

Annex A

RESULTS OF THE UK CONSULTATION ON THE PROPOSED EUROPEAN REGULATION ON THE CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES ADOPTING THE GLOBALLY HARMONISED SYSTEM ON THE CLASSIFICATION AND LABELLING OF CHEMICALS (GHS) IN THE EUROPEAN UNION**Executive Summary**

1. Consultative Document (CD) No 213 was published on 14 August 2007. Consultation closed on 2 November 2007. The CD set out an introduction to the systems for the classification and labelling of chemicals (both the current EU one and the GHS), an indication of key issues for the UK, the proposed Regulation text together with its technical annexes, and an initial Regulatory Impact Assessment (RIA).
2. The CD asked 24 questions, several of which focused on the assumptions and estimates made in the initial RIA.
3. Approximately 30,000 consultees were contacted. These were made up from those that subscribe to HSE's web site; subscribers that have indicated a particular interest in chemical matters; separately targeted industry, business, trades unions, academic and other contacts who have previously been consulted on amendments to the CHIP Regulations; and a Standing Committee of ACTS, specialising in classification and labelling matters.
4. Thirty-three responses were received, principally from industry and trade associations. The great majority supported adoption of the GHS – only one respondent rejected the proposals in their entirety and saw no value in the adoption of GHS in European Member States. However, a number of respondents qualified their support. The concerns raised largely mirrored those already highlighted in the CD. Certain sectors, most notably the cleaning products and detergents industry, noted that they face proportionately higher costs of compliance as a result of applying the new classification criteria.
5. Few respondents commented in detail on the initial Regulatory Impact Assessment. Where the original cost assumptions were challenged, little evidence was presented to substantiate the revised costs suggested. Sometimes the costs quoted by respondents supported the figures in the initial RIA, eg reclassification costs.
6. The final Regulatory Impact Assessment shows total implementation costs for the new Regulation of £95,680,000 (low estimate) and £215,680,000 (high estimate). This cost has the potential to be increased significantly if the proposals to extend the need for child resistant closures and tactile warning devices on packaging are accepted. However, negotiations on this aspect continue and we believe standards in the existing EU system will be maintained.

7. Industry has progressed with its understanding of GHS, the options and flexibilities provided by the provisions, and how a more managed migration from the existing system to the new regime can be achieved. This improved understanding is helping industry to better assess the actual impact and practicalities of the new Regulation.
8. Negotiations in the Council and in the European Parliament continue.

Introduction

9. Consultation ran from 14 August – 2 November 2007 in the form of a Consultation Document (CD No 213), approved by the Health and Safety Commission. The CD represents one part of an on going process of consultation. It followed earlier consultation with approximately 1500 stakeholders, including other Government departments, trades unions, trade associations and others in 2006 on the draft European proposal, which culminated in a participative workshop in September of that year. Consultation has continued with HSE officials meeting with many representatives of industry and business sectors, as well as delivering numerous presentations both at UK and European level.
10. The timing of the CD was determined by the publication of the European Commission's (EC) formal proposed Regulation on the Classification, Labelling and Packaging of Substances and Mixtures, on 27 June 2007 and the immediate start, thereafter, of Member State negotiations and consideration in the European Parliament.

CD format and publication

11. The CD was published on the Internet and was available as a hard copy on request. It comprised: an introduction to the classification and labelling of hazardous chemicals; the current European system and the proposed international system; the Globally Harmonised System for the Classification and Labelling of Chemicals, known as 'GHS'; the proposed European Regulation (60 Articles); the seven technical annexes to the Regulation; and the draft initial Regulatory Impact Assessment. The entire package ran to approximately 700 pages.
12. The CD was written for as wide an audience as possible, both those well-versed in classification and labelling matters and those with a far more limited knowledge. It posed 24 questions, designed to establish a profile of the respondents, their specific involvement in the classification and supply of chemicals, and the potential or anticipated impact of the proposed Regulation on them, both financially and as benefits. The questions focused on key issues that had been highlighted in earlier consultations with stakeholders and in the development of the UK's initial response to the EC's draft proposals in 2006, or which emerged from early Member State negotiations. The issues included:

- the proposed scope of the Regulation, moving from classifying the chemical as supplied, or extending classifications to take into account the uses of the chemical concerned;
- the role of the different 'actors' in the supply chain, especially the assumed competence and expertise of distributors to carry the same duties as manufacturers and/or importers;
- the proposed transitional period to migrate from the existing European system to the new one;
- the proposal to select only those elements (known as 'building blocks') of GHS that most closely reflect the existing European system;
- the proposal to extend those hazard classes (or end points) that would require child resistant closures and/or tactile warning devices.

