

European Commission proposal for a Regulation on the Classification, Labelling and Packaging of Substances and Mixtures

This consultative document is issued by the Health and Safety Commission in compliance with its duty to consult under section 16(2) of the Health and Safety at Work etc Act 1974.

Comments should be sent to:

Jan Harris
International Chemicals Unit
Health and Safety Executive
9th Floor South Wing
Rose Court
Southwark Bridge
London SE1 9HS

Tel: 020 7717 6251 Fax: 020 7717 6891

E-mail: jan.harris@hse.gsi.gov.uk

to reach there no later than **2 November 2007**

The Commission tries to make its consultation procedure as thorough and open as possible. Responses to this consultative document will be lodged with the Health and Safety Executive's Information Centres after the close of the consultation period where they can be inspected by members of the public or be copied to them on payment of the appropriate fee to cover costs.

Responses to this consultative document are invited on the basis that anyone submitting them agrees to their response being dealt with in this way. Responses, or part of them, will be withheld from the Information Centres only at the express request of the person making them. In such cases, a note will be put in the index to the responses identifying those who have commented and have asked that their views, or part of them, be treated as confidential.

Many business e-mail systems now automatically append a paragraph stating the message is confidential. If you are responding to this CD by e-mail and you are content for your responses to be made publicly available, please make clear in the body of your response that you do not wish any standard confidentiality statement to apply.

Further single copies of this document may be obtained from HSE Books – see back cover.

**European Commission Proposal to implement the UN Globally
Harmonised System of Classification and Labelling (GHS) within the EU
by means of 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**

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PREFACE

The Health and Safety Commission (HSC) would like your comments on the European Commission's proposal to adopt the Globally Harmonised System of Classification and Labelling (GHS) within the EU by means of a Regulation of the Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

A response form is included at Annex J, at the back of this booklet to help you do this. It repeats the questions set out in the main text below. Please feel free to circulate this consultative document more widely.

A limited number of hard copies are available from the address on the back cover, or you can download this document from the Internet on the Health and Safety Executive (HSE) home page at:

<http://www.hse.gov.uk/consult/live.htm>

Acknowledgements:

HSC wishes to thank all those who have assisted HSC and HSE with the development of these proposals.

Why are we consulting you?

HSC seeks to inform its decision-making by consulting a wide range of interested bodies and individuals. HSC believes that this will enable an open and transparent approach to decision-making, which is essential if policies and decisions are to have widespread ownership and reflect the needs and aspirations of the people they will affect. HSC then decides on the best way forward based on an interpretation and analysis of the results of this exercise.

What we would like you to do:

We would like you to comment on these proposals by 2 November 2007. However, we would welcome comments on the text of the EC's proposed Regulation by early September, so that we can take them into account, as we anticipate the detailed Member State negotiations will start in mid-September. Please send your comments to:

Jan Harris
International Chemicals Unit
Health and Safety Executive
9SW Rose Court
2 Southwark Bridge
London SE1 9HS

Tel: 020 7717 6251
Fax: 020 7717 6891
e-mail: jan.harris@hse.gsi.gov.uk

If you reply to this consultative document in a personal capacity, rather than as a post holder of an organisation, you should be aware that information you provide may constitute “personal data” in the terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the “data controller” and will process the data for health and safety and environmental purposes. HSE may disclose these data to any person or organisation for purposes for which it was collected, or where the Act allows disclosure.

You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected. Please note all replies will be made public unless you specifically state you wish yours to be made confidential.

Responses in electronic form are welcome. Many business e-mail systems now automatically append a paragraph stating that the message is confidential. If you are sending your comments by e-mail please state clearly if you are not content for your response to be made public.

We have included a response form at Appendix 5 summarising the areas where we would particularly welcome your views; it will also help us to analyse responses. It is not intended to restrict the scope of the comments: we would welcome any comments you wish to make on the proposal.

What happens next?

We will give full consideration to the substance of arguments in all responses to the consultation in developing the Government’s negotiating position; we may also contact you again if, for example, we have a query.

Respondents should be aware that the EC proposal is a direct-acting Regulation, therefore it is vital that all stakeholders engage at this stage, as once agreed the UK will not have any flexibility in implementation. Respondents should also consider raising their concerns via other channels, such as national and EU trade associations, trade unions and Non-Governmental Organisations (NGOs).

Making responses public:

To make our consultation process as transparent as possible we make the comments we receive available to the public at our knowledge centre in Bootle. Copies will be made available at a small charge to cover costs, from the following address:

Knowledge Centre
Health and Safety Executive
1G Redgrave Court
Merton Road
Bootle
Merseyside L20 7HS

If you do not want your comments made publicly available please make this clear in your response.

Feedback, queries and complaints:

The Health and Safety Commission/Executive would also like to know what you think about the content and presentation of this consultation. Your views may help to improve other consultations. If you are not satisfied with the way in which this consultation exercise has been conducted you can complain by contacting:

**Robin Foster
International Chemicals Unit
Health and Safety Executive
Rose Court
2 Southwark Bridge
London
SE1 9HS**

We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with the Chief Executive of HSE at the Health and Safety Executive, Rose Court, 2 Southwark Bridge, London SE1 9HS. You can also write to your MP to take up the case with us. Your MP may refer the matter to the Parliamentary Commissioner for Administration (the Ombudsman) who will investigate your complaint.

EXECUTIVE SUMMARY

1. Chemicals have properties that can be harmful to humans and/or the environment. These 'hazardous' properties are the same the world over. Many countries have developed laws to protect people and the environment when hazardous chemicals are supplied and used.
2. While existing classification and labelling laws and regulations around the world are similar in many respects, their differences are significant enough to result in different labels or *Safety Data Sheets*¹ (SDS), for exactly the same product in different countries. Because of variations in hazard definitions of hazards, a chemical may, for example, be considered to be flammable in one country, but not in another.
3. Decisions on when or how to communicate hazards also vary around the world, which means there are inconsistencies in the level of protection offered to workers, consumers and the environment.

