

**UK INITIAL REGULATORY IMPACT ASSESSMENT
ON THE PROPOSED EUROPEAN REGULATION ON THE
CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES
AND MIXTURES (BASED ON THE UN GLOBALLY HARMONISED
SYSTEM)**

(July 2007)

1. This is an initial Regulatory Impact Assessment (RIA) considering the UK's negotiation of the European Commission's draft proposal for a Regulation of the European Parliament and of the Council on the Classification, Labelling and Packaging of Substances and Mixtures (based on the UN Globally Harmonised System – the GHS).

1. PURPOSE AND INTENDED EFFECT

1.1 Issue

2. This document examines the impact on the UK of the above proposed Regulation to implement the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS) within the EU. This assessment is subject to change as more information becomes available and negotiations progress. At present, the European Commission (EC) is negotiating with Member States on how the UN system should be implemented into European law.

1.2 Objectives

3. The overall aim of the UN GHS is to have the same criteria worldwide to classify and label the hazards of chemicals, and so promote their responsible handling and use at a global level. The UN believes that the GHS will also reduce trade barriers, facilitate the worldwide trade in chemicals, and, at the same time, protect human health and the environment.
4. The UN GHS is expected to promote sustainability on a global scale, in particular through the intended improvement in human health and environmental protection, through higher economic efficiency as a result of increased global trade and competition, and through the inclusion of developing countries in the global trade in chemicals. These goals are in line with the global, EU and UK sustainable development¹⁴ objectives¹⁵.

¹⁴ **Sustainable development** - A widely-used and accepted international definition of sustainable development is: 'development which meets the needs of the present without compromising the ability of future generations to meet their own needs', taken from the UK Sustainable development Government website: www.sustainable-development.gov.uk

¹⁵ **European Commission** - *Global Europe: Competing in the world. A contribution to the EU's growth and jobs strategy* (October 2006), and *Securing the Future – The UK*

5. The current EU classification and labelling system for supply and use of chemicals is mature, well developed, and widely understood. It is unlikely the EU (and therefore the UK) will experience significant benefits for human health or environmental protection from implementation of the United Nations Global Harmonised System of Classification and Labelling of Chemicals (GHS), compared with the current EU classification and labelling system. It is countries that as yet do not have a regime in place to control the supply and use of hazardous chemicals, that are expected to benefit the most from the UN GHS, and for them it will be a significant step forward in the safer management of chemicals.
6. The principal economic benefit of the GHS for the EU, and therefore the UK, is considered to be the facilitation of international trade, over the longer term, due to the lowering of technical barriers to trade. Despite the limitation on the benefits for Europe, the UN GHS has benefited from political and industry support since its inception¹⁶. All costs and benefits are explored more fully later in the RIA.
7. In order to achieve the 2008 deadline for implementation (which the UK signed up to in the 'Plan of Implementation' adopted in Johannesburg in September 2002¹⁷), in August 2006 the European Commission (EC) launched an Internet based consultation on a draft Regulation to adopt the United Nations' Global Harmonised System of classification and labelling of chemicals (GHS). The European Commission has reported that responses to its Internet based consultation have indicated broad support for the UN GHS¹⁸.
8. The proposed draft European Regulation on Classification, Labelling and Packaging of substances and mixtures will replace the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC), which are both implemented as the Chemicals Hazard Information and Packaging for Supply (CHIP) Regulations in Great Britain.
9. In practical terms, the introduction of the UN GHS in the EU will mean:
 - New scientific criteria to assess the hazardous properties of chemicals;

Government Sustainable Development Strategy (March 2005) www.sustainable-development.gov.uk/publications/uk-strategy/index.htm.

¹⁶ For example, the European Commission has reported that of the 370 responses received to its Internet consultation, 97% of respondents (including 254 from industry) were supportive of the implementation of the GHS in Community law, please see:

www.unece.org/trans/doc/2006/ac10c4/UN-SCEGHS-12-inf08e.doc.

¹⁷ www.johannesburgsummit.org

¹⁸ For example, the European Commission has reported that of the 370 responses received to its Internet consultation, 97% of respondents (including 254 from industry) were supportive of the implementation of the GHS in Community law, please see:

www.unece.org/trans/doc/2006/ac10c4/UN-SCEGHS-12-inf08e.doc.

- New globally harmonised hazard warning symbols (called pictograms); and
 - New standard hazard warning and precautionary statements for labels.
10. The new European Regulation will be directly applicable in the UK. Once the Regulation has been adopted at the European level, the UK will only need to introduce limited supplementary legislation, including providing for enforcement and penalties for non-compliance. In addition, as the proposal will replace, or amend, a number of existing measures (Directive 67/548/EEC for example), the repeal or amendment of several UK legislative instruments will be necessary, primarily CHIP (Chemicals Hazard Information and Packaging for Supply) Regulations¹⁹, which implement the existing European classification and labelling legislation.
11. As currently drafted, the provisions of the GHS based Regulation will apply to substances 3.5 years after the entry into force of the REACH Regulation (i.e. 3.5 years after 1 June 2007), and to mixtures a further 4.5 years later. This will mean that the existing European classification and labelling legislation will not be fully repealed until June 2015.
12. Finally, in line with better regulation principles, the proposal seeks to enhance the transparency of European classification and labelling legislation, and to simplify legislation, through the replacement of 2 European Directives, including 10 amendments and more than 30 adaptations to technical progress, with one Regulation.

2. BACKGROUND

13. 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.
14. 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*²⁰ (SDS), for the same product in different countries. Through these variations in definitions of hazards, a chemical may, for example, be classified as flammable in one country, but not in another.

¹⁹ For more information on CHIP please see: www.hse.gov.uk/chip

²⁰ 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.

15. Decisions on when or how to communicate identified hazards also vary around the world. Businesses wishing to be involved in international trade must have resources available to advise on the different requirements of these laws and regulations in different countries, and to prepare different labels and SDS for international trade. These activities can be undertaken internally by businesses or can, in some cases, be outsourced at some cost.
16. Under existing legislation, a chemical may have to be classified and labelled in several different ways to comply with various countries' legal requirements. The examples below show the range of different symbols and styles currently in use around the world:

EU



'Skull and Crossbones'

Canada



'Flammable and combustible'

17. Once countries have consistent and appropriate information on the hazardous properties of the chemicals they import or produce in their own countries, the infrastructure to control chemical exposures, and to protect people and the environment, can be significantly improved.
18. Given the extensive global trade in chemicals, and the inconsistencies (and sometimes complete lack) of chemical classification and labelling systems worldwide, it was recognised that an internationally harmonised approach to classification and labelling was needed.

2.1 Current EU Classification and Labelling System for Supply

19. The EU has in place a long-established system (dating back to 1967) that results in harmonised (agreed) classifications for the most hazardous substances, as well as providing rules for self-classifying other substances and preparations (to be called "mixtures" under the new Regulation), and providing instructions on how identified hazards are to be communicated to users. This is achieved by requirements for standardised labelling that contain both symbols and information to explain the hazard(s) present. Appropriate and proportionate protection controls can then be applied.
20. This system has proven to be successful. There are well established criteria within the European Union for identifying the hazards of chemicals

to human health and the environment. Within the general scheme approximately 8000 substances have been assigned harmonised classifications and labelling requirements, protecting people and the environment, and ensuring a fair and level playing field in the chemicals market across the EU.

21. The current UK classification and labelling system is based on three pieces of EU legislation: 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 the UK as the Chemicals (Hazard Information and Packaging for Supply) (CHIP) Regulations²¹.
22. Examples of current EU labelling symbols, “risk phrases”, and “safety phrases” are provided below.

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



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**

²¹ For more information on CHIP please see: www.hse.gov.uk/chip

23. The Earth Summit held in Rio de Janeiro in 1992 generated an

globally harmonised hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols”.

24. The work on the UN GHS began with the examination of the major existing classification and labelling systems (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 should not be reduced as a result of harmonizing the classification and labelling systems”²².

25. The UN GHS aims at ensuring that information on the hazardous properties of chemicals is available, in order to enhance the protection of human health and the environment during the supply and use of hazardous chemicals. The UN GHS also provides a basis for harmonisation of regulations on chemicals at national, regional and worldwide level, as an important factor to facilitate trade.

26. 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 recognized framework for those countries without an existing system;
- reduce the need for repeat testing (including animal testing) and evaluation of chemicals for classification and labelling purposes; and
- facilitate trade in chemicals whose hazards have been properly assessed and identified on an international basis²³.

27. The idea behind the UN GHS is that if there was one system, not only would developing countries be able to implement that system (the UN and ILO are encouraging the uptake of the GHS system – further details are in Annex 1), but, as the hazard classification and labelling system would be consistent, those receiving the chemicals will more readily understand the information, leading to an increase in protecting of both human health and the environment.

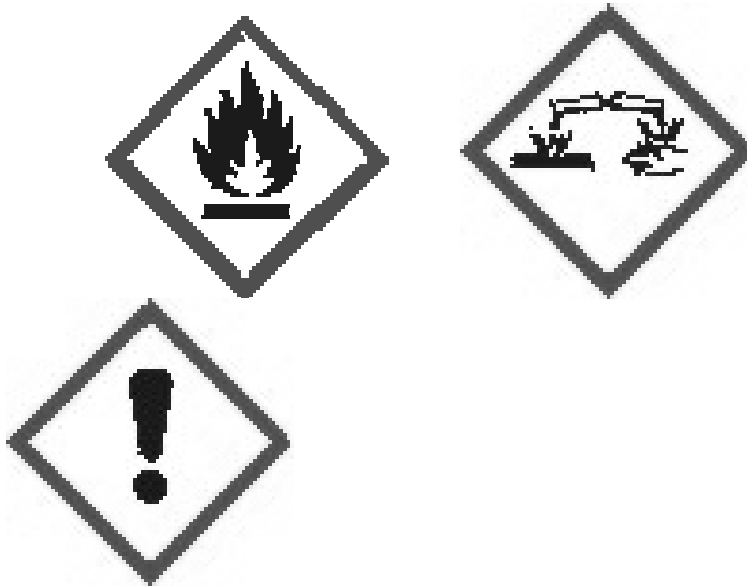
28. *In practical terms, the introduction of the UN GHS in the EU will mean:*

²² *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, First revised edition, UNITED NATIONS, New York and Geneva, 2005, p.4

²³ *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, First revised edition, UNITED NATIONS, New York and Geneva, 2005, p.3

- *New scientific criteria to assess the hazardous properties of chemicals:*

- *New globally harmonised hazard warning symbols (called pictograms), for example:*



New standard hazard statements for labels, for example:

H240 - Heating may cause an explosion

H320 - Causes eye irritation

H401 - Toxic to aquatic life

New 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

2.3 The UN GHS 'building block' approach

29. In order to encourage the global adoption of the GHS, the United Nations system allows a certain degree of flexibility. This means countries (or trading blocks) can elect to introduce either all, or only selected parts of the GHS. The European Commission (EC) has committed to introduce the

UN GHS elements that most closely reflect the scope of existing EU system.

30. The European Commission is currently proposing to implement all 27 'hazard classes' (for example 'Flammable gases') and to retain the existing EU class for 'Hazardous to the Ozone layer'. This complies with the GHS principle that countries should not lower protection levels, as it is a continuation of current EU standards. Of the available 83 UN GHS 'hazard categories' (these distinguish the severity of the 'hazard classes'), the EC is proposing to implement 77²⁴. Therefore the EC will be implementing the vast majority of the UN GHS. It is envisaged that over time full global harmonisation will be achieved worldwide, although exact timescales are difficult to predict.
31. It is worth noting that the UN GHS is based on the chemical regimes of the major chemical markets (including the USA, Canada, the EU and Japan), and much of the UN GHS is based on the EU system, so it is broadly similar to the existing EU system in many ways. For example, as currently drafted, there will only be minor changes to the hazard warning symbols, with the introduction of a few new symbols. Radical changes are not anticipated due to the introduction of the GHS Regulation.
32. The most important similarities between the UN GHS and the existing EU system include²⁵:
- Both systems provide for one single system for hazard classification and labelling.
 - The UN GHS covers virtually all hazards that are currently covered by the EU system (and allows additional hazards if they are not covered by the GHS).
 - The UN GHS mostly uses broadly similar or equal classification criteria.
 - The UN GHS sets up a system of hazard communication that is equivalent to the EU system, with both consisting of labels and safety data sheets. In particular the GHS adopts the EU approach to safety data sheets, including the 16 headings under which the information is required to be presented in the EU.
33. There will, however, be some changes in classification within a hazard class. For example, for acute toxicity, the UN GHS had 5 hazard classes. Four of these are planned to be adopted in the EC GHS based Regulation (applying the 'building block' approach), aligning with the existing lower boundary for 'harmful' in the existing EU system. However, in the existing

²⁴ The draft Regulation does not include: Flammable liquids category 4, Acute toxicity category 5, Skin corrosion/irritation category 3, Aspiration hazard category 2, Acute aquatic toxicity category 2, and Acute aquatic toxicity category 3.

²⁵ 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

EU system there are 3 categories (Very Toxic, Toxic, and Harmful) whereas under the UN GHS there will be four categories (1, 2, 3 and 4).

2.4 GHS Implementation world-wide²⁶

34. One of the main risks of implementing UN GHS within the EU is that at present it is a voluntary agreement at the UN level and countries are not obliged to implement it. However, it is considered highly unlikely that the majority of the EU chemical industry's trading partners will fail to implement the GHS, as the majority committed to an implementation date of 2008 (having signed up to the 'Plan of Implementation' adopted in Johannesburg in September 2002²⁷).
35. A summary of the plans for up-take of the GHS within a number of major EU trading partners can be found in Annex 1.

2.5 EC Regulation - Step Forward not immediate 'Full Global Harmonisation'

36. It is important to point out that the implementation of the draft EC Regulation will not immediately lead to a fully harmonised global system for classification and labelling of hazardous chemicals worldwide. The principle that no country or trading block should be forced to lower its standards on implementing the GHS would mean that full harmonisation could only be achieved if every country adopted the highest standard at the outset. This is not practical or necessarily desirable.
37. The EC proposal is, however, seen as a major step change towards a truly harmonised system, and that full harmonisation will be achieved over time. This is for a number of reasons including:
- An immediate transition from the existing plethora of classification and labelling systems to one single system worldwide is not considered to be realistically achievable, or necessarily desirable. Therefore, it would be preferable to have a step-by-step approach to implementing a fully harmonised system, amending and refining the system as it is developed.
 - The flexibility within the UN GHS system (called the 'building block approach'- which allows countries to pick up, or leave different 'building blocks') means that initially most countries are expected to pick up the sections of the GHS which most resemble their current system. However, the EC proposal is a major step change towards a fully harmonised system. At a recent meeting on the UN GHS in Germany, industry representatives predicted that it could be 20-30 years before the full benefits of a completely harmonised GHS are achieved.

