish a formal proposal in June 2007, and to press for early agreement;
 - although we support the principle of the proposal we do have concerns over the intended scope of the Regulation and the potential costs, especially for SMEs;
 - we will seek HSC agreement to a Consultation Document, probably in July 2007.

Background

4. The EU's current system for classifying and labelling hazardous chemicals is long-established and well understood by the chemical manufacturers and suppliers. The system is implemented in Great Britain through the Chemicals (Hazardous Information and Packaging for Supply) Regulations (CHIP).

5. In 1992, governments at the Rio World Summit recognised that trade in chemicals is global, and presently suppliers of chemicals have to meet different requirements in Europe, the US, Canada, Australia, Japan, etc. It was also recognised that many countries, especially developing ones, do not have classification and labelling systems at all. The Summit generated an international mandate to make available "a globally harmonised hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols" - GHS. This was reinforced at the World Summit on Sustainable Development held in Johannesburg in 2002, at which

countries were encouraged to implement the GHS as soon as possible, with a view to having the system agreed and implemented by the end of 2008.

6. The UK joined many other countries in agreeing to implement GHS by 2008. As the GHS is not legally binding, it is necessary for governments around the world to adopt it through national or internationally agreed legislation. The European Commission (EC), in agreement with Member States, has responded to this commitment by proposing a new Regulation that, if adopted, would act directly on all European Union (EU) Member States. Although we would not have to transpose the Regulation into national law, we would still have to prepare enforcement regulations. Transport, although part of the UN GHS, has been excluded from the scope of the EC Regulation because this sector is already addressed by other EU legislation compatible with GHS.

7. In March 2006, Ministers agreed that the HSE would lead for the UK on the GHS Regulation. More detailed information about the current EU classification and labelling system and the GHS is at Annex A.

Argument

8. On 21 August 2006, the EC launched a 2 month Internet-based consultation on a draft Regulatory package to introduce the UN GHS within the EU. The package included a draft Regulation, impact assessments and a study on the potential effects of the GHS Regulation on other EU legislation. The consultation exercise was launched without warning, resulting in little practical time for Member States' competent authorities, industry and others to consider the draft proposal fully, consult and respond.

9. The August launch and the short consultation period also indicated the EC's wish to progress quickly with the Regulation in order to secure a text to allow an entry into force date of 2008 and to align the new Regulations with the proposed REACH Regulation. Early indications are that the EC is seeking a First Reading deal on the GHS Regulation between the European Parliament and the Council. The current German Presidency (Jan – June 2007), and the incoming Portuguese Presidency (Jul – Dec) are known to be supportive of GHS and keen to progress formal negotiations. Internal discussions between the EC and its Legal Service have resulted in a delay in publishing the formal proposal. Nevertheless, once published the EC will be keen to progress matters and a First Reading Deal is a possible, though ambitious target.

10. A formal proposed Regulation is now expected in early June 2007, with negotiations expected to start almost immediately under the German Presidency. HSC will be invited to approve a Consultation Document setting out the formal proposal.

11. As the proposed Regulation will be progressed through the co-decision procedure, UK Parliamentary scrutiny is required. An Explanatory Memorandum is being prepared and will be submitted to the Parliamentary Scrutiny Committees on receipt of the formally proposed Regulation.

Consultation

12. On receiving the EC's draft Regulation in August 2006, HSE initiated a wide-ranging consultation via the Internet (alerting over 1500 stakeholders to the EC consultation), involving OGDs, the devolved administrations, industry, trades unions, trade organisations,

non-departmental government bodies, small business associations and others. HSE set up an Internet-based discussion forum designed to prompt debate about issues raised by the draft Regulation. HSE also hosted a well-received workshop for interested stakeholders on 25 September. The DTI has established a 'rapid response' group of industry representatives that will assist UK Government during negotiations which are expected to move quickly. At the European level, the GHS Regulation does not appear to have as high a profile with trades unions as it does with other stakeholders. This has been reflected in our own initial consultations.

13. Within Government HSE officials are working closely with colleagues in other Departments, the Devolved Administrations and LACORS on the detail of the proposed Regulation and its supporting documentation.

14. The proposed Regulation was discussed at HSE's Challenge Panel on 27 February. The Panel reinforced the policy approach to the Regulation and noted the benefits a global harmonisation in chemical hazards could bring. However, the Panel raised a concern about the disproportionate impact on those companies (particularly small firms) that do not trade outside the EU Single Market, and for whom such benefits would be minimal. The Panel encouraged HSE to seek EU funding to help small firms comply with GHS.