United Nations GHS

4. It was widely recognised that an internationally harmonised approach to classification and labelling of chemicals was needed.
5. The Earth Summit held in Rio de Janeiro in 1992 generated an international mandate², to create "a globally harmonised hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols". The work needed to develop such a system was taken forward within the United Nations Social and Economic Council. The outcome is a UN publication 'Globally Harmonised System of Classification and Labelling of Chemicals' (GHS) commonly known as the 'Purple Book'. The 2nd Revised edition has recently been published.
6. The UN GHS is a voluntary international agreement developed by national experts, including the input of the UK and other European Member States. In order to gain international agreement the UN GHS allows countries to implement the 'building blocks' they wish, within certain limitations and to keep national requirements that are not currently covered by the GHS – provided they do not contradict the GHS.
7. This flexibility will mean that, initially, the system will not be completely globally 'harmonised'. However, it is seen as a major step forward, and it is envisaged that once the major trading blocks, like the European Union, use the GHS the system will become fully harmonised over time.

¹ Safety Data Sheets (SDS) – are the primary tool for communicating reliable information (supplementing the label information) between suppliers of substances and mixtures and workers. SDS contain information about the hazards and the recommended precautions that are essential to protect health, safety and the environment.

² Set out in Agenda 21 of the United Nations Conference on Environment and Development

Aim of UN GHS

8. The UN GHS sets out internationally accepted definitions and criteria to identify the hazards of chemicals (called 'classification') and communicate these hazards via labels and safety data sheets. If the same classification criteria and labelling are used to describe the hazards, the level of protection of human health and the environment becomes more consistent, transparent and comparable throughout the world. Professional users of chemicals and consumers all over the world benefit from such harmonisation.
9. Industry will also save costs if they assess hazard information for their chemicals against the same criteria, and in future this will lead to a reduction in the need for re-testing the same chemical for classification purposes.

Proposed EC Regulation

10. The European Commission (EC) is proposing to replace the current EU classification and labelling system for hazardous chemicals with a new system based on the UN GHS. This new system will take legal effect through a direct-acting Regulation. The proposed Regulation was published at the end of June 2007, and negotiations in the European Council of Ministers started in early July. The proposal will also be discussed in the European Parliament.
11. The EC is proposing to replace of the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC) with the new direct-acting European Regulation on Classification, Labelling and Packaging of substances and mixtures (based on the UN GHS). The two existing Directives [together with the Safety Data Sheet Directive (91/155/EEC)] have been implemented in the UK by the Chemicals (Hazard Information and Packaging for Supply) (CHIP) Regulations. The EU requirements for Safety Data Sheets will remain with the EC Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) (EC) No 1907/2006.
12. Although there are many similarities between the GHS and the existing EU classification and labelling system, there are also some differences. The introduction of a European Regulation based on the GHS will mean some new:
 - scientific criteria to identify hazardous properties of chemicals
 - hazard warning pictograms (symbols) and new standardised warning and precautionary text for labels
 - terminology, e.g. 'mixtures' instead of 'preparations', 'hazardous' instead of 'dangerous', 'hazard statement' instead of 'risk phrase' and 'precautionary statement' instead of 'safety phrase'

13. The new European Regulation comprises:

- (i) main Text (60 Articles)
- (ii) seven supporting technical Annexes

14. The EC is proposing a phase-in approach to the new Regulation, with a 3.5 year period for substances, followed by a further 4.5 year transition period for mixtures (currently called 'preparations'). In line with the transitional periods, Member States will be required to allow the classification and labelling of substances and mixtures to 'switch off' the corresponding existing requirements in national law, and have enforcing regimes in place.

ISSUES

15. We intend to question any proposed extensions in scope and obligation relative to the existing system and the UN GHS, and seek their removal unless there is sound evidence to retain them.

TIMING FOR RESPONSES

16. Although the formal UK consultation will run for the full 12 week period until the 2 November 2007, substantive Member State negotiations started in July 2007 and will recommence in mid-September 2007.

17. We would therefore appreciate any early responses to this consultation. When responding to the consultation we request that you provide supporting evidence and examples, as this will greatly assist the UK during the negotiations.

18. Please feel free to copy this Consultative Document more widely; hard copies are available from the address on the back cover, and are also available via the HSE's website (<http://www.hse.gov.uk/consult/live.htm>).

INTRODUCTION

19. Chemicals often have harmful or hazardous properties. People and/or the environment may suffer adverse effects if exposed to these chemicals. As a result, many countries have developed laws that require certain controls to be in place when supplying and using hazardous chemicals that could cause harm, to ensure that people and the environment are protected.
20. This consultative document seeks comments on the formal draft European Regulation on Classification, Labelling and Packaging of Substances and Mixtures, proposed by the European Commission (EC) to adopt the Globally Harmonised System of Classification and Labelling (GHS) within the European Union (EU).
21. It is proposed that the new Regulation will replace the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC).
22. The existing European legislation and the new Regulation are both concerned with:
 - hazardous substances (chemical elements or compounds, such as mercury or sulphuric acid); and
 - hazardous mixtures (preparations or solutions of substances, such as paints or inks).
23. The term 'chemical' is used here for both substances and preparations.
24. The existing and proposed new European systems require suppliers of hazardous chemicals to decide what types of danger their products present (known as 'classification'), package them suitably, and provide information to their customers in the form of warning labels and safety data sheets.
25. The purpose of the European laws, both current and proposed, is to make sure that people are properly informed about the danger of chemicals both at work and in the home. They also improve the Single Market by requiring all suppliers of hazardous chemicals to provide the same standard of information to their customers.