²⁶ Information on the implementation of the GHS has been taken from:

www.unece.org/trans/danger/publi/ghs/implementation_e.html

²⁷ www.johannesburgsummit.org

38. The current proposal will mean that when the UN GHS is implemented several of the major chemicals trading partners for the UK (including the US, EU, Canada, Australia and Japan) will all be using virtually the same classification criteria, and communication terminology, which will be a major step forward from the existing situation. However, the new EC Regulation will not immediately result in a fully harmonised system worldwide. The full benefits of the UN GHS will not be realised for many years. The benefits section of this RIA will explore this further.

2.6 Future Amendments to the UN GHS

39. The UN GHS is continually being refined and amended through a two-year work programme of the UN Sub-Committee of Experts on the GHS (SCEGHS) (which the UK attends and contributes to). It is envisaged that the draft EC Regulation will be amended by means of a technical adaptation in step with the 2-yearly revisions to UN GHS. This parallels the current EU system, which is updated periodically through similar technical updates. It should also be noted that changes to the UN GHS are agreed by consensus.

2.7 Impact of the GHS Regulation on other European Legislation

40. The European Commission has undertaken a study of the impact of the draft European Regulation on 'downstream legislation'²⁸.

41. The European Commission's report was necessary because approximately 20 pieces of European legislation refer to, or are 'triggered' by, the Dangerous Substances Directive, and/or the Dangerous Preparations Directive in some way²⁹. In anticipation of both these Directives being repealed by the proposed Classification, Labelling and Packaging Regulation, assessments need to be made to ensure that the introduction of the GHS criteria, terminology or provisions will not have an unintended consequence on (i.e. inadvertently extend the scope of) other existing European legislation, requiring more stringent and costly controls.

42. For the most part the study concludes that the introduction of the draft Regulation based on the GHS will not have a particular impact on existing legislation. However, the study acknowledges that the Classification, Labelling and Packaging Regulation is likely to have a greater impact on the Seveso-II Directive (implemented in the UK through the Control of Major Accident Hazards Regulations 1999 (COMAH)).

²⁸ The term 'downstream legislation' means any piece of legislation that is referenced in the legislation being introduced or altered. For example there are many pieces of European legislation that refer to the Dangerous Substances Directive (67/548/EEC), such as the Control of Major Accident-Hazards involving Dangerous Substances (96/82/EC).

²⁹ See Annex 2 (Affected European Legislation) for more information

43. The UK has welcomed the study, but remains concerned that, in practice, the impact on downstream legislation is not as straightforward as the EC study presents. The HSE will continue to encourage the European Commission to amend all affected community legislation prior to June 2015, with the intention, in the first instance, of maintaining the current status quo in terms of chemicals caught in the scope of the downstream legislation.
44. Details of which European legislation will be amended within the draft Classification, Labelling and Packaging Regulation, and which will be amended in a separate review are listed in Annex 2. However, this approach does not consider that Directives are transposed at the national level by Member States. Any change to a Directive would need to be assessed at the national level and amendments/the repeal of national legislation may also be required.
45. HSE has also initiated a review of the affected UK legislation, with the intention of minimising the impact of any change, and to prepare to remove/amend any existing legislation that implemented the requirements of the previous system prior to the removal of the existing EC legislation (by June 2015).

REACH

46. The new Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, introduces a process under which hazard and safety data must be provided for all existing and new substances, providing a basis for classification and labelling³⁰.
47. REACH contains basic requirements for the testing of substances, from which a substance or mixture can then be classified. However, REACH does not provide classification criteria, but instead relies on the existing Dangerous Substances and Dangerous Preparations Directives (and, once implemented, the new GHS criteria).
48. As safety data sheets will be one of the main tools for communication in the REACH Regulation, it is proposed that the provisions to provide safety data sheets (currently in the Safety Data Sheet Directive (91/155/EEC)) will remain within REACH, and will not be part of the new Classification, Labelling and Packaging Regulation (based on the GHS). The requirements in REACH are consistent with the UN GHS agreement. It is envisaged that this will not affect businesses, as the Safety Data Sheet requirements will be exactly the same under both REACH and the proposed GHS Regulation.
49. The European Commission has decided to amend the affected sections of the REACH Regulation within the draft Classification, Labelling and

³⁰ For more information please see:
www.defra.gov.uk/environment/chemicals/reach/index.htm

Packaging Regulation to avoid any extension in the scope of the REACH due to the introduction of the draft Regulation.

50. In order to avoid 'double counting' of costs and benefits, this RIA will only cover the impact of the proposed Classification, Labelling and Packaging Regulation. A separate RIA has already been undertaken by Defra for the impact of the REACH Regulation³¹.

2.8 Timing of the proposed European Regulation

51. In Johannesburg, in September 2002, all EU Member States signed up to the recommendations of the UN World Summit on sustainable development, which included the implementation plan to have the GHS fully operational on a global scale in 2008. As the classification and labelling of chemicals is already regulated at the Community level rather than the national level, the Member States called on the Commission to come forward with a proposal to implement the GHS in the EU.
52. The European Commission is also aiming to minimise the cost of implementing the GHS Regulation, by aligning it with trigger dates in the REACH Regulation (June 2008, one year after entry into force of the REACH Regulation). The classification and labelling of chemicals must be reviewed once the REACH Regulation enters into force. During the registration phase of REACH, new information will be generated and collected to meet the requirements of REACH. This will mean that the classification, and subsequent labelling, will have to be reviewed. This will be necessary regardless of whether the existing or new GHS classification and labelling system is in place.
53. The EC believes that, during the registration phase of REACH, as new data is generated, any reclassification and re-labelling, required for a specific substance, can be carried out at the same time by applying the GHS classification and labelling criteria. A number of representations made by the UK chemicals industry to HSE also support this approach, and the majority of stakeholders consulted have stated that they would prefer that the provisions of the GHS and REACH Regulations come into force together. Industry would prefer to take 'one hit', rather than two changes in quick succession.
54. There is a risk that, as the EU will be one of the first to legislate to introduce the GHS agreement, other major trading partners will fail to take up the GHS. At present, it is believed to be unlikely that this situation will occur given the amount of preparatory work undertaken by the other major trading partners (such as Japan and the United States). It is highly unlikely that other major trading partners will implement the GHS at exactly the

³¹ A copy of the Defra REACH RIA can be found at:
www.defra.gov.uk/environment/chemicals/reach/index.htm

same time, and in exactly the same way, as the EU (3 years for substances and a further 4.5 years for mixtures).

55. By implementing early (being one of the first to introduce the GHS), it is expected that the EU can better influence the content of the GHS that others pick up, and better influence future UN GHS negotiations, by leading the way in responding to the Johannesburg commitment. However, this approach runs the risk of delaying any international trade benefits for EU Member States until other major trading partners have also implemented the GHS.

2.9 Rationale for government intervention

56. The main purpose of a common classification and labelling system for chemicals is to provide a coherent approach to defining and classifying hazardous properties of chemicals and to communicate hazard information (via product labelling and safety data sheets), and to reduce confusion and potential risks that may otherwise arise from a lack of information regarding the hazardous properties of chemicals.
57. By increasing awareness of the hazards to human health and environment associated with specific chemicals, chemical classification and labelling increases the extent to which consumers and users of chemicals are able to effectively manage the use of chemicals, either through precautions and protective measures in the use of specific chemicals, reducing exposures, or by switching to alternative, less hazardous chemicals. In turn, it is expected that benefits would be obtained in terms of reducing the risks to human health and the environment from exposure to, or release of, chemicals.
58. As previously summarised, the European Union already has a mature, well developed classification and labelling system for the transport and supply of chemicals, set out in EU Directives. For the supply of chemicals, these are implemented in the UK by the Chemicals (Hazard Information and Packaging for Supply) (CHIP) Regulations³². However, there are, currently, several different regulatory systems worldwide, for classifying and labelling chemicals. It is likely that the existence of different systems generates barriers to international trade, by increasing the costs to businesses of exporting products to areas that apply a different classification and labelling system, therefore reducing international trade in chemicals, and restraining competition in domestic markets. Therefore, there may be benefits in terms of increased international trade and competition, from implementing the GHS within the EU.
59. A further rationale for implementing the UN GHS is that an internationally consistent approach to classification and labelling of chemicals will support the development of chemical classification and labelling regimes in

³² For more information on CHIP please see: www.hse.gov.uk/chip

developing countries. Developing countries have lagged behind developed countries in the development of such systems. An internationally consistent approach will reduce difficulties that developing countries may otherwise have in establishing adequate, internationally acceptable, standards within their existing technical capacity and resources.

60. In order to adopt the UN GHS in the EU it is necessary to amend existing EU legislation. The EC has chosen to do so by introducing a new EC Regulation on the Classification, Labelling and Packaging of substances and mixtures, to replace (with long transitional arrangements) the existing Directives. The choice of an EC Regulation is driven by:

- precedent of REACH, which was an EC Regulation;
- experience of frequent changes to the EU Directives, which Member States then have to transpose in national legislation (as illustrated by frequent changes to CHIP);
- knowledge that the UN GHS will continue to be developed at the UN level, and consolidated in a new edition of the 'purple book' every 2 years, so there will be a need for frequent changes at the EU level.

61. The UK Government, together with other EU Member States signed up to the GHS at the UN Earth Summit in 1992, and reinforced its commitment to the 2008 deadline for implementation at the World Summit on Sustainable Development (WSSD) in 2002.

62. If the UK fails to participate fully in the Member State negotiations, the opportunity would be missed for the UK to influence the adoption of the new classification and labelling system in Europe. The UK Government is well respected in the chemicals arena, and the EC responded positively to many of the UK's comments in its response to the two-month Internet consultation. We wish to influence the EU proposal further by fully engaging in the forthcoming negotiation process.

63. As the proposed Regulation is currently drafted, the UK has a number of concerns, which it would wish to resolve during the negotiation process. These concerns are mainly regarding the extension of scope (beyond both the existing provisions and the UN GHS), and regarding the practicalities of some proposed provisions. The UK wishes to see the implementation of a Regulation that is as light-touch as possible, limiting burdens on stakeholders, whilst being practical and not reducing the current levels of protection enjoyed by workers, consumers and the environment in the European Union. Further details of the main concerns that the UK wishes to negotiate are considered further in the options and cost and benefit sections of this assessment.

64. In the past, the UK Government has fully supported the principle of the UN GHS, which is in line with its stance on sustainable development and globalisation. The UN GHS has enjoyed political support throughout its development, and a commitment to implement the UN GHS was signed by

the UK Government (and all other EU Member States) at the 2002 Johannesburg summit.

65. The results of the EC Internet-based consultation, in 2006, also indicate that there is broad support for the introduction of the GHS within the EU. The Portuguese and Slovenian Presidencies of the European Union have also signalled they are keen to progress the draft Regulation negotiations as far as possible during their tenures, and all other Member States appear keen to introduce the GHS with the EU³³.

2.10 Importance of International Trade

66. Data gathered by CEFIC (European Chemical Industry Council) in 2005³⁴ shows the pattern of sales of chemicals from the European Union chemical manufacturers, by country of destination. This data indicates that, for European Union countries, domestic markets represent, by value, 26% of sales, and intra-EU trade represents 49% of sales (by value). Exports of chemicals to countries outside the European Union accounts for the remaining 25% of sales.

67. According to data produced by the UK Chemical Association, for UK firms, exports of chemicals to countries outside the EU account for a higher proportion of total exports than shown by the CEFIC data for the European chemicals industry as a whole. Approximately 40% of UK exports, by value, are to non-EU countries³⁵. It is also worth noting that the EU is the only major economic region with a positive trade balance in chemicals (the total value of exports of chemicals is higher than the total value of imports of chemicals).³⁶ According to data from the UK Chemical Association, around two-thirds of imports, by value, into the UK are from within the EU, and approximately one-third are from outside the EU³⁷.

3. INITIAL CONSULTATION

3.1. Consultation by the European Commission

68. The European Commission undertook a two-month Internet based public consultation on the proposed draft GHS Regulation on the 21 August 2006. The consultation ended on the 21 October 2006. It focused on three areas:

- the legislative proposal;

³³ This is based on the Internet consultation responses and the feedback HSE has received from the UK Permanent Representation in Brussels.

³⁴ *Impact Assessment of Implementing the GHS: Work Package 1- Final Report, RPA, May 2006, p.7*

³⁵ For more information please see Table 3 in Annex 2.

³⁶ *ibid.*

³⁷ *ibid.*

- two impact assessment studies undertaken by consultants; and
- the analysis of potential effects on EU downstream legislation.

69. All responses, including those from the UK Government and UK-based respondents, were published on the Internet³⁸.

70. Approximately 370 contributions were received. Around 82% of these were sent by industry (companies or associations). Out of the 254 company responses, 45% were received from enterprises with less than 250 employees. Ten Non-Governmental Organisations responded. One response from a Trade Union body was also received.

71. The EC produced a paper for the UN GHS meeting in December 2006, stating that 97% of respondents supported the implementation of the GHS in EU, and out of these, 96% supported a Regulation. The EC also stated that, overall, the draft Regulation was positively received by Member States authorities and industry.

72. A copy of the UK Government response can be found on www.hse.gsi.gov.uk/ghs. The European Commission has already taken into account a number of the concerns raised by the UK (and other stakeholders) including, for example, transferring the entirety of Annex I of the Dangerous Substance Directive into the new Regulation to ensure all the work of the last 30 plus years are not lost, and to reinstate the current exemption for munitions from the classification and labelling requirements.

73. The European Commission commissioned two consultancy firms to assess the potential economic impact of implementing the UN GHS within the EU. Whilst the studies contain useful information about the EU chemical industry, there are a number of assumptions and gaps in the cost and benefit analysis. The reports are based on a very limited number of responses from stakeholders³⁹. In the absence of other available data, this RIA has used data from these impact assessments. However, where possible, this RIA has endeavoured to obtain more accurate information, and to improve the estimates provided by the reports produced on behalf of the European Commission. This RIA also takes, as appropriate, a UK rather than European perspective in assessing the impact of the GHS Regulation.

3.2 Consultation in the UK

Within Government

74. In preparing the UK Governments response to the EC draft proposed Regulation and supporting documents, HSE officials worked closely with

³⁸ For more information please see: ec.europa.eu/enterprise/reach/ghs_consultation_en.htm

³⁹ *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.

other UK Government Departments on the detail of the proposed Regulation and its supporting documentation. The Business, Enterprise and Regulatory Reform (BERR), the Department for the Environment, Food and Rural Affairs, the Department for Transport, the Environment Agency, the Scottish Environment Protection Agency, HM Treasury, the Better Regulation Executive (now within BERR), the BERR's Small Business Service, the Department of Health, the Local Authorities Co-ordinators of Regulatory Services, and the Northern Ireland Health and Safety Executive have all been actively consulted since the launch of the EC Internet consultation.