13. Standard questions were also included on whether the CD and the RIA provided sufficient information for respondents to understand and comment on the issues involved.

Question structure

14. In keeping with developing arrangements for consultation, an on-line questionnaire was prepared, modelled on the Bomel tool to assist with analysis of responses. The questions were designed to have selective responses that would allow more effective analysis: disagree; partly agree; agree; don't know; not applicable. Approximately half the consultees responded through the Bomel questionnaire.

15. Not all the respondents answered all the questions. Where no answer was provided, the corresponding on-line question field was left blank. Answers were not inferred or assumed.

16. Respondents were invited to reply in whatever form best suited their circumstances. A reply form was included in the CD.

Summary and numbers of consultees

17. Small business representatives were particularly targeted. HSE officials delivered a presentation to the HSC's Small Business Trade Association Forum, to raise the profile of GHS, to alert members to the forthcoming proposal and to invite the trade associations to engage with HSE and other stakeholders. Advice was sought on using the Small Business Service, and relevant trade associations and federations were invited directly to comment on the CD.

18. Overall, some 30,000 subscribers to HSE's web site were advised of the CD's publication, together with a further 3000 subscribers who have, in the past, indicated a particular interest in chemicals. A further 300 (approx) representatives of industry, business, academia, trades unions, trade associations and others, who have been invited to comment on regulatory changes to existing classification and labelling legislation were also invited directly to respond to the CD.

19. The Advisory Committee on Toxic Substances was consulted on the draft CD. No comments were received.
20. A further Stakeholder Workshop was held on 19 February 2008. Over 60 industry representatives attended and discussed the latest developments on many of the key issues raised in the CD. The event was well-received by those who attended. Delegates welcomed the participative and debating nature of the day.
21. Finally, HSE officials have chaired an inter-departmental sub-group on GHS since mid-2006. The sub-group's members have been consulted fully on the draft proposal, its subsequent development into a formal proposal, the development of the initial Regulatory Impact Assessment (especially Better Regulation Executive), and the development and agreement of the UK negotiating strategy. The Devolved Administrations have also been consulted.

Number of responses received

22. Thirty-three responses were received:

- Industry/business representatives = 15
- Trade associations = 12
- Trade Union = 1
- Member of public = 1
- Academia = 1

23. Three responses were received from abroad (USA, Australia, Belgium). The comments provided by these respondents were not taken into consideration as the consultation was focused on UK based organisations only.

24. Given the number of those consulted, this may seem a disappointing figure. However, HSE has either met or discussed the proposals with a number of industry representatives over the past year, and continues to do so. Those meetings have allowed many to express opinions and comments which informed the development of the overall negotiating strategy. Anecdotal evidence shows that the strategy has received the support of many in industry and there have been no objections to the way the UK has negotiated its interests.

25. There were several examples of respondents submitting the same or very similar responses. This was welcomed as indicating consultation, discussion and agreement within sectors.

New or emerging issues

26. Respondents representing the cleaning products and detergents sector highlighted an additional area of potentially significant costs - the potential packaging changes resulting from the requirement to ensure packaging is fitted with Child Resistant Closures (CRC) and/or Tactile Warning Devices (TWD) for substances/mixtures assigned the hazard category of 'serious eye damage' or are

re-classified as 'skin corrosive' following the implementation of the lower GHS base concentration limits. Due to these lower concentration limits, calculation in GHS means that more products may be classified or classified more severely, thereby triggering the CRC and/or TWD provisions.