BACKGROUND

The Existing European Classification and Labelling System for Supply

26. The European Union (EU) has in place a long-established chemical classification and labelling system (dating back to 1967) that result in harmonised (agreed) classifications and labels for many hazardous substances. It also provides rules for self-classifying other substances and

preparations (to be called 'mixtures' under the GHS), together with requirements on how identified hazards are to be communicated to users. This is achieved by standardised labelling requirements containing symbols and written information to indicate the hazard(s) present. Appropriate and proportionate protection controls can then be applied.

Examples of current EU labelling symbols (on an orange background):



"Explosive"



"Highly flammable"



"Harmful"

Examples of current EU 'risk phrases':

- R25 - Toxic if swallowed**
- R38 - Irritating to skin**
- R50 - Very toxic to aquatic organisms**

Examples of current EU 'safety phrases':

- S2 - Keep out of the reach of children**
- S15 - Keep away from heat**
- S51 - Use only in well-ventilated areas**

27. This system has proven to be very successful and provides well established criteria for defining the hazardous properties of chemicals for both people and the environment. Within the EU system, approximately 7000 substances have been assigned harmonised classifications and labelling requirements, protecting people, the environment and ensuring a fair and level playing field for the chemicals market across the EU.

28. The current classification and labelling system is established by the Dangerous Substances Directive (67/548/EEC), the Dangerous Preparations Directive (1999/45/EC), and the Safety Data Sheet Directive (91/155/EEC as amended by 2001/58/EC). These Directives have been

implemented in Great Britain by the Chemicals (Hazard Information and Packaging for Supply) (CHIP) Regulations³.

United Nations (UN) Globally Harmonised System of Classification and Labelling of Chemicals (GHS)

29. While existing classification and labelling laws and regulations around the world are similar, in some respects their differences are significant enough to result in different labels or Safety Data Sheets⁴ (SDS), for exactly the same product in different countries, even though the same hazards are present. For example, a chemical may be classified as flammable in one country but not in another.
30. Hazard warning labels can vary in size, colour (orange, red, black, yellow) and shape (square, round, triangular). The pictures used can vary in style with some designs clearly illustrating the hazard, while others take more imagination.
31. The wording used on labels can also be different. Some countries use the word “poison” instead of “toxic”.
32. Decisions on when or how to communicate hazards also vary around the world, and companies wishing to trade their products internationally must either devote significant resource to complying with these different legal requirements or outsource at some cost.
33. Given the extensive global trade in chemicals and the desire to prevent exposure to dangerous chemicals, the Earth Summit held in Rio de Janeiro in 1992 generated an international commitment⁵, to create “a globally harmonised hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols”.
34. The work to develop a ‘Globally Harmonised System for the classification and labelling of chemicals’ (the GHS) was taken forward in the United Nations (UN). The work began with the examination of the major existing classification and labelling systems from around the world (including that of the EU). A number of key principles of harmonisation were agreed at an early stage, including a commitment that:

“the level of protection offered to workers, consumers, the general public and the environment [provided by existing systems] should not be reduced as a result of harmonizing the [different] classification and labelling systems”⁶.

³ For more information on CHIP please see: www.hse.gov.uk/chip

⁴ Safety Data Sheets (SDS) – are the primary tool for communicating reliable information (supplementing the label information) between suppliers of substances and mixtures and workers. SDS contain information about the hazards and the recommended precautions that are essential to protect health, safety and the environment.

⁵ Set out in Agenda 21 of the United Nations Conference on Environment and Development

⁶ *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, First revised edition, UNITED NATIONS, New York and Geneva, 2005, p.4

35. The outcome is a set of agreed definitions and criteria to identify the hazardous properties of chemicals – known as ‘the GHS’. The GHS includes:
- *the hazard class* - .this refers to the nature of the physical, health or environmental hazard;
 - *the hazard category* - this refers to the severity of the hazard within each hazard class;
 - *pictograms* – hazard symbols;
 - *signal words* – these refer to the relative severity of the hazard present for example: “danger” or “warning”;
 - *hazard statements and precautionary statements* – phrases that describe the nature of the hazard and the recommended measures to minimise or prevent the adverse effects from exposure due to its use.
36. The definitions and criteria apply to both transport and the supply of chemicals. The GHS is fully documented in a UN publication known as the ‘Purple book’⁷.
37. The GHS aims to ensure that information on the hazards from chemicals is available in order to enhance the protection of human health and the environment during the handling, transport and use of hazardous chemicals. The GHS provides a basis for harmonising regulations on chemicals at national, regional and worldwide level, an important factor for trade facilitation. The GHS also aims to provide a basis for those countries that do not yet have a classification and labelling system.
38. The UN anticipates that, once fully implemented, the GHS will:
- enhance the protection of human health and the environment by providing an internationally comprehensible system for hazard communication;
 - provide a recognised framework for those countries without an existing system;
 - reduce the need for testing and evaluation of chemicals (agreeing/harmonising classification will help to reduce the need for animal testing); and
 - facilitate trade in chemicals whose hazards have been properly assessed and identified on an international basis⁸.

⁷ The GHS is available at: www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

⁸ *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, second revised edition, UNITED NATIONS, New York and Geneva, 2007 ISBN -13: 978-92-1-116957-7

39. To encourage the global adoption of the GHS, the UN agreement allows a certain degree of flexibility. This means countries (or trading blocks) can select to introduce either all, or only parts of the UN GHS. However, those parts selected must be implemented in full and as prescribed by the UN. The EC intends to introduce those GHS elements that most closely reflect the scope of the existing EU classification and labelling system.
40. It is worth noting that the UN GHS is broadly similar to the existing EU system in many ways. For example, as currently drafted, there will be only minor changes to the hazard warning symbols with the introduction of two new symbols or pictograms. Radical changes are not anticipated, although there may be more mixtures (preparations) classified under the GHS criteria, and some substances and mixtures may be classified more severely.
41. The most important similarities between the UN GHS and the existing EU system include⁹:
- both provide a single system for hazard classification and labelling of both substances and mixtures (preparations) for supply;
 - the GHS covers virtually all hazards which are currently covered by the EU system (and allows additional hazards if they are not covered by the GHS, for example, the EU requirement to classify 'hazardous for the ozone layer');
 - the GHS uses broadly similar classification criteria;
 - the GHS sets up a system of hazard communication that is equivalent to the EU system, consisting of both labels and safety data sheets (for workers). Under the GHS, safety data sheets also have the same 16 headings as in the current EU system.
42. The GHS is a voluntary international agreement, therefore countries or trading blocks must introduce implementing legislation in order to make the GHS requirements mandatory.