Stakeholder Consultation

75. HSE alerted over 1500 UK external stakeholders to the European Commission's consultation, encouraging them to share their responses with HSE (after Germany, the UK had the highest number of responses per Member State).
76. HSE also initiated an Internet based discussion forum (with around 190 members) designed to prompt debate about issues raised by the EC's consultation and the draft Regulation. HSE posed a number of questions on the forum, targeting such issues as cost, benefit, increased trade opportunities and the detail of the Regulation itself. These points, and others, were explored in more detail at a Stakeholder Event in Birmingham, in September 2006. Stakeholders were encouraged to consider the practical implications of the Regulation, including compliance costs and anticipated benefits such as increased trade opportunities.
77. An example of responses received by HSE includes the 'Joint Industry Statement on the Proposal for GHS Implementation in the EU' from the Confederation of British Industry (CBI), the Chemicals Industries Association (CIA), together with a number of other representatives of UK industry organisations⁴⁰. In the statement the organisations supported the concept of the GHS and welcomed the EC proposal to implement the GHS Regulation at the same time as REACH Regulation. Reservations remained as to whether the GHS, within the EU or otherwise, will be a truly globally harmonised system immediately.
78. BERR has also established a 'rapid response group' from a diverse range of industry stakeholders, to assist and review amendments to the policy as it develops. This has been done to ensure stakeholder views continue to be taken on board during negotiations.
79. As part of the Small Firms Impact Test, HSE also contacted a number of small firms, and trade bodies responsible for small business. Policy

⁴⁰ The 'Joint Industry Statement on the Proposal for GHS Implementation in the EU' paper presented the view of the British Association for Chemical Specialities (BACS), the British Coatings Federation (BCF), the Chemical Business Association (CBA), the Confederation of British Industry (CBI), the Chemicals Industries Association (CIA), the Cosmetic Toiletry and Perfumery Association (CTPA) and the UK Cleaning Products Industry Association (UKCPI).

officials also produced a paper, and gave a presentation at the January meeting of the Small Business Trade Association Forum.

80. In August 2007 HSE will launch a formal 12 week consultation on the draft Regulation and this RIA. HSE will also continue to undertake stakeholder consultation throughout the negotiation and implementation process, and the responses that are received will help to inform the UK negotiating line.
81. Consultees are invited to contribute to the development of this Regulatory Impact Assessment and the UK negotiating position by providing information to develop and refine the costs and benefit assumptions made in this RIA. Where you consider that the assumptions and/or estimates are inaccurate, please provide the necessary supporting detailed information to improve the RIA.

4. OPTIONS

Option 1 – ‘Do nothing’ - Adopt/accept Commission’s proposed draft Regulation without any negotiation

82. The European Commission has presented the draft Regulation together with a detailed supporting package, including impact assessments and a study of the effects of GHS on downstream European legislation. The UK Government could ‘do nothing’ during the negotiations and accept the scope and intention of the draft Regulation and accept the outcomes of the negotiations as agreed by other Member States.
83. This option would result in the UK not challenging the intention, scope and transition arrangements, or other aspects of the European Commission’s proposals. Such an approach could lead to a significant extension in the scope and costs of the existing classification and labelling system.
84. Without input from the UK there could be areas where the Commission has either intentionally, or unintentionally, extended the scope of the Regulation beyond either the existing system, or the UN GHS agreement. If the UK was not to negotiate, it could not influence the Regulation, nor ensure that the Regulation is as light-touch as possible, avoiding any ‘gold-plating’.
85. If the UK Government were not to actively negotiate there is a risk that other Member States (based on past performance) may attempt to extend the scope of the GHS Regulation in order to either increase environmental/human health protection beyond the existing provisions,, without due consideration of wider practical or financial implications. For example, other Member States have suggested extending the scope to include ‘category 5’ acute toxicity. This would extend the provisions beyond the existing EU system, something the UK Government would want to avoid without evidence of significant benefit and stakeholder support.

Option 2 – Oppose the introduction of the Regulation based on the UN GHS

86. This option would involve opposing the introduction of the UN GHS as a Regulation in the European Union, and supporting the maintenance, in the European Union, of the existing chemicals classification and labelling directives, as implemented in Great Britain by the Chemical Hazard Information and Packaging for Supply Regulations. This option provides the baseline against which other options are considered in this impact assessment.
87. The existing European classification and labelling system, although beneficial to the Single European Market, does not provide the same level of protection in non-EU markets where it is not applied.
88. The responses to the EC Internet-based consultation, and the representations made to HSE, have suggested that there is stakeholder support for the introduction of the UN GHS in the EU.
89. A consequence of actively opposing the proposed GHS Regulation, if such an attempt were successful, would be to retain the barriers to international trade in chemicals that are presented by the existence of multiple classification and labelling systems. The international trade, and international development, benefits of implementation of GHS are considered later in this impact assessment.
90. The costs and benefits of this option are dependent upon whether the UK could successfully influence all other Member States and the EC to not implement the UN GHS, and to retain the current classification and labelling system within the European Union.
91. The UK chemical industry benefits from the single trading area, and single classification and labelling system, provided by the Single Market. However, as identified in the background section of the RIA a number of the key UK chemical trading partners are already preparing for the introduction of the UN GHS by the end of 2008. UK firms that export outside the EU would in any event have to classify and label according to the UN GHS as it is, over time, adopted in other countries and trading blocks.

Option 3 – Active negotiation –Support the introduction of the UN GHS, making it as light-touch as possible, avoiding any ‘gold-plating’

92. This option would involve supporting the introduction of Regulation based on the GHS, but negotiating to avoid extension of scope or ‘gold plating’ of the Regulation.
93. HSE has identified a number of issues where the requirements in the proposal appear to go beyond the provisions of the GHS and the

requirements of the existing EU classification and labelling system. These include, for example, whether classification relates to the state or form in which the substance or mixture is placed on the market, or in which it is subsequently used; the conditions associated with derogations for research and development; and the proposed differentiation in the duties placed on different parts of the supply chain.

94. In addition we have highlighted the need for the EC to consider how it can assist SMEs with the introduction and/or compliance with the new GHS Regulation. The UK will continue to have a dialogue with the EC to ensure the requirement of SMEs are considered at a European level.

95. The overall aim of the UK negotiation is to ensure the new GHS Regulation does not extend the provisions or scope of the new Regulation beyond that of the existing system, or the UN GHS building blocks that most closely reflect it.

5. COSTS AND BENEFITS

5.1 Sectors and groups affected

96. The whole of the UK chemicals industry, the chemicals supply chain including downstream businesses that use chemicals as an input to production, wholesalers and retailers, and consumers, of chemical products, are expected to be affected by the proposed GHS Regulation. This impact assessment has identified six main groups as affected by the Regulation: chemical manufacturers; downstream businesses; wholesalers; retailers; the public authorities; and retail consumers of chemical products.

5.2 Chemical manufacturers

97. Chemicals manufacturers have been identified in this impact assessment as including all businesses within SIC code 24 as classified in the Inter Departmental Business Register (Office for National Statistics (ONS)). Following this definition, the sub-sectors within chemical manufacturing are listed in table 1 below, together with the number of businesses in each sector, presented by size band⁴¹ (source: UK Business: Activity, Size and Location 2006 (Office for National Statistics⁴²)).

Table 1: UK Chemicals Manufacturers

Industry	SIC code	Number of micro	Number of small	Number of medium	Number of large	Total number of
----------	----------	-----------------	-----------------	------------------	-----------------	-----------------

⁴¹ The reported totals for each size band may not add to reported overall totals for each sub-sector. This is due to rounding in the UK Business: Activity, Size and Location report 2006.

⁴² http://www.statistics.gov.uk/downloads/theme_commerce/PA1003_2006/UK_Business_2006_Optimized.pdf

		businesses (0-9 employees)	businesses (10-49 employees)	sized businesses (50 – 249 employees)	businesses (250 or more employees)	businesses
The manufacture of basic chemicals	24.1	480	260	125	55	920
Pesticides and other agro-chemical products	24.2	25	15	15	5	60
Paints, varnishes and similar coatings, printing ink and mastics	24.3	275	115	55	15	455
Pharmaceuticals, medicinal chemicals and botanical products	24.4	220	65	50	40	380
Soap and detergents, cleaning and polishing mixtures, cosmetics, perfumes and toilet mixtures	24.5	330	140	65	30	565
Other chemical products	24.6	435	160	80	25	705
Man-made fibres	24.7	5	5	5	0	15
Total for all Sectors in SIC 24		1770	765	410	155	3105

As shown in table 1, the UK Business: Activity, Size and Location report 2006 (Office for National Statistics) indicates a total of 3105 businesses in this group.

5.3 Downstream businesses

98. All businesses that purchase and use chemical products will be potentially affected by the GHS Regulation, and the Regulation will therefore potentially affect, to a varying extent, all businesses in the UK economy. However, transitional costs for downstream businesses are expected to be largely accounted for by businesses that obtain chemicals as a significant proportion of their total purchases of inputs. There is no standard, or widely applied, definition of these businesses. For the purposes of analysis, this assessment has focused on downstream business sectors that obtain over 10% of intermediate inputs, by value, from the chemical manufacturing industry (SIC code 24). It should be highlighted that, for specific businesses within these sectors, the proportion of total inputs that are obtained from the chemical manufacturing industry is likely to vary considerably.

99. Data regarding the value of intermediate inputs have been obtained from the Input-Output Supply and Use Tables 2004 (Office for National Statistics)⁴³. The sectors that obtain at least 10%, by value, of inputs for

⁴³ http://www.statistics.gov.uk/downloads/theme_economy/Supply_Use_04_bb2006.zip

intermediate consumption from the chemical manufacturing industry (SIC 24) are listed in table 2. Data regarding the number of businesses in each sector is obtained from the UK Business: Activity, Size and Location report 2006 (ONS).

Table 2: Downstream Industries

Industry	SIC code	Percentage, by value of inputs for intermediate consumption obtained from chemical manufacturing (SIC 24) (rounded)	Number of micro businesses (0-9 employees)	Number of small businesses (10-49 employees)	Number of medium sized businesses (50-249 employees)	Number of large businesses (250 employees or more)	Total number of businesses
Agriculture	01	13%	127,155	3,370	6,995	25	130,780
Textile fibres	17.1	13%	95	25	10	0	155
Textile weaving	17.2	32%	110	50	45	5	225
Textile finishing	17.3	36%	350	100	35	5	495
Other textiles	17.52 to 17.54	21%	660	140	65	5	870
Pulp, paper & paperboard	21.1	11%	170	55	35	20	275
Rubber products	25.1	16%	365	165	80	20	635
Plastic products	25.2	34%	3360	1815	590	125	5,890
Glass & glass products	26.1	12%	780	285	75	15	1,140
Weapons and Ammunition	29.6	13%	75	20	15	5	115
Miscellaneous manufacturing nec, recycling	36.6 and 37	13%	6620	825	95	5	7,560
Total Number of Businesses			139,740	6,850	8,040	230	148,140

100. In addition to the sectors listed in table 2, each sub-sector in chemical manufacturing (SIC 24) obtains more than 10% of intermediate inputs within SIC 24. However, in order to avoid double counting of impacts, these sectors have been excluded from this list of downstream industries, as the impacts of the GHS on businesses in these sectors will be reflected in costs incurred in the first round of production.

101. Pharmaceuticals and food additives will not be subject to the GHS where the product is intended for final use as sold. However, they are subject to the GHS in the manufacturing process where workers may be exposed. On this basis, the “human health and veterinary services” sector (SIC 85.1 and 85.2) has been excluded from the identified downstream sectors. Although this sector obtains over 10% of inputs from SIC 24, this is almost entirely output obtained from SIC 24.4 (pharmaceuticals, medicinal chemicals and botanical products). It is assumed that this will be for final use as sold in these sectors, and it would therefore not be within the scope of the GHS Regulation.

102. It should be noted that defining downstream business sectors as those that obtain over 10% of intermediate inputs, by value, from the chemical manufacturing industry (SIC code 24) assumption, has a very considerable impact on the number of businesses that are defined as “downstream businesses” in the chemical industry. This is examined below.

- If the definition of “downstream businesses” is those that obtain at least 20%, by value, of inputs for intermediate consumption from the chemical manufacturing industry (SIC 24), then agriculture, weapons, textile fibres, pulp paper and paper board, rubber products, glass and glass products, weapons and ammunition, miscellaneous manufacturing and recycling, would be excluded from the definition. The consequence of adopting this alternative definition would be to remove a total of 140,660 businesses from the identified population of downstream businesses in the chemicals industry. This is largely because of the removal of the agricultural sector (with a total of 130,780 businesses) from the definition. With this definition, a total of 17,360 businesses are identified as “downstream businesses” in the chemical industry
- If the definition of “downstream businesses” is those that obtain at least 30%, by value, of inputs for intermediate consumption from the chemical manufacturing industry (SIC 24), then plastic products, textile weaving, and textile finishing would be included, but all other sectors would be excluded. With this definition, a total of 6,610 businesses are identified as “downstream businesses” in the chemical industry

103. The analysis above indicates that the impact for the agricultural sector is the key uncertainty in estimating the number of downstream businesses affected. Therefore, estimated costs to the agricultural sector are also presented separately from costs to other downstream businesses in this assessment.

5.4 Wholesalers and Retailers of Chemicals

104. Two further groups that will be affected by the GHS Regulation are wholesalers and retailers of chemicals.

105. Wholesalers of chemicals have been identified as businesses in SIC code 51.55 (wholesale of chemical products). According to the UK Business: Activity, Size and Location report 2006 (ONS), there are 1340 micro businesses (with 0 – 9 employees), 255 small businesses (with 10 – 49 employees), 35 medium sized businesses (with 50 – 249 employees), and 10 large businesses (with 250 or more employees) in this group.

106. There is no standard definition of retailers of chemical products, and it has not been possible to identify the number of businesses that actually retail chemical products. However, to provide an approximation, the following SIC codes have been identified as sectors in which businesses may retail chemicals, either as specialist retailers, or as part of a wider range of products: 52.46 (retailers of hardware, paints and glass), 52.11 (retail sale in non-specialised stores with food, beverages or tobacco dominating), and 52.12 (other retail sale in non-specialised stores). According to the UK Business: Activity, Size and Location report 2006 (ONS), there are a total of 36,415 micro businesses (with 0-9 employees), 2490 small businesses (with 10-49 employees), 245 medium sized employees (with 50-249 employees), and 110 large businesses (with 250 or more employees) in these groups. It should be highlighted that there is likely to be a number of businesses within these sectors that do not retail chemical products and therefore would not be affected by the GHS regulations, but it has not been possible to identify these.