27. The introduction of CRCs and/or TWD to existing packages may increase implementation and compliance costs significantly. The bridging principles provided in GHS, and the new Regulation, and other flexibilities offered based on existing evidence of the chemicals' safety and the application of expert judgement, should help to reduce the instances where these more severe classifications need to be assigned. This sector is reassessing their approach to classification and to the collection and use of the supporting data on which to base their decisions. The estimated costs of these provisions appear on pages 54 – 57 of the final Regulatory Impact Assessment at Annex A.

Respondent groups

28. Respondents were asked to provide information about the organisation (if any) they represented and their interest in the supply of chemicals. This information included:

- If the respondent currently classifies, labels and packages chemicals/chemical products;
- What type of organisation (if any) they represent, including: member of the public; trade association; trades union; non-governmental organisation; charitable/voluntary organisation; industry/business/ other);
- The industry sector they represent;
- The number of employees in their organisations (the majority of respondents did not answer this question. Those that did show: 3 small firms; 3 medium sized firms; 4 large firms);
- If they were a safety representative (one respondent).

29. Responses showed that interest in the proposals came primarily from those who currently manufacture or supply chemicals, or use them as part of their work, or trade associations who represent them.

30. A number of key representative bodies responded, including:

- Chemical Industries Association
- British Coatings Federation
- British association of Chemical Specialities
- Chemical Business Association
- UK Cleaning Products Association
- Glaxo Smith Kline
- Unite

31. A full list of respondents appears at Annex C of this report. Seven responses were received from representatives or individuals who asked for their names not

to be recorded in the public record. These responses have been recorded as confidential.

32. In considering comments, HSE followed guidance on dealing with responses from individuals, groups and representative bodies designed to ensure that all responses were dealt with fairly.

33. Not all respondents answered all the questions. Similarly, not all respondents answered the questions actually asked but provided broader comment. Where this occurred, the comments have been reflected against the relevant question wherever possible.

34. A complete question set appears at Annex A.

DETAILED COMMENTARY AND ANALYSIS OF RESPONSES

35. Comments reflected verbatim, appear in italics.

Question 1(a): Do you currently classify, label and package chemical products (in other words, are you a chemical manufacturer, importer, supplier, distributor or retailer) or do you use chemicals in a professional capacity? (please tick all that apply)

- I currently classify, label and package chemical products
- I currently use chemical products in a professional capacity
- I do neither of the above

Question 1(b): Type of organisation:

- A member of the public
- A representative of a trade association
- A representative of a trade union
- A representative of a non-governmental organisation (NGO)
- A representative of a charity/voluntary organisation
- Industry/business
- Other (please specify)

Question 3(b): Please select your industry sector

36. These questions sought to establish a profile of the respondent by asking their current interest in the classification and labelling of chemicals and their role in the supply chain – ie manufacturer, importer, distributor or retailer. HSE also sought information on whether the respondent used chemicals in a professional capacity. Information on the respondent's organisation type and their specific role were also sought. Finally, 1(c) asked which sector type best described the respondent's area of activities (respondents could choose one or more options).

37. The responses showed the following:

- 17 respondents currently classify, label and package chemicals;
- 4 respondents use chemicals in a professional capacity; and
- 6 respondents do neither of the above.

38. Most respondents identified themselves with the chemical sector (17), most being manufacturers (10). Other respondents identified themselves with the agriculture (1), biocides (4), pesticides (3), plastics (2), police (1), cleaning (4), printing (1), construction (1), gas (1), and retail (1) sectors. Other sectors also specified: pharmaceutical (1), public health sector (1), composite material manufacturer (1), specialist aromatherapy essential oil trade (1), academia (1) and aviation (1).

Question 2: Do you agree that the scope of the proposed Regulation should be limited to only those ‘building blocks’ of the UN GHS that most closely reflect the current EU classification and labelling system, together with elements of the EU system that are not covered by the UN GHS (ozone depleters)?

39. Responses:	Disagree	x 4
	Partly agree	x 11
	Agree	x 13
	Don't know	x 1
	Not answered	x 4

The ‘building block’ approach

40. Recognising that worldwide, some countries have mature classification and labelling systems and some have none at all, the GHS allows governments (or ‘jurisdictions’ such as trading blocks), some flexibility in selecting appropriate parts of the GHS for local implementation. Where a part in the GHS is selected, however, the relevant GHS criteria must be applied. This is known as the ‘building block approach’.