Proposed Regulation of the European Parliament and of the Council on Classification, Labelling and Packaging of Substances and Mixtures (based on the Globally Harmonised System).

43. Because the classification and labelling of chemicals is already regulated at Community level rather than national level, the EC has, on behalf of European Member States, produced a proposed new European Regulation to classify and label substances and mixtures based on the GHS. The new Regulation will be direct-acting, so no UK transposing legislation will be required to implement it.

⁹ Taken from the EC report 'Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation, August 2006, available at: http://ec.europa.eu/enterprise/reach/docs/ghs/ghs_sc_study_final_110806.pdf

Background to the EC Regulation

44. A commitment to develop and implement a globally harmonised system for the classification and labelling of chemicals was agreed at the Rio Earth Summit in 1992 in the context of global sustainable development to improve health, safety and the protection of the environment, and to facilitate world trade in chemicals. The commitment was reaffirmed at the World Summit on Sustainable Development in Johannesburg in 2002, where world leaders, including the UK, agreed a timetable of 2008 to have such a system in place.
45. This timing was beneficial to the EU, as the REACH Regulation (No: 1907/2006), which came into force in June 2007, included provision for a classification and labelling inventory. REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. REACH aims to make the people who place chemicals on the market (mainly manufacturers and importers) responsible for understanding and managing the risks associated with their use. REACH is aimed at simplifying the control of chemicals in the European marketplace.
46. REACH requires manufacturers and importers to collect, collate and submit data to the European Chemicals Agency (ECHA) on the hazardous properties of all substances (except Polymers and non-isolated intermediates) manufactured or imported into the EU in quantities above 1 tonne per year. This is called Registration.
47. During the Registration phase of REACH, new information will be generated and collected. This will mean the classification and subsequent labelling of chemicals will have to be reviewed. By aligning the draft Classification, Labelling and Packaging Regulation with the REACH requirements for the Registration of high volume and particularly hazardous substances, the EC is aiming to reduce the cost of the draft Regulation. Any re-classification and re-labelling required for a specific substance can be carried out at the same time by applying the GHS classification and labelling criteria. Some UK industry representatives have indicated their support for this approach, and the majority of those consulted so far have stated that they would prefer that the provisions of the draft Regulation and REACH were aligned, resulting in duty holders taking the financial and practical arrangements of introducing two new Regulations in one 'hit'.
48. By being one of the first to introduce the GHS, the EU can better influence the content of the GHS others pick up and lead to a quicker adoption of harmonised classification and labelling through future UN GHS negotiations, as well as leading the way in responding to the Johannesburg commitment.
49. However, being among the first to adopt the GHS, the EU may run the risk of delaying any potential financial benefits for EU Member States until other major trading partners have also implemented the GHS. But, given

the amount of preparatory work currently being undertaken by the other major trading partners (such as Japan, the United States and Australia), such concerns are likely to be unfounded. It is recognised, however, that there will be a certain degree of transition as the major trading partners move to implement the GHS.

The ‘building block approach’

50. Recognising that worldwide, some countries have mature classification and labelling systems and some have none at all, the GHS allows governments (or ‘jurisdictions’ such as trading blocks), some flexibility in selecting appropriate parts of the GHS for local implementation. Where a part in the GHS is selected, however, the relevant GHS criteria must be applied. This is known as the ‘building block approach’.
51. The EC has used the building block approach and selected those ‘blocks’ that most closely reflect the current EU system. The outcome is a proposed Regulation that implements all 27 hazard classes (for example ‘Flammable gases’), while still retaining the existing EU class for ‘Hazardous to the ozone layer’ (this complies with the GHS principle of countries not lowering protection and is a continuation of current EU standards). Of the available 83 GHS hazard categories (these distinguish the severity of the hazard classes), the EC is proposing to implement 77, which correspond most closely with the provisions of the current EU system. Therefore, the EC will be implementing the most of the GHS.

Question – Do you agree that the scope of the proposed Regulation should be limited to only those ‘building blocks’ of the UN GHS that most closely reflect the current EU classification and labelling system, together with elements of the EU system that are not yet covered by the UN GHS?

Rationale for EU intervention

52. The EC has chosen to do this by introducing a new EC Regulation (with long transitional arrangements) to replace the existing classification and labelling Directives. The choice of EC Regulation is driven by:
- the precedent of REACH, which is an EC Regulation, and refers to classification and labelling;
 - the experience of the programme of frequent changes to the detail of classifications, which presently Member States have to implement in national legislation (the Adaptations to Technical Progress (ATPs) to the Dangerous Substances Directive and the Dangerous Preparations Directive) – in Great Britain this has meant changes to CHIP every 2 years or so;
 - the knowledge that the UN GHS will continue to be developed at the UN level, resulting in a new edition of the ‘purple book’ every 2 years, with consequential need to update the European Regulation at similar intervals.