Table 3: Retailers

Industry	SIC code	Number of micro businesses (0-9 employees)	Number of small businesses (10-49 employees)	Number of medium sized businesses (50 – 249 employees)	Number of large businesses (250 or more employees)	Total number of businesses
Retailers of hardware, paints and glass	52.46	4800	505	35	10	5350
Retail sale in non-specialised stores with food, beverages or tobacco dominating	52.11	25265	1645	130	65	27105
Other retail sale in non-specialised stores	52.12	6350	340	80	35	6805
Total		36415	2490	245	110	39260

5.5 Retail Consumers

107. Retail consumers are a further group that will be affected by the GHS regulations. Based on *Household Estimates and Projections: Great Britain* (updated March 2007) (Department for Communities and Local

Government)⁴⁴, there were an estimated 25.046 million households in Great Britain in 2006. On the basis that chemical products are generally purchased for household use, rather than individual use, and that all households will potentially purchase and use chemical products, this is applied as an estimate of the number of retail consumers of chemical products.

5.6 Public Authorities

108. This includes groups within the public sector that will need to be aware of the GHS Regulations. The groups within the public sector that will be affected by the implementation of the GHS are the authorities that have to enforce the GHS within the UK, and the emergency services who will have to be aware of the new labelling system.

Question - Are the sectors and groups affected by the Regulation reasonably represented in this Regulatory Impact Assessment? If you partly agree, or don't agree, please identify sectors that should also be considered and explain why.

5.7 Assumptions

109. In estimating the costs and benefits presented below, a number of assumptions have been made.

110. The costs estimated for the implementation of the GHS Regulation are the additional costs associated with transition, compared with the baseline of maintaining the existing classification and labelling system (which is presented as option 2). The proposed GHS Regulation will replace the existing classification and labelling system. Businesses that currently classify and label chemicals already incur costs to cover the classification and labelling activities. These ongoing costs will continue under the GHS. For example, with the current classification and labelling system, businesses have to, for the purpose of chemical classification and labelling, update or replace IT systems, provide regular staff training, and have to periodically update classifications.

111. It is not expected that the GHS Regulation, following transition, will increase the frequency or cost of these ongoing activities compared to the current chemical classification and labelling regulations. Such costs, beyond those of the one-off requirements created by transition, are therefore not included as additional costs of the GHS Regulation. For example, ongoing costs of producing labels and safety data sheets are not included, as these costs are not expected to increase compared with the current classification and labelling system. It is assumed that there will be no increase in long-term costs as a consequence of implementation of the

⁴⁴ <http://www.communities.gov.uk/index.asp?id=1156099>

GHS regulations, compared with the baseline of the current classification and labelling system.

112. As the EC has selected the elements (or 'building blocks') of the UN GHS that most closely reflect the current EU classification and labelling system, and much of the UN GHS is based on the EC system, it is assumed that the majority of substances and mixtures will not have to be reclassified once the GHS Regulation is implemented.
113. The EC has also undertaken a study to map out the possible impact of the proposed GHS Regulation on European 'downstream legislation'⁴⁵. As the EC has committed to either review and amend the legislation within the GHS Regulation, or in a separate review (which should be completed prior to the repeal of existing legislation, currently envisaged as 2015), it is assumed that downstream regulations will be amended where required so that there will be no impact on the provisions in 'downstream' legislation. HSE, for example is currently working on options to amend the Seveso-II Directive (implemented in the UK by the Control of Major Accident Hazards Regulations 1999 (COMAH). An objective of the review will be to minimise the impact of the GHS Regulation in terms of the interaction with COMAH. Where reviews are undertaken, UK Impact Assessments (IAs) will be undertaken as appropriate.
114. The EC has committed to 'translate' all of the current harmonised classifications (Annex I of the Dangerous Substances Directive – some 8,000 classifications⁴⁶) to the new GHS criteria. It is assumed that the EC will undertake this work, and produce a workable 'Translation' table (the proposed Annex VII) which will reduce the amount of time required by suppliers to convert their existing classifications to the new GHS criteria.
115. It is assumed that the GHS Regulation should not impact on current packaging costs (for example, the requirement to package with child-resistant fastenings), as the aim of the GHS Regulation is to not extend or amend the existing provisions, and therefore the number of substances and mixtures, covered in the current legislation.
116. All costs and benefits estimates are calculated as present values, and, where relevant, are discounted at a rate of 3.5%, in line with HM Treasury guidance. All costs estimates have been rounded.
117. In addition to the assumptions above, a number of further assumptions are made, and these assumptions are highlighted throughout the impact assessment.

⁴⁵ The term 'downstream legislation' means any piece of legislation that refers to the classification and labelling system to define its scope of application or trigger action in the legislation being introduced or altered. For example there are many pieces of European legislation that refer to the Dangerous Substances Directive (67/548/EEC), such as the Control of Major Accident-Hazards involving Dangerous Substances (96/82/EC).

⁴⁶ According to the European Chemicals Bureau website

5.8 Option 1 - 'Do nothing' - Adopt/accept Commission's proposed draft Regulation without any negotiation

118. The costs and benefits for option 1 are separated into two categories: transitional costs and long-term costs.
119. Transitional costs and benefits are the one-off costs and benefits associated with transition to the GHS Regulation. The European Commission's draft Regulation proposes that the transitional period will be 3.5 years for substances with an additional 4.5 years for mixtures (currently called preparations). During the transitional period, businesses will be able to choose whether to apply the GHS criteria immediately or continue to apply the current EU system for classification and labelling, while preparing for the GHS Regulation.
120. Long-term costs and benefits are those that apply following the transition to the GHS based Regulation in Europe. It should be noted that long term costs and benefits depend upon the extent of, and timescale for, global transition to the UN GHS, which is highly uncertain.

5.9 Transitional costs and benefits

Health and safety benefits

121. There are not expected to be any significant health and safety benefits to the UK during the transitional period. The new hazard classifications are not expected to generate significant additional health and safety benefits beyond the existing classification and labelling system. The new requirements for hazard communication are not expected to change significantly the levels of awareness, among those working with or using chemicals, of the hazards arising from chemicals. There may be, however, some unquantifiable benefits arising from greater awareness of chemical hazards in general because of the publicity/education campaigns that are likely to occur because of the changes to product labels. Conversely, there may also be an increased risk to health and safety in transition, because of the uncertainty created from moving to a new classification and labelling system.
122. Internationally (external of the EU and other countries that already have developed chemical safety regimes), it is expected that there may be significant human health benefits for those countries that do not currently have a classification and labelling system in place and that adopt the GHS, depending upon the extent to which the UN GHS is adopted in these countries.

5.10 Environmental benefits

123. There are not expected to be any significant environmental benefits to the UK arising from differences in the environmental hazard categories. It

is envisaged that there will be environmental benefits to developing countries that do not currently have a system for classification and labelling of chemicals and that adopt the GHS. As with international health benefits, this will be a benefit of the European Commission's GHS Regulation to the extent that adoption in Europe promotes adoption of the GHS internationally and in developing countries.

5.11 Costs

Costs to chemicals manufacturers

Replacement or Updating of Information Technology Systems

124. The introduction of the GHS Regulation is expected to lead to manufacturers having to update or replace their existing IT systems for the purposes of producing new labelling under the GHS. Several different sources of data have been identified regarding the possible costs of this. However, the only identified source that fully explains how the estimates were obtained is the RPA (2006) impact assessment of the GHS, produced for the European Commission⁴⁷. This estimated average IT modification costs of around £1,700 for small / medium sized businesses and around £6,800 for large businesses⁴⁸. It is assumed that average IT modification costs for micro businesses are around £1,700.

125. It should be noted that the estimates presented by the RPA impact assessment are based on responses from a very small sample of business, and therefore there is uncertainty that they are representative of these costs to all chemical manufacturers. The estimated total cost to chemical manufacturers of replacing or updating IT systems is presented below. These are estimated by multiplying the estimated per business costs from the RPA (2006) impact assessment, as described above, by the total number of chemicals manufacturers as identified in table 1.

Table 4: The cost to chemical manufacturers of updating IT systems

Costs to micro chemicals manufacturers of updating and replacing IT systems	£3,000,000
Costs to small,/ medium chemicals manufacturers of updating and replacing IT systems	£2,000,000

⁴⁷ A copy of the RPA impact studies are available are the EC website: http://ec.europa.eu/enterprise/reach/ghs_consultation_en.htm

⁴⁸ *Impact Assessment of Implementing the GHS: Work Package 1- Final Report, RPA*, May 2006, p.103 and Exchange rate: 1 Euro = £0.67730 (Source: European Central Bank; 23rd August 2006)

Costs to large chemical manufacturers of updating and replacing IT systems	£1,000,000
Total costs to chemical manufacturers of updating and replacing IT systems	£6,000,000

Staff Training and Familiarisation

126. The introduction of the GHS Regulation will generate requirements for familiarisation of employees of chemical manufacturers with the GHS Regulation. In some cases, staff training will be required. The total costs to chemical manufacturing businesses of familiarisation and staff training are presented below. These costs have been estimated by assuming that 1.5 days will be required for each employee requiring training⁴⁹. The number of employees, per business, that will require training has been assumed to average 1 for micro businesses (with 1-9 employees), 10 for small and medium sized businesses (with up to 249 employees) and to average 50 for large businesses (with 250 or more employees). The average cost of the employee's time is estimated to be £20.72., based on the mean average wage for all employees in SIC 24 of £15.94⁵⁰ from the Annual Survey of Hours and Earnings (ASHE) 2006 (Office for National Statistics⁵¹). Based on these assumptions, the cost per micro business is estimated to be £250, the cost per small / medium sized business of staff training and familiarisation is estimated to average £2,487, and the cost per large business is estimated to average £12,433. Table 5 presents the estimated total costs to chemical manufacturers, based on the number of chemicals manufacturers shown in table 1 above. While, due to staff turnover, there will be an ongoing cost of training and familiarisation, it is assumed that this will not increase beyond the current classification and labelling regulations⁵².

Table 5: The cost to chemical manufacturers of staff familiarisation and training

Costs to micro businesses of staff training and familiarisation	£400,000
---	----------

⁴⁹ A working day is assumed to consist of 8 working hours.

⁵⁰ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

⁵¹ <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=14630>

⁵² There will be a cost of delivering the training. This impact assessment assumes that training would be delivered internally within the business, by employees that have acquired familiarisation with the Regulation. The total time estimated includes the time of the employees that deliver the training internally, including the time allocated to initial familiarisation. It is assumed that there is minimal additional cost associated with use of facilities such as the use of meeting rooms, and for the preparation of training materials.

Costs to small/medium businesses of staff training and familiarisation	£3,000,000
Total costs to large businesses of staff training and familiarisation	£2,000,000
Total costs of staff training and familiarisation to chemical manufacturers	£5,000,000

Reclassification of Chemicals

127. The introduction of the GHS Regulation will lead to chemical manufacturers needing to carry out reclassification of chemicals in accordance with the new hazard end-points provided by the GHS. As currently drafted, the GHS Regulation also creates new requirements for chemicals to be classified to reflect the state in which a chemical may be used in the future, rather than (as with present system) the state in which it is placed on the market. This may create additional reclassification costs.

128. The cost of reclassification has been estimated based upon the number of substances and mixtures (or percentage of existing substances or mixtures) that it is expected will have to be reclassified (into higher, lower, or new categories), and the estimated average cost of reclassification per substance or mixture.

129. No data source has been identified regarding the number of substances and mixtures that are produced in the UK. The number of substances and mixtures that will require reclassification has therefore been estimated based on the following data and assumptions.

- The total number of substances manufactured in the European Union is approximately 29,000, and the total number of mixtures manufactured in the European Union is approximately 2 million (source: RPA, 2006).
- According to the European Chemicals Bureau, the European Commission will directly translate 8,000 harmonised classifications to the GHS criteria.
- As estimated in Annex 4 of this impact assessment, the value of turnover of the UK chemicals industry accounts for approximately 13% of the EU total.
- Assuming that the number of substances and mixtures manufactured in the UK, as a percentage of the EU total, is approximately the same as the UK share of total turnover of the European Union chemicals industry, it is estimated that, of the total number of substances and mixtures manufactured in the European Union, approximately 10% – 15% are manufactured in the UK. Based on this assumption, it can be estimated that around 3000 – 4000 substances, and 200,000 – 300,000 mixtures, are manufactured in the UK.

- According to the European Chemicals Bureau, the European Commission will directly translate 8,000 harmonised substances to the GHS criteria. It is assumed that, in line with the UK proportion of the turnover of the European Union chemical industry, 10-15% of these are manufactured in the UK. Therefore, it is estimated that this will apply to approximately 800-1400 harmonised substances manufactured in the UK that will not require re-classification.
- According to the *Small and Medium Enterprise Statistics 2005* (Small Business Service), micro enterprises (with 1-9 employees) accounted for around 2% of the total turnover by value of the UK chemicals manufacturing industry (SIC 24). Small and medium sized enterprises (with 10 - 249 employees) accounted for approximately 22% of this total. If the percentage of substances and mixtures requiring reclassification is assumed to be the same as the percentage of turnover, it can be estimated that there are approximately 60 – 80 substances and 4000 – 6000 mixtures, manufactured by micro chemicals manufacturers in the UK, requiring reclassification. For small and medium sized chemical manufacturers, the same approach can be applied to estimate that there are approximately 700 – 900 substances, and 40,000 – 60,000 mixtures produced by this group that will require reclassification.

130. It should be noted that there are very considerable uncertainties regarding these assumptions and estimates, and it has not been possible to actually identify the number of substances and mixtures that are produced in the UK.

131. The average cost of reclassification of a substance or mixture has been estimated to be between £80 and £500, which is the estimate provided in the Regulatory Impact Assessment (RIA) for the proposed amendments to the Chemical Hazard Information and Packaging for Supply Regulations (CHIP) regulations in 2005.⁵³

132. The total costs to businesses of reclassifying substances and mixtures are estimated in table 6 and 7. The low estimate assumes an average cost of £80 for reclassification of a substance or mixture, and the high estimate assumes an average cost of £500. The low estimate assumes that the number of substances and mixtures requiring reclassification is equal to 10% of the total number of substances and mixtures produced in the European Union. The high estimate assumes that the number of substances and mixtures requiring reclassification is equal to 15% of the total number of substances and mixtures produced in the European Union.