UK Government Response

15. Working with OGDs and others, HSE developed a full response to the draft Regulation. A summary of the UK Government's main concerns and issues appears at Annex B. HSE, departmental officials, Ministers and the Devolved Administrations have agreed that the UK negotiating strategy should be supportive of the introduction of GHS in the EU, provided certain policy principles are in place. Details of these policy principles can be found at Annex C. A full negotiating strategy is being developed and will be finalised once the formal proposed Regulation is published, subject to Ministerial agreement.

Industry response

16. Representatives of the UK chemicals industry have issued a joint statement on the proposed Regulation. This is attached at Annex D and has been seen by Ministers.

Presentation

17. There is expected to be considerable interest and involvement from many across the UK's chemical industries, suppliers and users, as the negotiations progress and the profile of GHS increases.

Costs and Benefits

18. Although the impact assessments accompanying the EC's proposal estimate that the economic benefits to the European chemical industry are likely to balance the costs of the proposed change, it is HSE's initial view that the underlying assumptions are optimistic and are unlikely to be met in practice. Furthermore, although all chemical companies (including SMEs) will face the costs of change, only those who trade outside the European Union are expected to experience any potential financial benefits (around 25% of the industry's trade is estimated to be outside the EU).

19. Central to the European proposal is a resolve not to allow any lowering in the levels of protection for European workers or the environment subsequent to the introduction of the GHS Regulation. The introduction of the new GHS criteria may result in an increase in the number of chemicals falling into scope of various downstream regimes and result in consequent cost. Both the EC and Member States are aware of this, and plans are underway to mitigate any unintended extensions in scope. The EC has also not calculated the cost of these changes in its impact assessment.

20. HSE is working up an initial RIA for the impacts on the UK, including any implications from affected downstream legislation, and we anticipate this will show a similar picture to that described above.

Financial/Resource Implications for HSE

21. HSE will be leading negotiations for the GHS Regulation and this can be accommodated through existing resources. Longer term, HSE inspectors are likely to be responsible for enforcing the legislation in premises they inspect now, and through the supply chain. Although the GHS Regulation will deal with areas already covered by existing legislation, there will be resource implications for training and awareness raising of the new aspects under GHS. It is not yet clear if there will be additional costs arising from broader regulatory issues. We will, of course, aim to minimise such costs, wherever possible.

Environmental Implications

22. The proposed legislation also deals with chemicals that are harmful to the environment. HSE is working with Defra; the EA; SEPA; the Department for Environment and Heritage Northern Ireland and the Pesticides Safety Directorate to ensure all environmental implications are identified, responded to and costed.

Other Implications

23. The proposed Regulation will not affect the existing EU chemical single market.

24. The EC's impact assessment indicates the SMEs are expected to bear a disproportionate cost in complying with the proposed Regulation and UK Government raised this as a concern during the Internet-based consultation. HSE has consulted with SME representative bodies, through the Small Business Trade Associations Forum for example, as well as DTI's Small Business Service, and also directly. The EC has responded to the UK Government's concerns and has requested suggestions for assisting SMEs with compliance. HSE is in the process of gaining ideas and best practice solutions from trade associations and OGDs. HSE will pay particular attention to SMEs when preparing the initial and later RIAs.

The EU system of classification, labelling and safety data sheets

1. The EU system is driven by the need to establish a level playing field and remove trade barriers. The system has been progressively developed and refined.
2. Hazardous properties of chemicals are identified (the process of classification) to indicate, for example, the presence and extent of:
 - Safety hazards such as flammability, and the potential to explode or oxidise (and so enhance combustion);
 - Health hazards such as acute and chronic toxicity (by ingestion, inhalation or skin contact), corrosivity, irritation, sensitisation (of the lungs or skin), carcinogenicity, mutagenicity and reproductive toxicity (including effects on fertility and on the developing foetus);
 - Environmental hazards such as acute aquatic toxicity, the potential for longer term effects in the aquatic environment, and the potential to affect the ozone layer.
3. The system provides warning pictograms such as the black 'skull and cross-bones' or the St Andrews cross contrasted against a square orange background, together with standardised risk and safety phrases and other information which has to appear on labels of hazardous substances.
4. For use at work the label information is supplemented by more detailed information in safety data sheets. This covers areas such as first aid, fire fighting, and accidental release measures, handling and storage, and measures to prevent and control occupational and environmental exposure.
5. Most chemicals are used in the workplace. The classification and labelling system triggers other EU legislation on the control of chemicals used at work. These controls include requirements for worker health and safety, and public safety from larger chemicals installations where hazardous chemicals are kept in significant quantities.
6. The classification and labelling system for the supply of chemicals also covers:
 - Protection of the environment; and
 - Chemicals supplied to the public and sold in, e.g. DIY stores.
7. DfT leads on separate requirements for transport of hazardous chemicals. They put in place a UN system for providing information to the emergency services when responding to transport incidents involving hazardous goods. One of the aims of the GHS is to provide a common basis for the supply and transport systems.