Impact of GHS on downstream European legislation

53. To adopt fully the GHS in the EU, it is necessary to amend certain existing EU legislation. The classification of a chemical is sometimes used to 'trigger' the application of 'downstream' regulations or controls. For example, classification of a chemical as a category 1 or 2 carcinogen or mutagen under the existing EU system normally triggers a ban on marketing and use to the general public, and also triggers specific control measures for use at work. Classification of particular hazards, such as flammability, acute toxicity and toxicity to the aquatic environment, together with the presence on site of quantities exceeding qualifying thresholds (typically in the region of 100 tonnes), also triggers application of the requirements to minimise and mitigate the potential for major accidents (the Control of Major Accident Hazard Regulations 1999 which implement the Seveso II Directive (96/82/EC)).
54. Downstream legislation will have to be reviewed and amended to reflect the new GHS hazard classifications. In most cases, this is straightforward because there is a direct correlation between the existing EU classification and the GHS. However, where there is no direct correlation, care will be needed to ensure that the scope of the downstream requirements is not unduly extended as a consequence of adopting the GHS.
55. The EC undertook a study that identified 22 sets of Directives and Regulations that will be affected by the GHS Regulation, although to varying extents. For most, little impact is anticipated because a reference to the new GHS hazard classification will not adversely affect the existing duty or place an additional burden on the duty holder.
56. As a result, the UK Government will be looking closely at the effect of the GHS on our transposing national legislation, with the aim of ensuring that the scope of the existing requirements is not unduly extended as a result of adopting the GHS.
57. The proposed transitional arrangements (see below) should ensure there is time for the EC to review the effect of adopting the GHS and to bring forward the necessary amendments to maintain the current position in terms of scope.

Impact on the CHIP Regulations

58. In Great Britain and Northern Ireland, the CHIP Chemicals (Hazard Information and Packaging for Supply) Regulations 2002, will have to be amended and eventually repealed at the end of the transitional period.

Enforcing regulations

59. Although the proposed Regulation will apply to Member States directly without the need to bring in national legislation, governments will need to bring into force appropriate enforcing regulations.

Practical Implications of the GHS Regulation

60. In practical terms, the introduction of the GHS in the EU will mean:

- some new *scientific criteria to assess the hazardous properties of chemicals*:
- the introduction of *globally harmonised hazard warning symbols (pictograms)*, including two new symbols for the EU. For example (please note the outside 'frame' should be red):



- the introduction of *standard hazard statements for labels*, for example:

H240 - Heating may cause an explosion

H320 - Causes eye irritation

H401 - Toxic to aquatic life

- the introduction of *standard precautionary statements for labels*, for example:

P102 - Keep out of reach of children

P271 - Use only outdoors or in well-ventilated area

P410 - Protect from sunlight

- the introduction of signal words, for example “danger” and “warning”
- the introduction of a duty to notify the European Chemicals Agency (ECHA) of classifications and labels for substances for which there is no harmonised classification, or where the

harmonised classification does not cover all the hazards of the substance

- a shift in the responsibility for classifications from Member State Governments to industry (carcinogens, mutagens, reproductive toxins and respiratory sensitisers will continue to be classified by Member States. All the existing harmonised classifications currently set out in the HSC's Approved Supply List (the UK version of Annex I of the Dangerous Substances Directive) will also remain in place.

Consultation by the European Commission

61. The EC launched a two-month internet-based public consultation on a draft proposed GHS Regulation on 21 August 2006. The consultation ended on the 21 October 2006. It focused on three areas:

- a draft Regulation;
- two impact assessment studies, undertaken by consultants, to assess the potential impact of implementing the UN GHS in the EU; and
- the analysis of potential effects on EU downstream legislation.

62. All responses, including those from the UK Government and UK-based respondents, were published on the Internet¹⁰.

63. Approximately 370 contributions were received. Eighty-two percent of these were sent by industry (companies or trade associations). Out of the 254 industry responses, 45% were received from enterprises with fewer than 250 employees. Ten non-governmental organisations responded. One response from a Trade Union was also received.

64. The EC produced a paper for the UN GHS meeting in December 2006 (see the web link details at footnote 10) stating that 97% of respondents supported the implementation of the GHS in the EU, and out of these 96% supported a direct acting Regulation. The EC also stated that, overall, the draft Regulation was positively received by Member States' authorities and those in industry that responded to the consultation.

Earlier consultation by HSE

65. HSE alerted over 1500 UK stakeholders to the EC's consultation, encouraging them to share their responses with HSE (after Germany, the UK had the highest number of responses per Member State). HSE also initiated an internet-based discussion forum (with around 190 members), as well as a stakeholder event in Birmingham, in September 2006, both designed to prompt debate about issues raised by the EC's consultation and the draft Regulation.

¹⁰ For more information please see: ec.europa.eu/enterprise/reach/ghs_consultation_en.htm

66. In preparing the UK Government's response to the EC draft proposed Regulation and supporting documents, HSE officials also worked closely with other UK Government Departments on the detail of the proposal. A copy of the UK Government response can be found at: <http://www.hse.gov.uk/hse/ghs/>
67. As a result of this consultation exercise, the UK Government indicated its support for implementing GHS in the EU, through a direct-acting Regulation.
68. It is understood that the EC has already responded positively to some of the issues raised by respondents. For example, the UK called for the inclusion of the 7000 harmonised classifications in Annex I of the Dangerous Substances Directive (67/548/EEC) and published in the HSC's Approved Supply List (ASL)¹¹.
69. The EC commissioned two consultancy firms to assess the potential impact of implementing the UN GHS within the EU. Although the two studies contain useful information about the EU chemical industry, there are gaps in the cost and benefit analysis. As the reports are based on a very limited number of responses from stakeholders, a number of assumptions have been made on how GHS will be implemented which may not reflect the proposed arrangements¹².