133. The estimates in tables 6 and 7 are obtained by applying the estimated ranges for the number of substances and mixtures that will require reclassification. Based on these assumptions, as shown in table 6, the total cost to chemical manufacturers of reclassification of substances is estimated at £250,000 to £2,000,000. The total cost to chemical

⁵³ <http://www.hse.gov.uk/ria/chemical/chip2005.pdf> page 7.

manufacturers of reclassification of mixtures is estimated, as shown in table 7, to be £15,000,000 to £130,000,000. This is a one-off cost associated with transition to GHS. There are assumed to be no additional ongoing costs of reclassification, following transition, as these costs are assumed to be the same as with the current classification and labelling regulations.

Table 6: Cost to chemical manufacturers of reclassifying substances

	Low	High
Cost of reclassification per substance	£80	£500
Number of substances produced by micro businesses and requiring reclassification	60	80
Total cost to micro businesses of reclassification of substances	£5,000	£40,000
Number of substances produced by small and medium sized businesses and requiring reclassification	700	900
Total cost to large businesses of reclassification of substances	£60,000	£450,000
Number of substances produced by small and medium sized businesses and requiring reclassification	2200	3000
Total cost to large businesses of reclassification of substances	£180,000	£1,500,000
<u>Total costs to businesses of reclassification of substances</u>	£250,000	£2,000,000

Table 7: The cost to chemical manufacturers of reclassifying mixtures

	Low	High
Cost of reclassification per mixture	£80	£500
Number of substances produced by micro businesses and requiring reclassification	4000	6000
Total cost to micro businesses of reclassification of mixtures	£300,000	£3,000,000
Number of substances produced by small and medium sized businesses and requiring reclassification	40,000	60,000

Total cost to large businesses of reclassification of mixtures	£3,000,000	£30,000,000
Number of substances produced by large businesses and requiring reclassification	150,000	200,000
Total cost to large businesses of reclassification of substances	£12,000,000	£100,000,000
<u>Total costs to businesses of reclassification of mixtures</u>	£15,000,000	£130,000,000

134. For an estimated small number of chemicals, reclassification of chemical hazard categories may also create further indirect costs, such as more restricted access to some markets, resulting in a move away from affected products by consumers, and may also require chemicals manufacturers to reformulate products so that they move into a lower hazard category.

135. The actual number of substances and mixtures requiring reclassification may be considerably higher than presented in tables 6 and 7. As noted above, it has not been possible to identify the actual number of substances and mixtures produced in the UK. The potential upper limit is that the UK produces 100% of the substances and mixtures produced in the European Union. In this case, if the cost of reclassifying a mixture or substances is assumed to be £500, it is estimated that the total cost to chemical manufactures of reclassifying substances would be approximately £13 million, and that the total cost to chemical manufactures of reclassifying mixtures would be approximately £860 million. **The estimated costs presented should therefore be regarded as illustrative only.**

Cost of Stock Losses

136. There is a possible cost of stock losses, regarding requirements to dispose of outdated labels, and products packaged with outdated labels, following the end of the transition period. However, experience with previous changes to the classification and labelling legislation (such as amendments to CHIP following adaptations to technical progress for the Council Directive 67/548/EEC) suggests that disposal costs incurred are negligible. As there will be a transition period for the implementation of the GHS Regulation, it is assumed that businesses will be able to minimise any potential stock losses, by reducing stocks of outdated labels and packaging over the transition period.

Informing Consumers and Downstream Users of Chemicals

137. Under the new GHS labelling criteria some well-known warning symbols will be replaced with new GHS symbols. This will mean that consumers and professional workers will have to be informed and educated about the changes. While there is a role for the UK Government, and the EC, the chemical industry and retailers will, as with the REACH Regulation, have a significant role in informing its customers of the changes. There will be costs associated with this. These costs to industry have not yet been estimated.

Cost of proposing new harmonised hazard classification

138. Under the new GHS Regulation, there is a provision to create a 'Classification and Labelling Inventory' maintained by the European Chemicals Agency (ECHA)⁵⁴. The inventory will contain a list of harmonised classification (including all of those currently in Annex I of the Dangerous Substances Directive (67/548/EEC). Industry (in addition to Member States) can put forward a proposal for a harmonised classification and labelling entry for inclusion on the inventory.

139. When industry puts forward a proposal, it must be accompanied by payment of a fee. This will be an ongoing cost, to chemical manufactures and suppliers, that is not incurred under the current classification and labelling regulatory system. The level of this payment has not yet been set, and will be determined by the new European Chemicals Agency (ECHA) (to be set up from June 2007). It is envisaged that the cost will only be to cover administrative charges, and not to generate revenue. Given the number of proposals that may be put forward, the total cost of this could be considerable. However, the European Commission is not currently able to provide an estimated cost per proposal, as the European Chemicals Agency will set the fees to be paid. As a result, it is not currently possible to quantify this long-term cost to chemical manufacturers and suppliers.

5.12 Total Costs to Chemical Manufacturers

140. The total quantified transitional costs to chemical manufacturers are presented in table 8.

⁵⁴ For more information please see: <http://ec.europa.eu/echa/>

Table 8: Summary of the estimated quantified transitional costs of GHS Regulation to chemical manufacturers

	Costs to micro chemical manufacturers		Costs to small/medium sized chemical manufacturers		Costs to large chemical manufacturers		Total costs to chemical manufacturers	
	Low	High	Low	High	Low	High	Low	High
Replacement or updating of information technology systems	£3,000,000		£2,000,000		£1,000,000		£6,000,000	
Staff training and familiarisation	£400,000		£3,000,000		£2,000,000		£5,000,000	
Reclassification of substances	£5,000	£40,000	£60,000	£450,000	£180,000	£1,500,000	£250,000	£2,000,000
Reclassification of mixtures	£300,000	£3,000,000	£3,000,000	£30,000,000	£12,000,000	£100,000,000	£15,000,000	£130,000,000
Total transitional costs to chemical manufacturers	£4,000,000	£6,000,000	£8,000,000	£35,000,000	£15,000,000	£103,000,000	£26,000,000	£144,000,000

5.13 Costs to Downstream Businesses

141. Downstream businesses have been identified as listed in table 2. These businesses will incur costs in adjusting to the GHS Regulation. This analysis assumes that all downstream businesses would implement transition to the GHS Regulation in the first year of the transition period to allow them to immediately interact with chemical manufacturers (national and international) who have taken up the UN GHS.

142. For downstream businesses, costs are presented separately for: (a) micro businesses (with 1-9 employees); small and medium sized businesses (with 10-249 employees); and (c) large businesses (with 250 or employees).

Staff Training and Familiarisation

143. As with chemical manufacturers, there will be a cost to downstream businesses of familiarisation with the GHS, which will, in some cases, include training of employees. The purpose of this will be to enable employees to review labels and safety data sheets. The average number of employees per firm requiring training is assumed to be 1 employee for micro businesses, 10 employees for small/medium sized businesses, and 50 employees for large businesses. The time required for training is assumed to be 4 hours per employee requiring training.

144. The average cost of this time has been estimated by calculating the weighted average wage rate for the downstream industries affected. Information on average wages for each identified industry has been

obtained from the Annual Survey of Hours and Earnings (ASHE) 2006⁵⁵. The number of businesses in each identified industry is applied as weights. The weighted average wage for these downstream industries is calculated to be approximately £8.47 (including agriculture) and £10.42 (excluding agriculture). This difference reflects the large number of enterprises in the agriculture sector relative to the other downstream industries, as shown in Table 2. The average cost of employees time is therefore estimated to be approximately £11 (including agriculture) and £13.55 (excluding agriculture) From these assumptions, average costs of staff training and familiarisation for downstream businesses are estimated to be approximately £44 for a micro business, £440 for a small/medium sized business, and £2200 for a large business.

145. The total cost to businesses of familiarisation and staff training is presented in table 9 below. This is estimated by multiplying the estimated average cost per business by the total number of downstream businesses, as shown in table 2. The total cost of staff training and familiarisation for downstream businesses is estimated at around £14,000,000.

⁵⁵ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

Table 9: The cost to downstream businesses of staff familiarisation and training

Total cost of staff training and familiarisation for micro businesses	£6,000,000
Total cost of staff training and familiarisation for small/medium sized businesses	£7,000,000
Total cost of staff training and familiarisation for large businesses	£500,000
Total cost of staff training and familiarisation to downstream businesses	£14,000,000

Reviewing Labels and Safety Data Sheets

146. Following the introduction of the GHS Regulation, downstream businesses will need to review labels and safety data sheets for chemicals that are used as an input to production, and compare these with previous versions.

147. No information has been found regarding the average number of products that will need to be reviewed by each business affected. In order to estimate the costs of this, the average number of products needing to be reviewed by each firm is assumed to be 11 (1 substance and 10 mixtures) for micro businesses, 110 (10 substances and 100 mixtures) for micro, small and medium sized businesses, and 1100 (100 substances and 1000 mixtures) for large businesses.

148. It is assumed that reviewing labels and safety data sheets for each substance or mixture will require one employee to allocate 1 hour time. The average cost of this time is estimated to be £11, based on a weighted average wage of £8.47 per hour per employee for the downstream industries identified, based on the Annual Survey of Hours and Earnings (ASHE) 2006⁵⁶. The average cost of reviewing labels and safety data sheets is therefore estimated to be around £121 for a micro business, £1,210 for a small/medium sized business, and £12,100 for a large business.

149. The estimated total cost of reviewing labels and safety data sheets for all downstream businesses is shown in table 10.

Table 10: The cost to downstream businesses of reviewing labels and safety data sheets

⁵⁶ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

Total cost of reviewing products for micro businesses	£17,000,000
Total cost of reviewing products for small/medium businesses	£18,000,000
Total cost of reviewing products for large businesses	£3,000,000
Total cost of reviewing products to downstream businesses	£38,000,000

Undertaking New Risk Assessments

150. If a chemical is reclassified under the GHS this will lead to a requirement for downstream businesses to undertake new risk assessments to identify the chemical-related hazards that may be present, and to undertake risk reduction measures that are identified to be necessary. The cost to downstream businesses of undertaking these measures has been estimated, in this assessment, per business rather than per product. For all businesses it is assumed that undertaking new risk assessments will take a total of 4 hours for a micro business, 30 hours for a small/medium sized business, and 60 hours for a large business. The average cost of this time is estimated to be £11, based on an a weighted average wage of £8.47 per hour per employee for the downstream industries identified, based on the Annual Survey of Hours and Earnings (ASHE) 2006⁵⁷. The average cost per business is therefore estimated at approximately £44 for a micro business, £330 for a small/medium sized business, and £660 for a large business. This does not include the cost to businesses of undertaking any changes to work processes that are identified to be required as a result of the risk assessment.

151. The total cost for all downstream businesses of undertaking risk assessments is presented in table 11.

Table 11: The cost to downstream businesses of new risk assessments

Total cost of new risk assessments for micro businesses	£6,000,000
Total cost of new risk assessments for small/medium businesses	£5,000,000
Total cost of new risk assessments for large businesses	£200,000

⁵⁷ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

Total cost of new risk assessments to downstream businesses	£11,000,000
---	-------------

Stock Losses

152. As with chemical manufacturers, It has been assumed that there will be only negligible costs to downstream businesses associated with disposal of outdated labels and packaging, due to the length of transition being proposed, within which downstream businesses will be able to reduce their stock of outdated labels and packaging.

Informing Consumers and Downstream Users of Chemicals

153. As for chemical manufacturers, there may be some costs to downstream businesses associated with informing consumers and professional workers. This cost has not yet been estimated.

Total Quantified Transitional Costs to Downstream Businesses

154. The total quantified transitional costs to downstream businesses are presented in table 12.

155. Costs attributable to the agricultural sector, shown in table 12, are estimated based on the proportion of the total number of businesses accounted for by agricultural sector businesses in each size group.

Table 12: Summary of the estimated quantified transitional costs to downstream businesses of GHS

	Costs to micro businesses	Costs to small/medium sized businesses	Costs to large businesses	Total costs to downstream businesses
Staff familiarisation and training	£6,000,000	£7,000,000	£500,000	£14,000,000
Reviewing labels and safety data sheets	£17,000,000	£18,000,000	£3,000,000	£38,000,000
Undertaking new risk assessments	£6,000,000	£5,000,000	£200,000	£11,000,000
<u>Total transitional costs to downstream businesses</u>	£29,000,000	£30,000,000	£4,000,000	£63,000,000
Of which: Costs Attributable to the Agricultural Sector	£26,000,000	£21,000,000	£400,000	£47,000,000

5.14 Costs to Wholesalers and Retailers

Wholesalers

156. Wholesalers of chemical products have been identified as businesses in SIC code 51.55 (wholesale of chemical products).

Staff Training and Familiarisation

157. There will be a cost to wholesalers of chemical products, associated with staff familiarisation and training requirements that are generated by the implementation of the GHS Regulation. The number of employees per firm requiring training is assumed to average 1 for micro businesses, 10 for small/medium sized businesses, and 50 for large businesses. The total time allocated per employee requiring training is assumed to be 2 hours. The cost of this time is estimated to be approximately £18.15 per hour, based on a mean average wage for employees in SIC code 51.55 of £13.96 (ASHE, 2006). The average cost per business, for wholesalers of chemical products, of staff training and familiarisation is therefore estimated to be around £36 for micro businesses, £360 for small/medium sized business, and £1800 for large business. The estimated total cost, to this sector, of familiarisation and staff training is shown in table 13.

Table 13: The cost of staff familiarisation and training to wholesalers of chemical products

Total cost of staff training and familiarisation to micro businesses	£480,000
Total cost of staff training and familiarisation to small/medium sized businesses	£105,000
Total cost of staff training and familiarisation to large businesses	£18,000
Total cost of staff training and familiarisation to retailers	£600,000

Provision of Information to Customers

158. Wholesalers of chemical products will also have to play a role in educating customers and will therefore also contribute towards the cost of informing customers of changes in labelling due to the GHS alongside other sectors.

Cost of Stock Disposal

159. As with other sectors there are assumed to be no or minimal stock losses to the wholesale sector, due to the length of the transition period within which wholesalers will be able to sell stock to customers that does not meet the new classification and labelling requirements.

Total Quantified Transitional Costs to Retailers

160. The only quantified transitional cost to wholesalers of chemical products, in this assessment, is the cost of staff familiarisation and training, which is presented above in table 13.

Retailers

161. As there is no standard definition of this group, affected retailers been identified and defined, as described above, as SIC codes 52.46 (retailers of hardware, paints and glass), 52.11 (retail sale in non-specialised stores with food, beverages or tobacco dominating), and 52.12 (other retail sale in non-specialised stores).