The Globally Harmonised system

8. The EU systems work well. However, trade in chemicals is global, and presently suppliers of chemicals have to meet different requirements in Europe, the US, Canada, Australia, Japan, etc. The Rio summit in 1992 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”.
9. A Sub-Committee of the United Nations Economic and Social Council has taken forward this work. All the key elements of the system are now available¹, though work to develop and refine the GHS continues. HSE and DfT officials represent the UK in this UN forum.
10. The political mandate to introduce GHS was reinforced at the World Summit on Sustainable Development held in Johannesburg in 2002, at which countries were encouraged to implement the GHS as soon as possible, with a view to having the system fully operational by 2008.
11. The proposed EC Regulation is planned to sit alongside the REACH requirements, for which political agreement was a notable success of the UK Presidency. The European Commission hopes that the requirements for GHS will be adopted around the same time REACH comes into force, i.e. in 2007. This is an ambitious objective, as key issues for negotiation include:
 - Which elements of the GHS to incorporate. GHS is not a legal text and is not mandatory - it gives jurisdictions the option to pick up certain elements or not (the building block approach);
 - Which elements of the existing system to retain, and how these should be incorporated into the GHS;
 - What transitional arrangements should be put in place to enable industry to migrate smoothly from the present EU system to the GHS, first for the 30,000 or more substances on the market, and then for the 1 or 2 million (estimates vary) of marketed preparations. Most chemical products are preparations, or mixtures of substances.

¹ *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, First revised edition, published by the UN, ISBN 92-1-116927-5, known as the ‘Purple Book’ (~500 pages)
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UK RESPONSE TO THE EUROPEAN COMMISSION'S DRAFT REGULATION TO IMPLEMENT THE UN'S GHS IN THE EU – MAIN CONCERNS AND COMMENTS

1. The UK's response was detailed and provided comment on UK Government's main concerns together with an article by article commentary. This Annex provides details of the principal concerns only.
2. The UK supports the implementation of GHS through a Regulation, subject to clarification and certain amendments.
3. UK Government's main concerns and comments as reflected in the formal UK response are set out below.

Main concerns

Legal base

The UK would query using only Article 95 of the Treaty of Rome as the legal base for this Regulation. It is striking that the draft Regulation states its legal base as the internal market (Article 95) but then goes on to say in the first line of the first recital, "The trade with chemical substance and mixtures is not only an issue of the internal market, but of the global market". The UK wishes to avoid a similar situation to the ECJ ruling on the implementation of the UN PIC legislation (Regulation 304/2003, concerning the export and import of certain dangerous chemicals), where the European Court of Justice ruled that this Regulation should have a dual legal base of Articles 95 and 133. The Commission is invited to consider whether this is also appropriate for GHS.

Role of Key Players

- The European Chemical Agency – the UK recognises the role of the Agency in dealing with classification and labelling. However, it is necessary to have a clearly defined role for the Agency, defining the scope of its authority, its powers, its commitment to acting within the timescales detailed in later Articles, and the appeals process open to Member States where disagreement exists or the Agency has failed to act within those designated timescales.
- An example of where further clarification is needed would be the provisions in Article 24.2. It is not clear if the Agency will have any power to challenge the scientific data presented to it, and timescales for updating the classification and labelling inventory.
- The Agency will also undertake considerable work in the initial years of REACH. The effective management of its increased role with the entry into force of the new Regulation will need to be a factor in negotiations on the transitional period.
- Industry – As currently drafted the text is not consistent, or clear as to the role of all of those within the supply chain. The existing system places the same duty on all those in the supply chain to be responsible for ensuring the correct classification and labelling of chemicals. According to the proposed text this will no longer be the

case, as retailers, for example, will not be responsible for ensuring the classification and label are up to date and correct. The EC must clarify this issue, and be clear of its intention.

Scope of proposed Regulation

- The UK would like further clarification on the intended scope of the Regulation to ensure a workable and effective system can be achieved. Currently there are two main areas of concern.
 - (i) The extension of scope of the current system, with the Regulation proposing to now include 'articles'.
 - (ii) The requirement to classify and label chemicals depending on the future use of the chemical, rather than how it is placed on the market as is currently the case.