Transitional arrangements and proposed implementation dates

70. Practical, workable arrangements for migrating from the existing EU system to the GHS criteria are essential, as industry will have to review and adjust, as necessary, the classifications and labels for the chemicals placed on the EU market. The draft Regulation sensibly proposes a two-stage process in which substances are re-classified first, over a 3 ½ year period, and then mixtures over a further 4 ½ years. The potential advantages of changing over these longer timescales need to be balanced against the disadvantages, mainly in terms of cost, of having to run both systems during the transitional period.
71. At the end of the transitional period, the existing Dangerous Substances Directive (67/548/EEC) and Dangerous Preparations Directive (1999/45/EC), will be repealed in their entirety.
72. While the transition period outlined above was supported by the majority of respondents to last years' public consultation by the EC, including the UK,

¹¹ The ASL contains detailed information about substances to help manufacturers, importers and suppliers with responsibilities under CHIP. The List contains information to be shown on labels when the substance is supplied in packages and information to be used to derive the classification and supply labels for preparations containing the substance. For more information please see: <http://www.hse.gov.uk/chip/information.htm>

¹² *Impact Assessment of Implementing the GHS: Work Package 1- Final Report*, RPA, May 2006, and *Impact Assessment of implementing GHS (Globally Harmonised System of Classification and Labelling of Chemicals) ENTR/05/054 – Final Report for work package 2*, London Economics, May 2006.

the benefits from aligning the new Regulation with REACH may, in practice, limit the time available to classify substances.

73. The EC is indicating that the transitional period it envisages started on 1 June 2007, the date on which the initial provisions of REACH came into legal effect. If this approach is agreed, manufacturers and importers will need to notify its substance classifications and labels to the European Chemicals Agency by 1 December 2010, in effect, allowing two years for transition, rather than three.
74. Companies that manufacture or import qualifying volumes of chemicals and have to comply with REACH, may welcome this approach as it prevents a duplication of effort. But others who deal with chemicals in much smaller quantities and have no immediate interest in REACH, may see such an arrangement as more challenging.

Question - Do you agree with the overall timescales being proposed? If you do not agree with the proposed timescales please provide details of a more suitable approach.

STRUCTURE OF THE EUROPEAN COMMISSION REGULATION BASED ON THE UN GLOBALLY HARMONISED SYSTEM

MAIN REGULATION

Title I - General Issues

75. This section details what is in and out of scope of the Regulation, information on the definitions to be used, the obligation to classify substances and mixtures as “hazardous”, or “dangerous” (“dangerous” is included to avoid the extension in scope for REACH and other pieces of European legislation that rely on classification to ‘trigger’ other obligations), together with details of the general obligation to label and package.

Question - If you classify chemicals now, do you think this Regulation introduces new obligations that are not in the existing system? If yes, please explain what you think these are.

Title II - Hazard Classification

76. Title II covers the duty to identify available information on hazards and examine if it is sufficient, adequate and reliable information.
77. Having evaluated all the information, classification is achieved by comparing the data with the criteria for classification for each hazard class and category so as to ascertain the hazards associated with the substance or mixture.

78. The section also sets out when to use specific concentration limits and the classifications of substances included in the classification and labelling “inventory”.

Title III - Hazard Communication in Form of Labelling

79. This section provides the detail required on labels for substances and mixtures that have been classified under Title I.

80. Included are the requirements for hazard pictograms, signal words, hazard statements, precautionary statements, as well as specific rules for confidentiality.

Title IV - Packaging

81. Title IV covers the general rules for packaging, including small or otherwise unsuitable packaging with certain exemptions, and the requirement to use child-resistant fastenings and to incorporate tactile warnings in certain circumstances.

Question - Are the obligations described in the labelling and packaging provisions in the Regulation (Title III and Title IV) reasonable?

Title V - Harmonisation of Classification and Labelling of substances and the Classification and Labelling Inventory

82. The provisions of Title XI of REACH have been moved to this section (amended to reflect the GHS criteria). This section sets out the procedure to add to the harmonised list (either by Member States, or industry), as well as when to ‘notify’ the European Chemicals Agency (ECHA), and details of the ‘classification and labelling inventory’.

Question - Do you have any comments about how the Classification and Labelling Inventory will operate? (Please see Article 43)

Title VI - Competent Authorities and Enforcement

83. This section includes the duties on Member States to appoint a “competent authority/authorities” for enforcement and body/bodies to receive information relating to health (such as Poison Centres). There are also duties on Member States to enforce the provisions of the Regulation, report back to the EC on enforcement activities and introduce penalties for non-compliance.

Title VII - Common and Final Provisions

84. Title VII includes provisions for advertising and the duty on suppliers to keep available all the information required for the purposes of classification and labelling (under the Regulation) for a period of 10 years. The

information should be made available to Competent Authorities when requested.

85. Also included are:

- details of the tasks assigned to the European Chemicals Agency (ECHA) under this Regulation
- the provision allowing the free movement of substances and mixtures that comply with the Regulation throughout the Single Market
- the so-called “safeguard clause”. This allows a Member State to take provisional measures considered necessary to protect people and the environment provided they notify the European Commission
- details on the arrangements for updating the Regulation, principally through Adaptations to Technical Progress (or ATPs).

86. This Title also includes details of the amendments necessary to both the Dangerous Substances Directive and the REACH Regulation, to allow for the introduction of the globally harmonised system and to ensure consistency between the related pieces of legislation.

87. Finally, this Title sets out the detail of the proposed transition period and the expected entry into force date (1 December 2010 for substances, and 1 June 2015 for mixtures).

Summary of the Technical Annexes

Annex I

88. This annex derives from the detail of the UN GHS and is made up of 5 Parts and provides the detailed information on the hazard classes and criteria for physical, health and environmental hazards:

- Part 1 – general principles for classification and labelling
- Part 2 – physical hazards
- Part 3 – health hazards
- Part 4 – environmental hazards
- Part 5 – additional hazard class (this part provides the detail of the EU requirements that, as yet, are not part of the UN GHS. This includes only one hazard class – “hazardous for the ozone layer”).