Staff Training and Familiarisation

162. There will be a cost to retailers of chemical products, associated with staff familiarisation and training requirements that are generated by the implementation of the GHS Regulation. The number of employees requiring training is assumed to average, per business, 1 for micro businesses (with 0-9 employees), 10 for small/medium businesses (with 10 – 249 employees), and 50 for large businesses (with over 250 employees). The total time allocated per employee requiring training is assumed to be 2 hours. The cost of this time is estimated to be £10.95 per hour, based on a mean weighted average wage for employees in the retail SIC code identified in table 3 of £8.42 (with the number of businesses in each sector applied as weights) (ASHE, 2006). The average cost per business, for retailers, of staff training and familiarisation is therefore estimated to be around £22.00 for micro businesses, £220 for small/medium sized business, and £1100 for large business. The estimated total cost to retail businesses of familiarisation and staff training is shown in table 14. This is calculated by applying the average estimated costs per business to the total number of businesses in each size band, as shown in table 3.

Table 14: The cost to retailers of staff familiarisation and training

Total cost of staff training and familiarisation to micro businesses	£800,000
---	----------

Total cost of staff training and familiarisation to small/medium sized businesses	£600,000
Total cost of staff training and familiarisation to large businesses	£1,200,000
Total cost of staff training and familiarisation to retailers	£2,600,000

Provision of Information to Customers

163. Retailers of chemical products will also have to play a role in educating customers and will therefore also contribute towards the cost of informing customers of changes in labelling due to the GHS alongside other sectors.

Cost of Stock Disposal

164. As with other sectors there are assumed to be no or minimal stock losses to the retail sector, due to the length of the transition period within which retailers will be able to sell stock to retail customers that does not meet the new classification and labelling requirements.

Total Quantified Transitional Costs to Retailers

165. The only quantified transitional cost to retailers, in this assessment, is the cost of staff familiarisation and training, which is presented above in table 14.

166. The costs presented above for retailers are averages for businesses in the identified sectors, but, as previously, highlighted, there is likely to be some businesses within these sectors that do not retail chemical products and therefore would not be affected by the GHS Regulation

5.15 Costs to the Public Sector

167. The Government recognises that there will be costs to the UK authorities associated with the regulatory requirements of the GHS Regulation. EU Member States shall each 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, and to enforce the provisions in the Regulation. The decision on who will be the GHS Competent Authority has yet to be agreed, but whatever the solution it will be consistent with the Better Regulation agenda, including the findings of the Hampton Review (2005)⁵⁸.

⁵⁸ A copy of the Hampton Review can be found at: http://www.hm-treasury.gov.uk/budget/budget_05/other_documents/bud_bud05_hampton.cfm

168. If we assume for this assessment that HSE and Local Authorities will be the Enforcing Authorities for the UK, (as for the current classification and labelling system), then 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. 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.

Training and Familiarisation of Enforcement Officers

169. In estimating the cost to HSE and Local Authorities of enforcement officers' familiarisation, it is assumed that the length of time for training for enforcement of GHS is 3.5 hours for all officers. The cost of familiarisation is presented below. The average cost of HSE inspector time is estimated at approximately £42 per hour, and the average cost of Local Authority officers' time is estimated at £34 per hour. This is calculated from the average wage rate for each pay band of HSE and Local Authority officers, and the number of enforcing officers within each pay band. It is assumed that all HSE and Local Authority (health and safety) enforcing officers would require this training. It is estimated that approximately 1500 HSE inspectors and 1100 Local Authority officers would require training. From these assumptions, the total cost of this training is estimated to be £220,000 for training of HSE inspectors, and £260,000 for training of Local Authority Officers. The total cost is therefore estimated to be £480,000.

Training and Familiarisation of Emergency Services Staff

170. The other area of the public sector that will incur costs from transition to the GHS is the emergency services. Front line emergency staff (paramedics) will need to be familiar with the new labelling system under the GHS. The cost of familiarisation and training for such staff is based on the assumption that the time required will be 4 hours per paramedic, and that there are 16,337 paramedics based on the 2005 Labour Force Survey (LFS) 2005 (SOC code 3213, with an hourly wage of £14.13 based on ASHE 2006). The cost of familiarisation for paramedics is therefore estimated to be £1,200,000.

171. As shown in table 15, the estimated total cost to the public sector of implementation of the GHS is estimated to be £1,680,000.

Table 15: The transitional costs to the public sector of the implementation of the GHS

Cost of staff training and familiarisation for HSE and Local Authority Enforcement officers	£480,000
---	----------

Cost of staff training and familiarisation for emergency services	£1,200,000
Total transitional costs to the public sector	£1,680,000

5.16 Costs to Retail Consumers of Chemical Products

172. According to *Household Estimates and Projections: Great Britain* (updated March 2007) (Department for Communities and Local Government), there were an estimated 25.046 million households in Great Britain in 2006. The main quantified transitional cost to this group has been identified as the cost of familiarisation with the new classification and labelling system.

173. The total cost of familiarisation has been estimated based on the assumption that each household will allocate, on average, a total of 10 minutes to familiarisation with the GHS hazard communication for all the chemical products purchased by the household. The average cost of this time is estimated to be £16.90 per hour, based on an average wage of £13 per hour for all employees in the UK economy, from the Annual Survey of Hours and Earnings (ASHE) 2006⁵⁹. It is assumed that only a proportion of households would allocate time to familiarisation. However, research has reported that only 5% of consumers actually consult the labels for chemicals products⁶⁰. If this percentage is applied to the number of households identified, then the total cost of familiarisation for consumers is estimated to be approximately £3.5 million.

5.17 Health and safety and environmental costs

174. There are not expected to be any significant health and safety costs arising from implementation of the GHS Regulation due to, for example, reclassification of chemicals or changes in hazard communication, or other aspects of the Regulation. The draft European Commission Regulation includes a commitment that health and safety and environmental protection standards will not be reduced as a consequence of the implementation of the GHS. There may be some environmental costs from the disposal of outdated labels and packaging at the end of the transition period but this is expected to be minimal.

175. However, concern has been raised by industry that, if certain mixtures are classified more severely, and labelled accordingly, it may have an affect on how people (both workers and/or consumers) perceive, and respond to, the hazard warnings on labels.

⁵⁹ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

⁶⁰ Riley, D. M., Fischhoff, B., Small, J. M., & Fishbeck, P. (2001). Evaluating the Effectiveness of Risk Reduction Strategies for Consumer Chemical Products. *Risk Analysis*, 21, 357-369.

176. One particular example has been raised to illustrate this point. According to parts of industry, under the UN GHS criteria, some washing-up liquids will be classified and labelled in exactly the same way as oven cleaner. If this were to be the case, then this could lead to a lowering of protection (whether real or perceived) as some consumers, for example, would conclude that oven cleaner was now as safe to use as washing-up liquid. Conversely, consumers may consider washing-up liquid as being more harmful than they actually are.

177. HSE has requested evidence from industry regarding this assertion, and is awaiting its receipt. In the meantime HSE has reviewed the possibility of this scenario and believes there are certain provisions in the GHS, including one that allows industry to present test/historical data to justify the continuation of the existing classification that can be applied and, therefore avoiding unintended increases in severity of classification.

Question - *Based on your experience, do you think that the assumptions made are reasonable? If you partly agree, or do not agree, please provide actual examples of products to demonstrate the possible cost to support your reasons.*

Long-term costs and benefits

Benefits

5.18 Trade benefits

178. The main economic benefits in the UK, from the implementation of the GHS, are expected to relate to international trade in chemicals.

179. Currently, businesses incur various costs in order to comply with differing chemical hazard classification and communication regulations worldwide. It is possible that these costs will be reduced by the implementation of the GHS Regulation. First, there will be a reduced need for testing against multiple classification systems and producing multiple labelling, packaging and safety data sheets. Second, there will be the possibility of lower costs associated with access to chemical markets worldwide, by reducing the need for expertise in multiple classification systems.

180. A reduction in the costs of international trade in chemicals may, in turn, support increased international competition in chemical products, leading to increased innovation, improvement in productivity, and lower prices for chemical products.

181. It is possible that more UK businesses than at present may be able to engage in trade outside of the EU if there is a reduction in the costs

currently associated with operating more than one classification and labelling system is achieved.

182. The RPA (2006) impact assessment, for the European Commission, found that while the companies interviewed by the study recognised the trade-related cost savings associated with the GHS Regulation, they were not able to estimate these costs, as trade-related costs are not recorded as a separate item in business accounting systems. However, the study estimated, on the basis of limited evidence, that cost savings would be equivalent to approximately 2.5% of the total non-tariff barriers to international trade in chemicals.

183. Table 16 below presents the estimated value of production, and percentage of the international total, for major trading regions. This shows that the European Union is the trading area with the highest value of chemical production, accounting for 31% of the international total. The USA and Asia (excluding Japan) also each account for a substantial share of international chemical production. These three areas, in total, account for almost 75% of the total value of international chemical production. The table indicates that, worldwide, the value of chemical production in 2005 is estimated to be approximately £1365 billion.

Table 16: Share of International Chemical Production

Region	Percentage of International Chemical Production (2005)	Value of Production (£ billion)
European Union	31.4%	429
USA	22.2%	303
Asia (excluding Japan)	20.8%	284
Japan	10.7%	146
Latin America	5.7%	78
Others	4.8%	66
Rest of Europe	4.4%	60
United Kingdom (data for 2004)	3.7%	50

Source: Adapted from data provided by German Chemical Industry Association / Baden-Wurttemberg International / Annual Business Inquiry (Office for National Statistics)

184. Table 17 below shows European trade flows (imports and exports) of chemicals in 2004. This shows that the largest trading area for chemicals (imports and exports) is North America, followed by Asia and Central / Eastern Europe.

Table 17: European External Trade Flows in Chemicals (2004)

Market	Exports To (£ million)	Imports From (£ million)
North America	19168	13275
Asia	11853	8331
Central/Eastern Europe	12733	6841
Japan	3928	3725
Latin America	4673	1693
Africa	3928	1287
Oceania	1761	271

Source: Adapted from data provided by Cefic (data for 2004)

185. The following table shows UK external trade in chemicals. In terms of both chemical imports and exports, the European Union is the major trading area for the UK. The European Union accounts for approximately 60% of exports of chemical products from the UK, and is the source of almost 70% of imports of chemicals.

Table 18: UK External Trade Flows in Chemicals (2004)

Market	Exports To (£ million)	Imports From (£ million)
European Union	19023	18707
Other Western Europe	1142	1249
North America	5336	3716
Far East	3575	3254
Rest of the World	2711	834

Source: UK Chemical Association Facts and Figures, 2006⁶¹

186. The actual scale of potential trade benefits from the GHS Regulation is very uncertain. The RPA (2006) impact assessment, for the European Commission, estimated that trade impacts for EU markets would be equivalent to less than 0.1% increase in exports, compared with the current classification and labelling system. For the European Union as a whole, this was estimated to amount to approximately €6 million in additional exports, and €4 million in additional imports. Converted to pounds sterling, this is approximately £4.1 million additional exports, and

⁶¹ http://www.cia.org.uk/newsite/industry_glance/facts_leaflet_2006.pdf

£2.71 million additional imports. This is equivalent to an increase in net exports from the European Union of approximately £1.39 million.⁶² These estimates were based on the assumption of full global and immediate harmonisation of the GHS and this assumption is highly unlikely to be realistic. It may, therefore, be regarded as an upper limit estimate of the potential trade benefits. This indicates that the value of any increase in net chemicals exports from the UK, arising as a consequence of implementation of the GHS, is likely to be very small.

187. The RPA (2006) assessment does not quantify the scale of potential economic benefits, such as access to a wider range of chemicals and suppliers, and lower prices for chemicals, which may arise from reduced costs of international trade in chemicals. The value of increased trade flows may not be a reasonable indicator of the scale of these types of benefits.

188. The scale of potential economic benefits depends upon a number of uncertainties. A key uncertainty is the extent to which the UN GHS is adopted consistently in different countries around the world. This will be dependent upon decisions made outside of the European Union. It is also likely that countries will use different timetables for transition. Trade benefits are also limited by the current scope for countries to choose different “building blocks” from the GHS, and to keep additional provisions that go beyond the GHS system. It is envisaged that over time full global harmonisation will be achieved. The exact timescale for this is difficult to predict, but it is expected to be several decades.

189. Additional research would be required to obtain further estimates of trade impacts and economic benefits from implementing GHS, beyond the estimates that are presented by the RPA (2006) impact assessment for the European Commission.

5.19 Health and safety, and environmental benefits

190. As with the transitional period, there are not expected to be any significant additional benefits to the UK related to health and safety, or environmental impacts related to adoption of the GHS, compared with maintaining the existing classification and labelling system. The draft EC Regulation includes a commitment that health and safety standards will not be reduced as consequence of implementation of the GHS Regulation.

191. There are expected to be health and safety, and environmental benefits to developing countries that adopt the GHS and that do not currently have a system for classification and labelling of chemicals.

192. As a indication of the potential scale of benefits from improvement in chemical health and safety, the World Health Organisation estimates that approximately a quarter of the global burden of disease is due to

⁶² . Exchange rate: 1 Euro = £0.67730 (Source: European Central Bank; 23rd August 2006)

environmental health determinants including contaminated water and soil, and toxic chemicals (source: *Food and Chemical Safety*, World Health Organisation, 2006)⁶³. However, the scale of benefits from GHS is very uncertain, and will be dependent upon the extent to which the GHS is adopted in developing countries, and the extent to which implementation of the system in these countries leads to a reduction in risks associated with chemicals.

193. There will also be transitional costs to developing countries associated with adopting the UN GHS, which would need to be considered alongside any benefits. The extent to which developing countries will implement GHS, and therefore the transitional costs, is very uncertain.

194. This assessment has therefore not attempted to quantify the costs and benefits to developing countries.

5.20 Other benefits

195. Once the UN GHS is 'fully' harmonised it should greatly reduce the need to undertake duplicate testing/evaluation for the same chemical across the world. This will mean a reduction in the need for animal testing which is consistent with a wider UK Government aim to limit all animal testing through the 3Rs initiative⁶⁴.

Question - Do you agree that the UK should proceed with Option 3? If you partly agree, or don't agree, please explain why.

Question - Do you think the benefits identified in the RIA are realistic? For example, increased trade opportunities outside the EU.

Question - Are there any additional benefits that should be included? Please provide explanation for your answer.

5.21 Total Costs and Benefits of Option 1

196. The total quantified costs of option 1 are presented in table 19 below. The total quantified costs of this option are estimated to be approximately £95,000,000 to £215,000,000.