Either option would go beyond the scope of the UN's GHS as well as resulting in potentially significant additional compliance costs for those in the supply chain.

Incorporation of the existing EU system

- The UK welcomes efforts to ensure that the new Regulation incorporates as much of the existing EU system as possible.
- We support the EC's approach to limit the hazard categories in the new Regulation to those that are currently in use.
- We support the incorporation of the approx 7000 harmonised classifications which appear in Annex 1 of the Dangerous Substances Directive (and published in the GB as the HSC's Approved Supply List) into the new Regulation. This recognises some 35 years of collective discussion, agreement and practice.
- We also support the extension of the new Regulation to ensure the continued inclusion of hazard categories that do not appear in GHS but are in usage throughout the EU – for example ozone depleters.
- The UK requests that the Commission clearly identifies any provision that is not taken directly from either the existing legislation, or the UN GHS. The UK would like to understand the justification and rationale behind any new provision, before agreeing to an extension of scope.

Links to other European downstream legislation

- The UK welcomes the EC's acknowledgement of the impact of the GHS Regulation on the Seveso-II Directive (major hazards, implemented in the UK through the COMAH Regulations), its commitment to amending it appropriately, and the substantial work on the impact on downstream legislation. However, the UK remains concerned that in practice, the impact on downstream legislation is not as straightforward as the report presents. The UK would therefore like to recommend that the EC reviews the downstream legislation report and amend any downstream legislation if there are unintended consequences, prior to the entry into force of this Regulation.

- The UK would also request that the EC considers how the impact of the proposed changes on SMEs could be reduced. As identified by the consultants' impact assessments, SMEs will be disproportionately impacted by this proposal and least able to cope with the proposed changes. Therefore, the UK would welcome any work by the Commission to assist SMEs to deal with the new Regulation.

Database / Inventory / Annex I of Dangerous Substances Directive (67/548/EEC)

As currently drafted the text and subsequent Annexes are not clear on what the database / inventory is, who will have access to the data in holds, who will have responsibility to populate, and exactly how entries can be challenged and how often it will be updated, for example.

The UK would welcome an explanation to the above questions, and the text to refer to the database / inventory consistently throughout.

Proposed transitional period

Agreement on a transitional period (for both substances and mixtures (formerly "preparations")) is fundamental in achieving a workable, structured and timely implementation of the new Regulation and a migration from the current system to the new one. Industry and other interested parties need to give detailed consideration to the transitional measures to ensure workability and practicability. Consideration needs to be given to the following issues:

- Sufficient time will be needed to allow for effective information campaigns to educate industry, users and consumers to the new terminology, pictograms and classification arrangements.
- As currently drafted, the provisions of this Regulation will apply according to when the REACH Regulation enters into force. The REACH Regulation comes into force on 1 June 2007, with an intention for the GHS Regulation to come into force a year later. This will mean industry will have 2 years, not 3, before the provisions apply to substances. This will mean that the GHS Regulation timescales will apply retrospectively, and the UK is not clear if this is legally possible.
- While a period of joint running of both current and new systems is expected, a prolonged arrangement would be costly to industry and should be avoided – for example providing both existing EU and GHS information on a single safety data sheet could be seen as unnecessarily burdensome and possibly confusing for end users.
- The European Chemicals Agency will undertake considerable work in the initial years of REACH. There are concerns over the capacity of the Agency to cope with the introduction of both REACH and the requirements of this Regulation at the same time.

Costs and benefits of the proposed Regulation and GHS in the EU

The impact assessment accompanying the EC's proposal calculates that the economic benefits to the European chemical industry are likely to balance the costs of the proposed change. It is HSE's view that the underlying assumptions are very optimistic and are

unlikely to be met in practice. Furthermore, although all chemical companies (including SMEs) will face the costs of change, only those who trade outside the European Union may experience any potential financial benefits (around 25% of the industry's trade is estimated to be outside the EU). HSE is working up an initial Regulatory Impact Assessment, in consultation with OGDs and stakeholders, on the potential impacts on the UK, and we anticipate this will show a similar picture.