Annex II

89. This annex is made up of 4 Parts and provides the detail on the rules for labelling and packaging certain substances and mixtures:

- Part 1 – supplemental hazard information (this Part includes the additional labelling provisions not yet covered by the GHS, as well as special rules for labelling certain substances and mixtures).
- Part 2 – special rules for supplemental label elements for certain substances and mixtures
- Part 3 – special rules on packaging (this Part covers the detail for child-proof fastenings and tactile warnings retained from the current EU system).
- Part 4 – special rules for labelling plant protection products

Annex III

90. This annex is made up of 3 Parts and lists the hazard statements (including additional R-phrases not covered by the GHS):

- Part 1 – hazard statements
- Part 2 – supplemental hazard information
- Part 3 – supplementary label elements / information on certain substances and mixtures

Annex IV

91. This annex is made up of 2 Parts listing precautionary statements and when they should be used:

- Part 1 – criteria for the selection of precautionary statements
- Part 2 – precautionary statements

Annex V

92. This annex is made up of 3 Parts and details the GHS pictograms and when to use them:

- Part 1 – physical hazards
- Part 2 – health hazards
- Part 3 – environmental hazards

Annex VI

93. This annex is made up of 3 Parts and provides a list of substances with harmonised classifications for specific hazard classes and categories (this Annex will include entries currently listed in Annex I of the Dangerous Substances Directive (published in the UK as the Approved Supply List), and adapted where necessary to the GHS criteria:

- Part 1 – introduction to the list of harmonised classifications and labelling
- Part 2 – dossiers for harmonised classification and labelling
- Part 3 – harmonised classification and labelling tables

Annex VII

94. This Annex includes a “Translation Table” to convert classifications made under the current Dangerous Substances Directive to the new GHS classifications.
95. However, where there is no direct one-to-one equivalent, the Annex has assigned the least severe classification and places a duty on the supplier to decide if a more severe classification is needed.
96. The Table is designed to help manufacturers, suppliers and importers. The EC are proposing that suppliers can either use the “Transition Table” to convert their self-classified substances and mixtures (where possible) or require the supplier to re-evaluate the classification using the criteria in Annex I of the Regulation.

Question - How helpful do you think this ‘Translation Table’ will be in helping you comply with the new Regulation? If it will not be helpful, please provide details of further information you may require.

MAIN ISSUES FOR CONSIDERATION

97. In negotiating the Regulation, we are seeking to limit, as far as possible, the implications for duty holders, while ensuring that the current levels of protection for both human health and/or the environment are not reduced and competition in the EU chemicals market remains unaffected.
98. As the results of the EC internet-based consultation show, there is broad support for the introduction of the GHS within the EU both from Member States and industry.¹³
99. However, the detail of the Regulation needs to be carefully considered to ensure that it achieves the intended objectives of contributing to a globally harmonised system that can operate effectively in the EU. The aims are to secure the trade benefits of the GHS in terms of harmonised classification and labelling, to limit the costs to UK industry by keeping the scope of the new system broadly in line with the present one, and, by ensuring workable transitional arrangements, to migrate from the existing system to the new GHS criteria.
100. Earlier consultation has raised a number of concerns focused mainly on the potential extension of scope of the Regulation, where the provisions appear to go beyond both the existing EU system and the UN GHS ‘building blocks that most closely reflect them, the roles and

¹³ This is based on the Internet consultation responses and the feedback HSE has received from the UK Permanent Representation in Brussels.

responsibilities of those who form the supply chain, and the possible reduction of the available transition period.

Scope of the Regulation

101. Articles 5 and 6 of the Regulation, set out the duty on a supplier to identify and examine available information which will allow the supplier to classify and label a chemical. However, both Articles state that this information shall relate to the “form or physical state” in which the chemical is “used, or reasonably expected to be used”.
102. As drafted, this provision has the potential to significantly extend the scope of the classification and labelling system by creating a duty to refine, revise or amend a classification (and the subsequent labelling requirements) depending on how a chemical may be used after it has been placed on the market. The current regime requires only classification and labelling according to the hazards present when a chemical is placed on the market.
103. As with the existing European classification and labelling system, we believe the GHS is focused on the inherent hazards of chemicals as supplied and not risks arising from different uses. This provision could result in a move away from the understanding of classification as being based on the inherent hazards present. Classifying for all potential uses could result in more than one entry for a chemical in the Classification and Labelling Inventory leading to confusion, while the need to produce different labels and safety data sheets for different end uses could be costly.

Question – Do you agree with the EC’s proposed new approach to classify chemicals according to their use/s (Article 5.1 for example), rather than classifying what is ‘placed on the market’ (as is the case now)? Please give your reasons, and details of any possible implications for your organisation.

Supply chain – roles and responsibilities

104. The Regulation defines the different “actors” (eg, “manufacturers”, “importers”, “distributors”, “downstream users” etc) in the supply chain and assigns various classification and labelling duties to them, in an attempt to align the Regulation with REACH.
105. The existing system imposes the same duty on all those in the supply chain to ensure that the classification and labelling of the chemicals they deal with are correctly classified and labelled. Enforcing authorities then decide who in the supply chain is at fault when a failing is identified depending on the circumstances. However, the approach set out in the Regulation goes beyond both the existing system and the GHS.

106. Although defining the different actors may suggest a clarification of roles and responsibilities, in the Regulation, the situation is inconsistent and, in places, unworkable.

107. For example, Article 1(b) places a duty on a “supplier” to classify chemicals. “Supplier” means “ a manufacturer, importer, downstream user or distributor placing a substance or mixture on the market”. However, Article 4.1 of the Regulation then removes that duty from distributors, only for Article 4.4 to place an obligation on the distributor to ensure any unchanged label is correct. In practice, how can a distributor fulfil this obligation if they are not routinely classifying and labelling?

Question – Do you agree with the Regulation attempting to split roles and responsibilities for each “actor” in the supply chain (e.g., manufacturer, importer, supplier, distributor, downstream user, as described in Article 4), rather than referring to a ‘supplier’ as is done now? If you disagree, or partly agree, please explain why.