Table 19: The total quantified costs from the implementation of the GHS

⁶³ <http://www.searo.who.int/EN/Section23/Section1001/Section1110.htm>

⁶⁴ For more information about the Home Office led initiative to reduce, refine and replace the use of animals in scientific procedures please see: <http://www.homeoffice.gov.uk/science-research/animal-testing/?version=1>

	Low	High
Cost to Chemical Manufacturers		
Total cost to micro chemical manufacturers	£4,000,000	£6,000,000
Total cost to small and medium sized chemical manufacturers	£8,000,000	£35,000,000
Total cost to large chemical manufacturers	£18,000,000	£97,000,000
<u>Total cost to chemical manufacturers</u>	<u>£26,000,000</u>	<u>£144,000,000</u>
Cost to Downstream Businesses		
Total cost to micro downstream businesses	£29,000,000	
Total cost to small and medium sized downstream businesses	£30,000,000	
Total cost to large downstream businesses	£4,000,000	
<u>Total Cost to downstream businesses</u>	<u>£63,000,000</u>	
Cost to Wholesalers of Chemicals		
Total cost to micro wholesale businesses	£480,000	
Total cost to small and medium sized wholesale businesses	£105,000	
Total cost to large wholesale businesses	£18,000	
<u>Total cost to wholesale businesses</u>	£600,000	
Costs to Retail Businesses		
Total cost to micro retail businesses	£800,000	
Total cost to small and medium sized retail businesses	£570,000	

Total cost to large retail businesses	£70,000	
<u>Total cost to retail businesses</u>	<u>£2,600,000</u>	
<u>Total cost to the public sector</u>	<u>£1,860,000</u>	
<u>Total Costs to Retail Consumers</u>	<u>£4,000,000</u>	
<u>TOTAL COSTS</u>	<u>£95,680,000</u>	<u>£215,680,000</u>

Administrative Costs

197. The administrative costs are identified as the costs associated with providing information to third parties, via labelling. These costs are presently generated under the current classification and labelling regulations and it is expected that there will be no net change to these costs from the GHS Regulation.

5.22 Option 2 - Oppose the introduction of the UN GHS

Benefits

198. This option will involve maintaining the current European Union classification and labelling system for chemicals, which provides the baseline for this impact assessment, and therefore will result in no additional benefits. The existing EU classification and labelling system provides a comprehensive system for classifying and providing information regarding the hazards related to chemicals. It is well understood and has been refined and developed over a number of years.

199. The EU system is already a globally recognised classification system, which is harmonised where the majority of sales occur. However, there is doubt as to whether this will continue as the GHS is implemented by the trading partners of the EU chemical industry.

200. The feasibility of this option would be dependent upon other European Union member states also opposing the introduction of the UN GHS.

Costs

201. The European chemicals industry incurs the costs of classifying and labelling chemicals under the present classification and labelling Directives. In addition to the costs of meeting current classification and labelling requirements, the existence of multiple classification and labelling systems worldwide currently creates costs for chemicals manufacturers

and suppliers related to classifying and providing hazard information separately for different markets, and creates trade-related costs. This option would result in no additional costs of complying with current classification and labelling legislation within the EU.

202. Depending on the extent to which other countries adopt the UN GHS, UK businesses may be disadvantaged in terms of capability to engage in international chemicals trade if the GHS Regulation is not adopted in the UK. In this scenario, the chemicals industry in the UK, and other European Union countries would have to continue to classify under the existing EU system, and also the UN GHS, in order to be able to export to both within and outside of the European Union. The extent of this requirement would depend upon whether GHS is implemented in other jurisdictions apart from the European Union.

203. Under this option, the continuing existence of multiple classification and labelling systems would continue to constitute a cost to international trade for UK businesses, and continue to present a barrier to international trade in chemicals. UK businesses would not be able to benefit from potential lowering in international trade costs arising from the harmonisation of classification and labelling systems. The UK would also forego potential economic benefits such as greater competition, lower prices for chemicals and an increased choice of chemical products and suppliers.

5.23 Option 3 - Active Negotiation – Support the introduction of the UN GHS, making it as light-touch as possible, avoiding any 'gold-plating'

204. The following sub-options have been identified as areas in which the UK could negotiate to achieve changes to the European Commission's current draft Regulation. Further quantification of the costs and benefits of these areas will be dependent upon additional information regarding the European Commission's proposal.

Classification of state/form of chemical 'placed on the market', or dependent on 'possible future use'

205. The current draft of the GHS Regulation moves away from both the existing legislation, and the UN GHS text which both state that it should be the product that is 'placed on the market' that should be classified and labelled. The new proposal is that the supplier should provide the classification for any intended future use of the product.

206. Costs of classification, under the assumption that classification would be required according to the state in which the chemical is placed on the market, are estimated earlier in this impact assessment. Costs of classification for substances and mixtures, associated with transition to GHS, depend on the number of substances and mixtures that are produced in the UK. As previously highlighted in this impact assessment, no information has been identified regarding this. However, as an illustration, if 15% of the total number of chemicals and mixtures, produced

in the European Union, are produced in the UK, the total cost to the UK is estimated to be approximately £130,000,000. (This assumes an average cost of reclassification of £500 per substance or mixture.) This may be a significant underestimate, as the UK could potentially, as an upper limit, produce 100% of substances and mixtures produced in the European Union. In this case, the total cost would be estimated to be around £870 million. This is further discussed and explained in section 5.11 of this impact assessment. These cost estimates are calculated on the basis that mixtures and substances would only require reclassifying once, according to the state in which the chemical is placed on the market

207. If it is assumed that there are multiple “possible future uses” for each chemical placed on the market, each of which would require a separate classification, the consequence of this would be to increase the costs of classification by a similar multiple. As an illustration, if there are, on average, 5 possible future uses for each chemical placed on the market, the consequence of this would be to increase costs of reclassification by a similar multiple. For example, if this is assumed to increase costs by a multiple of 5, the estimated costs of classification would increase by approximately £520 million (under the assumption that the UK produces 15% of the total number of substances and mixtures produced in the European Union), or by around £3.5 billion (under the assumption that the UK produces 100% of the EU total). This illustrative example indicates that the cost implications of the requirement to classify according to “possible future uses” are potentially very considerable.

208. Further evidence would be required regarding the potential benefits of this requirement.

Derogations for scientific research and development

209. The current classification and labelling legislation has derogations for research and development purposes, namely that they are not required to be fully classified and labelled if certain criteria are met. The new proposal is that any substance or mixture that is not fully classified must be treated as if it has been classified in the most severe category possible.

210. The impact of this requirement for chemical research and development activity, and for innovation in the chemicals industry, is uncertain but potentially substantial. This can be expected to due, for example, to the higher costs that would be generated from the requirement to treat chemicals, for research and development purposes, as if they have been classified in the most severe category. In 2005, expenditure on research and development in the chemicals and man-made fibres product group, in the UK, amounted to £616 million.(source: *UK Business Enterprise Research and Development 2005*, Office for National Statistics)⁶⁵.

Assistance for SMEs to comply with the new Regulation

⁶⁵ <http://www.statistics.gov.uk/pdfdir/erd1106.pdf>

211. The UK has already highlighted the need of the EC to consider how it can assist SMEs with either the introduction, and/or and compliance with the new GHS Regulation. The UK will continue to have a dialogue with the EC to ensure the requirements of SMEs are considered at a European level.

Impact on other European legislation

212. It is possible that the EC's proposed Regulation may result in unintended consequences in terms of interaction with downstream regulation (other than those already identified by the EC study), including to the Control of Substances Hazardous to Health Regulations⁶⁶ (COSHH). However, as previously described, the EC has committed to review and amend all affected European legislation, and the UK Government is currently undertaking a review of affected UK legislation, with the aim of amending any UK law prior to the repeal of the existing European legislation.

5.25 Other Uncertainties for all 3 options

213. A considerable number of uncertainties have been identified, in this impact assessment, in estimating the costs and benefits of the GHS Regulation. There is also considerable uncertainty regarding the timescale over which other countries will implement the GHS. There is a risk that other countries may not implement the GHS (although this is unlikely given the commitments given, and the amount of work already carried out as described earlier in this RIA). It is possible that other countries will select different 'building blocks', and retain elements of existing systems, which go beyond the requirements of the GHS (at this stage this is highly likely as currently most countries are aiming to introduce the GHS sections that most closely resemble their existing system). In this case, the potential initial trade benefits of the GHS would be limited.

5.26 Interaction between REACH and GHS regulations

214. When considering the impacts of the GHS Regulation it is important not to double count the costs associated with the REACH Regulation (Registration, Evaluation, Authorisation (and Restriction) of Chemicals)⁶⁷. There are a number of provisions and implications of the REACH Regulation, and these costs should remain attributed to REACH and not to the GHS.

⁶⁶ For more information please see: <http://www.hse.gov.uk/pubns/indg136.pdf>

⁶⁷ For more information please see: www.defra.gov.uk/environment/chemicals/reach/index.htm

5.27 Review and re-classification

215. Currently all substances and mixtures are either self-classified, or harmonised under the Dangerous Substances Directive (67/548EEC). When substances are registered under the REACH Regulation, manufacturers and importers will review their classification and labelling or where there is insufficient information to satisfy the registration requirements they must undertake more testing. The review of the classification and labelling will take place whether or not the GHS criteria are implemented in the EU.
216. It is envisaged that the main provisions of REACH and GHS Regulations will enter into force at the same time. Any overlap with the implementation of the two Regulations will mean there will be no additional costs to manufacturers and importers as the GHS classification and labelling can be undertaken at the same time as the REACH registration.
217. In practice this will mean that it is likely that those substances that are carcinogenic, mutagenic, toxic to reproduction and respiratory sensitizers, as well as those produced in quantities over 1000 tonnes will definitely overlap in terms of timescales. Manufacturers and importers that produce other substances that wish to register ahead of schedule will benefit. As the classification of mixtures are based on the classification of constituent substances, REACH will have a knock on effect and make manufacturers and importers of mixtures review the classification of their mixtures following the review of substances.

5.28 Safety data sheets

218. The REACH Regulation also requires manufacturers and importers to provide Safety Data Sheets (SDS) for all substances and mixtures that are classified as 'dangerous' under the existing system, and update them once new information becomes available. Therefore, as REACH requires updates of SDS, a review of SDS is likely to take place anyway because of new test data and during the registration process, whether or not the GHS criteria are implemented in the EU. To note, the provisions for SDS in the REACH Regulation are compliant with the UN GHS provisions.

5.29 Assisting stakeholders to comply with the GHS Regulation

'Translation' Table

219. One of the Annexes of the proposed Regulation is a 'translation' table. It is envisaged that this Annex will be used by those self-classifying substances and mixtures that have already been evaluated under the existing European legislation, for those hazard categories where a simple equivalence is possible.
220. The EC are proposing that the table will provide an option for suppliers/importers of substances and mixtures to fulfil their obligations under the new Regulation without having to undertake a reclassification, as long as the chemical has already been classified under the existing

system. If a supplier/importer chooses not to use the table they must fully re-evaluate the substance or mixture using the criteria in the Regulation.

221. At this early stage it is unclear how this translation table will work, and under what circumstances it will, or will not be appropriate to use it.

'Conversion of Annex I of the Dangerous Substances Directive'

222. Another Annex of the proposed Regulation is a list of Community harmonised classifications of specific substances. The Annex will include Annex I of the Dangerous Substances Directive (67/548/EEC) (implemented in the UK as the Approved Supply List), but with entries adapted to the GHS classifications. The current list of harmonised substances extends to some 8,000 entries. This will be a further 8,000 substances that will not have to be reclassified by industry.

223. As with the current classification and labelling system substances will continue to be added to the list of harmonised classifications. It is also envisaged that the resources of authorities will be focussed on substances of the highest concern, mainly substances classified for carcinogenicity, germ cell mutagenicity or reproductive toxicity (categories 1A or 1B according to GHS), respiratory sensitisation or for other effects on a case-by-case basis.

In addition to the Regulation

'RIP 3.6: Guidance on Classification and Labelling under Global Harmonised System'⁶⁸

224. The European Chemicals Bureau has the responsibility for developing methodologies, tools and technical guidance needed for REACH through a number of REACH Implementation Projects (RIPs).

225. The aim of the REACH Implementation Projects (RIP's) is to ensure an efficient implementation of the future legislation through the development of guidance and IT-tools for the European Chemicals Agency (ECHA), industry and the authorities. The RIP's include 7 main areas and a number of sub-subjects. The activities are coordinated closely with the main stakeholders i.e. Member States, industry and non-governmental organisations. The actual preparation of the technical guidance, etc. is sub-contracted through open tendering procedures.

226. As part of this RIPs work, RIP 3.6 aims to produce guidance on the classification and labelling under the GHS. The work on this RIP is currently on hold until the European Commission proposal is adopted. Costs of familiarisation with this guidance are included in the costs to business of familiarisation with the GHS Regulation, which are estimated above.

⁶⁸ For more information please see: <http://ecb.jrc.it/reach/rip>

Other Guidance/Tools

227. The EC is also potentially developing an on-line tool to assist business with complying with the GHS Regulation. At this stage no further details are known about the tool.

228. The UK Government will also work with the European Commission, Trade Associations, industry and other stakeholders to develop guidance and help educate those affected. HSE is keen to play its part, but as with the REACH Regulation, all stakeholders must take responsibility when developing tools and guidance for understanding the GHS. At this stage HSE is unable to confirm the exact work that will be undertaken, as this will depend on the work of the European Commission, and other stakeholders. Business will incur costs of familiarisation with this guidance. Costs of these activities to HSE, other stakeholders, and businesses is included in the costs of the familiarisation estimated above.

6. SMALL FIRM IMPACT TEST

229. The cost estimates presented in this impact assessment indicate that a considerable proportion of the businesses that will incur costs from transition to GHS will be micro and small / medium sized businesses. The estimated total costs to micro businesses and small and medium sized businesses, associated with the GHS Regulation, are summarised in the table below.

Table 20: Costs to Micro, Small and Medium Sized Businesses

	Low	High
Cost to Chemical Manufacturers		
Total cost to micro chemical manufacturers	£4,000,000	£6,000,000
Total cost to small and medium sized chemical manufacturers	£8,000,000	£35,000,000
Cost to Downstream Businesses		
Total cost to micro downstream businesses	£29,000,000	
Total cost to small and medium sized downstream businesses	£30,000,000	

Cost to Wholesalers of Chemicals	
Total cost to micro wholesale businesses	£480,000
Total cost to small and medium sized wholesale businesses	£105,000
Costs to Retail Businesses	
Total cost to micro retail businesses	£800,000
Total cost to small and medium sized retail businesses	£570,000

Question - Do you agree that the estimated costs to micro, small and medium sized businesses are accurate? If you do not agree, please provide actual examples of products to demonstrate the possible cost to support your reasons.

230. Benefits to small businesses, as for other sectors, are expected to be largely associated with the potential reduction of barriers to international trade in chemicals, benefiting small and medium sized businesses that engage in international trade in chemicals. There may be potential benefits to small businesses that purchase chemicals as an input, arising from increased international competition in chemicals, with consequent benefits of access to a wider range of chemicals and suppliers, and lower prices for chemicals.