41. The EC has used the building block approach and selected those ‘blocks’ that most closely reflect the current EU system. The outcome is a proposed Regulation that implements all 27 GHS hazard classes (for example ‘Flammable gases’), while still retaining the existing EU class for ‘Hazardous to the ozone layer’ (this complies with the GHS principle of countries not lowering protection and is a continuation of current EU standards). Of the available 83 GHS hazard categories (these distinguish the severity of the hazard classes), the EC is proposing to implement 78, which correspond most closely with the provisions of the current EU system. Therefore, the EC will be implementing most of the GHS.

42. **While there was overall support for this proposal, some respondents expressed the need to qualify the adoption of building blocks.** A number of respondents including Polartech, Picon, UKCPI, McBride, BACS, saw an “*inherent flaw*” in having ‘optional’ elements of GHS. This was seen as a “*barrier to global standardisation*”, and was “*compounded*” by no firm definition at UN level as to what a ‘building block’ actually was with some respondents noting

differences between EU Member States in how best to interpret the available description of a 'building block'.

43. Polartech advocated EU permission to apply the *“non-mandatory or voluntary”* use of GHS hazard categories not regulated by the EU *“to enable international traders having to avoid relabelling where it also supplies products to/from markets where other 'building block' hazard categories of GHS are being implemented. We do not agree that the EU should add requirements that are not yet part of GHS”*.
44. The CIA said: *“we would encourage Council and Parliament to be very cautious in changing or adapting the criteria given by the UN GHS as changes may affect the level playing field envisioned by the GHS. Unless the CLP regulation is well aligned with the UN GHS, the long term 'trade benefits' described in the EU impact assessment will not materialise”*.
45. The CIA welcomed moves from the EU or individual EU Member States to *“introduce such additional elements as ozone depleters into the UN GHS scheme during the biennial review process so that they are agreed and adopted on a global basis”*.
46. Some respondents, including UKCPI and McBride supported the proposal but did not wish to see the extension of the existing provisions child resistant closures.
47. BACS and Advanced Composites Group Ltd saw *“benefits to be achieved for smaller companies by keeping EU GHS to a scope similar to that of the current legislation, the EU scheme will be bound to differ from that implemented in non-EU countries. We should be aiming for a world agreed system on supply classification and labelling that would truly be implemented globally. In failing to do so, one of the benefits for industry in GHS implementation is removed”*. The respondents did not *“believe the additional blocks add any H & S benefits to the supply role and agree with the necessity to retain those classifications currently in use which are beyond the scope of current GHS”*.
48. The University Chemical Safety Forum was strongly opposed to the introduction of GHS. The Forum said: *“UCSF does not support the introduction of UN GHS because we are not convinced of the benefits, especially in health and safety terms, not only to us, as end users, but also to other stakeholders in changing a perfectly adequate working system for the classification and labelling of chemicals. It is quite understandable to see why UK Chemical and 'downstream' industries have accepted UN GHS proposals when their proposed introduction coincides with the Registration Evaluation and Authorisation of Chemicals (REACH) timetable. We believe Industry would not have been so accommodating and forthcoming had this not been the case. Unfortunately, it appears that UN GHS will be accepted by the UK and implemented: parts of the Consultative Document are presented as a fait accompli.. Whilst we have strong reservations about the implementation of UN GHS we are nonetheless resigned to the fact that it will more than likely be agreed by the UK and we would hope that the HSE would advise HM Government to minimise the impact and facilitate a smooth transition”*.

49. The British Coatings Federation (BCF) did not support the “*unilateral introduction of hazard class differentiations*” as proposed by the EC. The BCF believed amendments should only follow changes to the UN GHS in order to achieve harmonisation. The BCF expressed similar reservations about the introduction of hazard pictograms that are not reflected in GHS.