POLICY PRINCIPLES UNDERPINNING THE UK'S NEGOTIATING STRATEGY FOR THE INTRODUCTION OF GHS IN THE EU

HSE, in agreement with Lord Hunt and Ministers from DEFRA, DTI, DoH, DfT, HMT, FCO and representatives from Scottish Parliament, the Welsh Assembly and Northern Ireland, proposes that the UK's negotiating position should be supportive of the introduction of GHS in the EU provided that:

- (a) there is no reduction in the level of protection for people, or the environment, compared to the existing classification and labelling system;
- (b) GHS is adopted in such a way that the new system aligns, as far as possible, with the existing system for both supply and transport;
- (c) the final Regulation provides a practicable, workable system, incorporating the experience from operating the existing classification and labelling system;
- (d) the interface between GHS and REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals – the new chemicals regulatory system successfully brought to common position by the UK during its Presidency last year) is coherent;
- (e) transitional arrangements for migrating from the present system to GHS are practicable and workable;
- (f) any consequential changes to the scope of 'downstream' controls on chemicals are proportionate and appropriate.

The above principles seek to ensure the proposed Regulation will strike the right balance between maintaining the benefits of the long-established and well understood EU system and securing the wider global benefits of sustainable development and simplification of world trade. Very broadly HSE considers that the proposal gets the balance about right. However, HSE's analysis has identified a number of drafting, technical and procedural points within the draft Regulation that the UK's response and subsequent negotiations will seek to clarify or resolve. The UK's principle aim is to agree with Member States and the European Parliament a workable system for the EU under GHS, and a sensible, timely migration from the current system to the new one.

So far there has been no discussion (either formally or informally) by Member States on whether it is right for the EU to implement GHS early, or wait for other jurisdictions to pick up GHS first. It has been argued that by implementing early the EU can influence the content of GHS others pick up, as well as lead the way in responding to the Johannesburg commitment. However, by leading in this way the EU risks the disadvantage that any potential financial benefits will be delayed until other jurisdictions have also implemented the GHS.

Annex D

UK Industry Joint Statement on the Proposal for GHS Implementation in the EU

The UK chemical manufacturing & downstream industries⁽¹⁾ support the concept of GHS in view of its potential to achieve a standardised hazard classification and labelling system for chemicals across the world. However, we are concerned that, due to differences in interpretation internationally, the end product of GHS for specific substances will not be harmonised globally, thus falling short of the intended objective.

Subject to the provisos set out below, we welcome the EU proposal for implementing GHS at the same time with the forthcoming REACH regulations. To ensure the effective implementation of GHS, UK industry calls for the following points to be considered:

- We strongly urge the UK authorities to ensure that all stakeholders receive adequate communication and education on the details of the new system. This is essential to ensure that GHS delivers its promise in terms of enhanced protection for workers and consumers, as suggested within the consultation. We also call for the introduction at UK and community level of an education programme for consumers so that they understand the meaning of the new labelling system.
- Running both the existing EU classification & labelling system and the new GHS system in parallel during the proposed phase-in period is likely to cause major confusion and increased costs to industry.
- The effects on related EU chemicals legislation, and the resulting consequences, need to be considered carefully and guidance developed to ensure a common EU interpretation. Examples include the supply of safety data sheets & thresholds for COMAH.
- The current use of abbreviations for risk and safety phrases in the current system, for example R50/R53, is not a part of GHS. We support the codification of the GHS risk and safety phrases so that they may be used in technical documentation such as Safety Data Sheets. General guidance on how to write the combined Safety Data Sheet and labelling requirements will need to be provided.
- Test data generated from human testing under other legislation must be deemed acceptable under GHS.
- Careful thought must be given to the application of the regulation to mixtures and mixtures of mixtures in terms of both timescale and impact. To simplify communication issues, we would call for all substances to go through the reclassification process prior to any mixture being considered for reassessment. At this stage, we believe that a 3-year transition period for substances is appropriate, relative to the introduction of the GHS Regulation.

- Once the 3-year process is completed for substances, we support the proposal for an additional 5-year transition period for mixtures to ensure that all industry sectors have sufficient time to adapt to the changes that the reclassification of some substances may require.
- The communication of classification changes down the supply chain needs to be carefully managed, particularly with the retailing industry. It is essential that any changes to classification apply to products at the time that they are first placed on the market, in line with other community legislation. This will prevent the unnecessary expense of recalling products from the distribution chain, and from retailers, because of labelling changes.

Finally, the chemicals industry questions the cost – benefit analysis for the implementation of GHS in the EU. A working EU system is being replaced, but it will still be different to the classification & labelling systems being introduced under GHS in other parts of the world. Industry will still have to work with multiple systems.

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Statement made by: Chemical Industries Association, Chemical Business Association, UK Cleaning Products Industry Association, Cosmetic Toiletry and Perfumery Association, CBI, British Coatings Federation, British Association for Chemical Specialities