Question - Will this split of roles and responsibilities help you in your business? Please give your reasons, identifying which part of the supply chain you represent.

Scientific research and development

108. The Regulation provides a derogation for scientific research and development. However, the conditions described in Article 1.2(d) apply the highest possible standards, i.e. those for carcinogens and mutagens GHS category 1A or 1B (currently CMR category 1 and 2).

109. This may be over-precautionary, disproportionate to the hazards present and potentially costly, resulting in limited effective research conducted in the EU. A suggested way forward is for the supplier, where the hazards of the chemical are known, to package and label according to the Regulation. If it is not possible to provide a complete label, the label should bear the following: “Warning – substance not yet tested completely” or “Warning – mixture not yet tested completely”, together with “For use only in scientific research and developments”.

Question – Do you agree with the new proposed derogation for scientific research and development as described in Article 1.2(d)? If you don’t agree, or partly agree please explain why.

Child-resistant fastenings and tactile warnings on packages

110. Article 37 sets out the duties relating to child-resistant fastenings and tactile warnings on packages. The technical detail is in Annex II, Part 3.

Child-resistant fastenings

111. Currently, child-resistant fastenings must be fitted to containers containing chemicals classified as toxic or very toxic, corrosive, mixtures containing 3% or more of methanol, 1% or more of dichloromethane and substances which are assigned the “R65 – harmful. May cause lung damage if swallowed” (with exceptions).
112. The Regulation extends the duty by requiring child-fastenings to be fitted to containers supplied to the general public where they contain:
- substances and mixtures classified as acutely toxic (Category 1,2 and 3) and
 - substances and mixtures classified as Specific Target Organ Toxicity – single exposure (Category 1 and 2) and repeated exposure (Category 1)
 - substances and mixtures having ‘skin corrosion’ hazards
 - mixtures containing 3% or more of methanol
 - mixtures containing 1% or more of dichloromethane
 - substances and mixtures presenting ‘aspiration hazards’ (with exceptions).
 - substances and mixtures causing ‘serious eye damage’.

Tactile warnings

113. Currently, tactile warnings are required to be carried by containers containing chemicals classified as toxic or very toxic, corrosive, harmful, extremely flammable (with exceptions), or highly flammable (with exceptions).
114. The Regulation extends this duty by requiring tactile warnings to be carried by containers supplied to the general public where they contain:
- substances and mixtures classified as acutely toxic or STOT
 - substances and mixtures having ‘skin corrosion’ hazards
 - substances and mixtures presenting ‘aspiration hazards’
 - substances and mixtures causing ‘serious eye damage’
 - germ cell mutagenicity (cat 2), carcinogenicity (cat 2), reproductive toxicity (cat 2)
 - flammable gases, liquids and solids,(cat 1 & 2)
 - skin or respiratory sensitisation.

Possible implications

115. The new provisions concerning child-resistant fastenings and tactile warnings have increased the number of individual substances and/or mixtures requiring them. These increases are due partly to the new requirement for “serious eye damage” substances/ mixtures and partly to the new lower specified concentration limits.

116. As a result, these new provisions may increase the number of consumer products having to be fitted with child-resistant fastenings or bear tactile warnings, particularly for certain cleaning products.

Question – do you agree with the extension of the provision for child-resistant fastenings and tactile warnings to cover the additional hazard classes and hazard categories listed? If not, please provide actual examples of products to demonstrate the possible cost and/or practical implications to support your reasons.

GUIDANCE AND ASSISTANCE

117. The European Commission, Member States' Governments (including the UK), industry and others (trade associations, and trade unions for example) will all have a role to play in providing guidance and assistance on what the Regulation is for, and what needs to be done to comply with its provisions. Assistance could be in the form of leaflets, on-line guidance or workshops, for example.

118. Please consider what type of supporting guidance has been helpful to you in the past.

Question - Where do you think guidance would be useful? What type of guidance or assistance will be helpful to you or your organisation in preparing for and complying with the new Regulation? Please also state your order of priority / importance.

UK INITIAL REGULATORY IMPACT / COST BENEFIT ASSESSMENT

119. Before introducing any new piece of legislation, the HSC carries out an assessment of the costs this legislation would impose on industry and other stakeholders, and the benefits it is expected to bring. Since October 1998, this assessment has been included in the Regulatory Impact Assessment (RIA). An RIA is not carried out, however, when the legislation does not impose additional costs to industry.

120. In relation to implementing the Regulation in the UK, HSE has carried out an initial assessment of the costs and benefits that will result from its implementation, as proposed (Appendix 2). HSE estimates that there will be a one-off cost to the UK (industry, Government and other stakeholders) of between £95 million and £215 million spread over the 7½ year implementation/transition period. The RIA also concludes that, depending on the option taken forward, the ongoing costs of compliance with the Regulation will be broadly the same as under the current classification and labelling system.

121. HSC would welcome comment on the Regulatory Impact Assessment to ensure the estimates of the impact and benefits are reasonable (please see Annex E for further details).

INVITATION TO COMMENT

122. The HSC invites comments on these proposals. For your convenience, a response form is included at Annex J, which contains all the questions that appear in both the Consultative Document and the initial Regulatory Impact Assessment. You may find it helpful to use this for your reply. We are happy to receive your written comments in any form convenient to you. We will acknowledge receipt of all comments sent to us and will give them careful consideration. The HSC would also like to know what you think about this consultation, both in terms of content and layout. Your views will help us to improve future consultations.

123. Please send your comments by 2 November 2007 to Jan Harris whose contact details are below:

Jan Harris
International Chemicals Unit
Health and Safety Executive
9SW Rose Court
2 Southwark Bridge
London SE1 9HS

Email: jan.harris@hse.gsi.gov.uk

Telephone: 020 7717 6251

Fax: 020 7717 6891