Current position

50. The UK continues to support the proposal to adopt those GHS building blocks that, as far as possible, reflect the existing EU system. Discussions are already underway at UN level to agree, as part of GHS, suitable criteria for ozone depleters. This approach is welcome by the European Commission and further aligns GHS with the existing system.

Question 3: Do you agree with the EC’s proposed new approach to classify chemicals according to their use/s (Article 5.1 for example), rather than classifying what is ‘placed on the market’ (as is the case now)? Please give your reasons, and details of any possible implications for your organisation. If you disagree or partly agree, please explain why.

51. Responses:

Disagree	x 13
Partly agree	x 3
Agree	x 7
Don’t know	x 1
Not answered	x 9

Scope of the Regulation

52. The current draft of the new 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. As drafted, this provision has the potential to significantly extend the scope of the classification and labelling system by creating a duty to refine, revise or amend a classification (and the subsequent labelling requirements) depending on how a chemical may be used after it has been placed on the market. Classifying for all potential uses could result in more than one entry for a chemical in the Classification and Labelling Inventory leading to confusion, while the need to produce different labels and safety data sheets for different end uses could be costly.

53. **Overall, there was strong disagreement with this proposal.** The main concerns focused on the inevitable multiple entries that would result from classifications based on use rather than inherent hazard. Such an approach would move away from a hazard based system – GHS is strongly rooted in identifying and acting on hazards – to one that is more risk based.

54. Polartech recognised that this approach may be an advantage to the retail detergents industry, but rejected the proposal for many other situations where the possibility of a number of classifications for one substance were possible depending on its uses. Polartech also pointed out that this proposal went beyond the provisions of GHS. The proposal could also lead to complications, depending on its interpretation. Many of Polartech's products (emulsifying metalworking fluids) are supplied in concentrated form, then diluted for use on site, being further diluted for use by the end user. Polartech expressed concern that by applying the proposal they would need to determine multiple classifications for its products.
55. The CIA and Glaxo Smith Kline believed that the intention of Article 5.1 and the proposed Regulation required clarification. The CIA said: *"Since this article is part of Title II (Hazard Classification), [its] wording may suggest that the data used for the classification of a substance should relate not simply to the form or physical state in which the substance is sold but to the end use in which it may be used. This could potentially result in the same substance having different classifications for different applications. If this were the case, the application (and appropriate conditions of control) would have to be published as part of the classification and labelling inventory alongside a substance classification"*. As a result, CIA would prefer to maintain the current method for classifying a substance or mixture based on its inherent hazard properties *"which may constitute a risk during normal handling or use"*.
56. McBride and another respondent called for consistency between the proposal and other European legislation in defining *"placing on the market"*.
57. Picon said *"Classifying as a "user" is not workable because of the possibility of dilution during the life cycle of the product. Classification must be based on the intrinsic hazard of the product when placed on the market. It would place an unacceptable burden on the supplier to examine all possible uses before classification. This is not controllable and would require expert judgement. The best method of classification would be based on concentration levels"*.
58. One respondent said the proposal would be difficult to implement because *"since not all applications are known to the Regulators or declared by manufacturers, due to commercial sensitivity. REACH will address this to an extent, however, the timelines for low usage chemicals is long for registration and some of the chemicals which may affect revised labelling are not imported into the EU, making REACH ineffective at capturing this data"*.
59. Not all respondents opposed this proposal. Advanced Composite Group Ltd said: *"The current system fails to accurately describe the actual health and environment risks from the use of our products which, although fall under the chemicals regulations, are highly specific and specialised.....As a supplier we have far more knowledge of our products and an understanding of the ways they are used by our customers and hence can provide a more detailed, realistic and rationalised approach to risk management. The current system often forces us to over estimate the actual hazard potential of the materials we supply and therefore we welcome this proposed change. However the additional training/competence of classifiers/risk assessors that is required to produce accurate, meaningful*

judgements, especially within SME's, will create a major challenge. There will also be a considerable implication on the time required to perform classifications based on risk compared to those based on hazard. In addition this creates difficulties for those users of software based classification systems as assessments based on risk will be less prescribed and more judgement or experience based".