7. COMPETITION ASSESSMENT

231. The GHS Regulation will potentially generate impacts for a wide range of different businesses, including chemicals manufacturers, downstream businesses that use chemicals as an input to production, and wholesalers and retailers of chemical products.

232. The competition assessment undertaken for the partial Regulatory Impact Assessment of the REACH Regulation⁶⁹ provides information, including a description of the market structure of the UK chemical industry, which is relevant to informing the competition assessment for the GHS Regulation. The partial impact assessment for the REACH Regulation identified three distinct markets in the chemical manufacturing sector.

⁶⁹ Defra (2006) "REACH Partial Regulatory Impact Assessment after Common Position"
<http://www.defra.gov.uk/environment/chemicals/pdf/reach-partialria-commonposition.pdf>

- Bulk/commodity chemicals (those sold to specification and price)
- Speciality chemicals (those sold on performance)
- Consumer product chemicals (performance products sold on the basis of brand)

233. In addition to chemical manufacturing, the following downstream sectors can be identified to be affected, based on the identification of downstream sectors earlier in this impact assessment:

- Agriculture
- Weapons and ammunition manufacturing
- Textile manufacturing
- Pulp, paper and paperboard manufacturing
- Rubber products manufacturing
- Plastic products manufacturing
- Glass and glass products manufacturing
- Wholesale of chemical products
- Retailing of chemicals products

234. No significant negative consequences to competition, arising from the GHS Regulation, have been identified. However, the following issues have been identified as relevant to considering the competition impacts of the GHS Regulation.

- Transition to the GHS would generate greater costs for some businesses than others. This will generally be in proportion to the number of chemical products produced, sold, or used, with businesses that produce, sell, or use more chemical products incurring higher transitional costs.
- GHS is not expected to lead to a significant change in market structure in the affected markets. The GHS Regulation is not expected to increase costs of market entry or market exit, or ongoing costs, for chemicals manufacturing businesses, or downstream businesses, wholesalers or retailers, or generate additional restrictions to the number of businesses entering or leaving the affected markets, compared with the current classification and labelling system.
- It is possible that some businesses, such as chemical manufacturers or downstream businesses may choose to exit their respective market because of the transitional costs and a possible associated short-term impact on profitability, although no evidence has been obtained regarding this.

235. In the long term, GHS may increase international competition via the lowering of barriers to trade that currently arise from having, worldwide, several different classification and labelling systems. However, the extent of this positive competition effect is highly uncertain and it will, in

particular, depend upon the extent to which the GHS is adopted consistently in different jurisdictions.

Question - Considering your sector, and those you do business with, what do you think the overall potential impact will be on competition as a result of the introduction of the new Regulation?

Are there any additional costs and/or benefits that you think should be included in this assessment? Please provide actual examples of products to demonstrate the possible cost or benefits to support your reasons.

8. ENFORCEMENT AND SANCTIONS AND MONITORING

236. HSE will draft UK legislation in order to allow the Enforcing Authorities to enforce the GHS Regulation, and to provide for proportionate sanctions. The EC draft Regulation also places duties on Member States to report back to the European Chemicals Agency (ECHA) every 5 years on the results of the official controls, and other enforcement measures taken.

9. EVALUATION AND MONITORING

237. To be completed after consultation.

10. IMPLEMENTATION AND DELIVERY PLAN

238. To be completed after consultation.

11. POST-IMPLEMENTATION REVIEW

239. The EC plans to review the technical Annexes of the GHS Regulation, with a view to proposing amendments (if appropriate) subsequent to it coming into force. The timing of these reviews will be subject to negotiation.

12. SUMMARY AND RECOMMENDATION

240. To be completed after consultation.

Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed

Date

Lord McKenzie, Parliamentary Under Secretary, DWP

Contact point for enquiries and comments: Jan Harris, HSE, International Chemicals Unit, Rose Court, 2 Southwark Bridge, London, SE1 9HS, 020 7717 6251, jan.harris@hse.gsi.gov.uk.

UK Initial Regulatory Impact Assessment - Annex A

GHS Implementation World-wide (taken from UNECE website)⁷⁰

Australia

1. Work on implementation of the GHS is proceeding across various chemical regulatory sectors (workplace chemicals, poisons, agricultural and veterinary chemicals, industrial chemicals, dangerous goods transport and therapeutic goods) in Australia. Most chemicals are captured by the scope of more than one sector.
2. For the workplace chemicals sector, the Office of the Australian Safety and Compensation Council (the ASCC) is well advanced in reviewing the national standards and codes of practice relating to workplace use of chemicals, including classification, labelling and safety data sheets. The new suite of documents will use the GHS as the primary hazard classification and communication tool. The first draft documents in the suite and a regulation impact statement relating to the implementation of the GHS for workplace chemicals were released in September 2006.
3. The public comment process will remain open until 1 February 2007. Additional documents providing detailed guidance for preparation of labels and safety data sheets are currently being finalised. In 2007, comments received from all stakeholders will be analysed and a final regulation impact analysis will be conducted to allow the ASCC to make a decision on GHS implementation, including transition/implementation timeframes to harmonise with trading partners.
4. Progress towards implementation of the GHS across other chemical sectors in Australia is ongoing, with regular consultation occurring between policy developers and regulators of the different sectors.
5. Australia is working towards being in a position to implement the GHS in 2008. Although details are not yet clear as to how many, or which 'building blocks' Australia is planning to implement, at the UN GHS meeting in December 2006, the Australian delegate confirmed that (similar to the EU) Australia planned to implement the vast majority of the GHS.

Canada

6. In August 2003, Canada released its situational analysis, which compared the systems in Canada with existing hazard communication requirements to the GHS. Two months later, Canada held a workshop to launch GHS implementation. The purpose was to build a common understanding of GHS and to identify issues and options for the implementation of GHS in Canada.

⁷⁰ Taken from http://www.unece.org/trans/danger/publi/ghs/implementation_e.html

7. Since 2004, Canada has been conducting technical consultations. A multi-stakeholder cross sector committee serves to identify and address issues common to the sectors and address issues which may arise as a result of potential changes to the current system. The objective is harmonization to the greatest extent possible between sectors in Canada and between trading partners. In addition, expert working groups are addressing specific issues of environmental and chronic hazard labelling.
8. In February 2006, a document was developed to provide a summary of the results of the deliberations by the sectors affected by the implementation of the GHS. The "Comparison of Sector Interim Recommendations or Preferred Options" reflects the current status of interim recommendations for adoption up to 23 February 2006.
9. Next steps in the implementation process will be:
 - Consultation on implementation phase-in options;
 - Consultation with trading partners;
 - Economic analysis;
 - Development of final recommendations;
 - Draft regulations;
 - Regulatory process;
 - Decision making;
10. It is understood that Canada is also working towards the adoption of the GHS in 2008.

Japan

11. The Japanese Government started in 2001 a series of activities at national and international level for the implementation of the GHS.
12. The translation of the first edition of the GHS into Japanese started in 2001 and was achieved in 2004. Since 2005, it is available at the MHLW, METI and MOE websites. During the translation process, government officers engaged in the translation work became familiar with the GHS. The differences between current Japanese laws and the GHS, with respect to the classification and labelling of hazards were analysed and listed and chemicals which are regulated under the current single or duplicate Japanese laws were identified. Thus, gap analysis was accomplished.
13. The Japanese government also launched the Chemicals Classification Program based on the GHS, for the purpose of assisting industries to develop their Safety Data Sheets (SDS's) and labels. In that context, they have so far completed the classification of 700 chemicals out of approximately 1,500 target chemicals to be classified under the program and they plan to classify the remaining chemicals and publish the results until the end of 2006.

14. The Industrial Safety and Health Law which aims at ensuring workers' safety and health at the workplace was amended in 2005 in order to implement GHS labelling and SDS, replacing current national requirements.
15. In December 2005, the Japanese government started recommending industries to voluntarily apply GHS labelling in the framework of the Poisonous and Deleterious Substances Control Law which regulates chemical products containing toxic or corrosive substances and requires labelling on that products.
16. Until March 2006, there were no standards for chemical labelling under Japanese laws. The development of Japanese Industrial Standards, in which standard labelling methods corresponding to GHS, was achieved in March 2006
17. Many training courses concerning chemical management as well as seminars and workshops focusing on the classification of chemicals according to the GHS, organized by the Japanese Government and private sectors were held in Japan and in other Asian countries. It is believed that, as with other countries, Japan is also working towards an implement date of 2008.

United States

18. The United States actively participates in the United Nations Subcommittee of Experts on the GHS. Four regulatory agencies are potentially impacted by GHS: Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Department of Transportation (DOT) and Consumer Product Safety Commission (CPSC). OSHA has completed a comparison of the GHS elements with the OSHA hazard communication standard (HCS) elements.
19. OSHA has also prepared a Guide to the GHS and participated in the NAFTA (North American Free Trade Agreement) discussions regarding coordination of implementation of the GHS.
20. A pilot project between occupational safety and health authorities in the USA and the European Union and European Economic Area was conducted in 2005. The project was recommended at a 2003 joint conference on occupational safety and health where implementation of the GHS was discussed and its objective was to better understand the application of the GHS.
21. OSHA has also prepared an advance notice of proposed rulemaking to consider modifications to their hazard communication standard to adopt GHS in the workplace. The advance notice details how OSHA expects

implementation of the GHS to affect the current requirements for hazard communication. OSHA is currently seeking public comment (until 13 November 2006) on the implementation of the GHS.

22. The Environmental Protection Agency (EPA) has outlined initial thinking on the application of the GHS to pesticide labels in a "White Paper" and solicited public comment on their plans through a notice published in the U.S. Federal Register. On the other hand, discussions within the NAFTA Technical Working Group on Pesticides are also ongoing.
23. The US Department of transport (DOT) is in the process of aligning all related regulations with GHS. It is expected that the process be completed in 2007. The US Consumer Product Safety Commission (CPSC) has taken initial steps to compare its requirements to GHS.
24. The American Chemistry Council is being active in further development of GHS and drafting of ANSI (American National Standards Institute) standards. The ANSI Material Safety Data Sheets standard has been aligned with the GHS.

UN/ILO GHS Capacity Building Programme⁷¹ and the World Summit on Sustainable Development (WSSD) Global Partnership for Capacity Building to Implement the GHS⁷² (two programmes established to encourage the uptake of the GHS, especially in developing countries)

25. Widespread introduction of the GHS and effective hazard communication into national legal and technical infrastructures is only likely to occur if adequate support for training and technical assistance is made available. To this aim, the United Nations Institute for Training and Research (UNITAR) together with the International Labour Organisation (ILO) established the GHS Capacity Building Programme. This programme comprises a series of country-based activities and regional activities, as well as guidance development and other work.
26. The programmes work demonstrates the wide range of countries that are likely to move to the GHS in the future. For example, country-based activities are already underway in: Indonesia, Nigeria, Philippines, Senegal, Thailand and the Gambia.
27. A series of regional workshops for ASEAN countries⁷³ (Association of South East Asia Nations) has been held, and informal consultation has been undertaken with participants from the SADC (Southern African Development Community) countries on their work towards the adoption of the GHS.

⁷¹ www.unitar.org/cwg/ghs

⁷² www.unitar.org/cwg/ghs_partnership/index.htm

⁷³ ASEAN member states are: Brunei Darussalam; Cambodia; Indonesia; Laos; Malaysia; Myanmar; Philippines; Singapore; Thailand and Vietnam

28. A Global Thematic Workshop on Strengthening Capacities to Implement the GHS, was also held in November 2005 in Johannesburg, which brought together 87 representatives from developing countries, industrialised countries, international organizations, industry and non-governmental organisations.
29. The goal of the WSSD Global Partnership for Capacity Building to Implement the GHS is to strengthen capacities at all levels and sectors (in particular in developing countries) to ensure a higher degree of chemical labelling and related precautionary measures for industrial chemicals, agricultural chemicals, chemicals in transport and consumer chemicals. Dangerous chemicals traded internationally and produced locally are to be appropriately classified and labelled in accordance with the GHS by the year 2008.

UK Initial Regulatory Impact - Annex B

Affected Downstream European Legislation⁷⁴

The list below sets out the European laws, as identified by the EC report, on which will be affected by the introduction of the draft Regulation on Classification, Labelling and Packaging of substances and mixtures, together with how the European Commission is currently planning to amend the affected legislation.

European legislation that will be amended within the draft Classification, Labelling and Packaging Regulation

Regulation (EC) 1907/2006 of the EP and Council concerning REACH

Dangerous Substances Directive 67/548/EEC

European legislation that the European Commission will amend in a separate review

Consumer products

Regulation (EC) 648/2004/EC of the EP and Council on detergents, as amended

Regulation (EC) 1980/2000 of the EP and Council on a revised Community eco-label award scheme, as amended

Council Directive 76/768/EEC on cosmetic products

Council Directive 88/378/EEC concerning the safety of toys

Council Directive 75/324/EEC relating to aerosol dispensers

Handling chemicals for particular uses

Directive 1998/8/EC of the EP and Council concerning biocidal products, as amended

Council Directive 91/414/EEC concerning plant protection products

⁷⁴ As identified by 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

Control of dangerous / hazardous chemicals

Council Directive 1996/82/EC on the control of major-accident hazards involving dangerous substances, as amended

Regulation (EC) 304/2003 of the EP and Council concerning the export and import of dangerous chemicals

Council Directive 1999/13/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC, as amended

Council Directive 1996/62/EC on ambient air quality assessment and management

Directive 2000/60/EC of the EP and Council establishing a framework of Community action in the field of water policy

Occupational health and safety

Council Directive 1998/24/EC on the protection of workers from chemical agents at work, as amended

Directive 2004/37/EC of the EP and Council on the protection of workers from carcinogens or mutagens at work

Council Directive 1994/33/EC on the protection of young people at work, as amended

Council Directive 1992/85/EEC on the health and safety at work of pregnant workers and workers who have recently given birth or are breastfeeding, as amended

Council Directive 1992/58/EEC on minimum requirements for the provision of safety and/or health signs at work

Waste and end-of-life products

Council Directive 91/689/EEC on hazardous waste

Directive 2000/53/EC of the EP and Council on end-of-life vehicles

Directive 2002/95/EC of the EP and Council on the restriction of certain hazardous substances in electrical equipment

Council Directive 91/157/EEC on batteries and accumulators containing certain dangerous substances

UK Initial Regulatory Impact Assessment - Annex C

UK Policy Principles (Agreed by Ministers, in September 2006, in order to respond to the EC Internet-based Consultation)

The UK's negotiating position should be supportive of the introduction of GHS 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.

A copy of the full UK Government response to the European Commission Internet consultation can be found at: (www.hse.gov.uk/ghs/eureg.htm)

UK Initial Regulatory Impact Assessment - 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.

.....

(1) 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