60. The Aromatherapy Trade Council (ATC) commented in considerable detail on this point, saying: *"This proposed new approach presents a dangerous and unnecessary precedent that completely changes the concept of classification and labelling of hazards by conflating and potentially confusing the concept of hazard, an intrinsic/inherent property of a chemical with the risk of that hazard causing harm, i.e. risk. Whilst the hazard can be identified and harmonised with some degree of scientific certainty the risk of causing harm is dependent on a variety of factors that can only be known by the manufacturer/supplier of a chemical by reference to all sectors of the supply chain both upstream and downstream. In order to avoid duplication of effort with REACH, classification and labelling of hazards must remain as a separate activity from risk assessment"*.
61. The ATC expressed some concern that SME's would *"be forced out of business as a result of increased cost and complexity or else they will ignore it altogether"*. The ATC went on *"in practice extending hazard classification to risk assessment in this type of regulation is completely impractical and wholly unnecessary especially since it will be implemented alongside of REACH in the same time-scales. This regulation should compliment REACH and other existing risk assessment approaches like COSHH not compete with it or duplicate effort"*.
62. Seldon Research Ltd sought *"guidance and interpretation of this clause needs to be very simple. SMEs do not have the resources to implement anything ambiguous"*.
63. The British Coatings Federation (BCF) reinforced the point that this proposal was *"in direct contradiction to GHS"*.

Current position

64. This proposal is subject to active negotiation.

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

65. Responses:
- | | |
|--------------|------|
| Disagree | x 14 |
| Partly agree | x 6 |
| Agree | x 4 |
| Don't know | x 2 |

Not answered x 7

66. The Regulation defines the different “actors” (eg, “manufacturers”, “importers”, “distributors”, “downstream users” etc) in the supply chain and assigns various classification and labelling duties to them, in an attempt to align the Regulation with REACH. The current proposal imposes the same duty on *all* those in the supply chain to ensure that the classification and labelling of the chemicals they deal with are correctly classified and labelled. The approach set out in this proposal goes beyond both the existing system and the GHS and promoted considerable comment not only in response to this consultation but also since both domestically and in Member State negotiations.
- 67. The majority of respondents wanted to keep the existing system, focusing most concerns on the anticipated role of the ‘distributors’.** The term ‘distributor’ has a fairly fluid meaning between Member States. For example, in the UK, the organisation Marks and Spencer would be termed a retailer or an outlet; in many other European Member States, however, Marks and Spencer would be termed a ‘distributor’.. While a seemingly minor point, such a distinction is enough to result in misinterpretation and/or misunderstanding in assigning reasonable duties to a distributor.
68. Principle concerns focused on whether or not it was reasonable for a distributor to be assigned the same duties as a chemical manufacturer or importer in ensuring that the correct classification and labelling had been applied.
69. The CIA and one other respondent disagreed with the proposal saying *“we have concerns over the split of responsibilities put forward by the proposed text. The wording in Article 4 should be changed to ensure that there can be no misinterpretation of the role of a distributor in communicating information. Distributors acting as re-salers must have the same obligations as importers and producers to communicate up and down the supply chain they are a part of. This has to include ensuring the classification and labelling is correct. Having a clear and straight-forward line of communication and responsibilities for that communication process has to be a priority. Ensuring that re-sellers retain their current responsibilities will add a layer of security in terms of communicating accurate information within the supply chain”*.
70. There were also concerns regarding stock *“which has since been reclassified by the producer or importer being sold with the old classification/label even though the new classification has been communicated to the distributor. It is unclear who would be responsible for any harm caused to downstream users due to inappropriate handling caused by inaccurate labeling in such circumstances”*.
71. Glaxo Smith Kline wanted to see the ‘distributor’ have a more qualified role, saying *“we believe that to be consistent with REACH text, the Regulation must attempt to split responsibilities for each actor in the supply chain. However, we do have concerns about classification and labelling being modified as a substance moves down the supply chain ad through distributors. Article 4 of the text should include a requirement for downstream users and/or distributor to communicate up*

the supply chain if they have data or experience that indicates that a classification and label provided by the manufacturer/importer is incorrect”.

72. The UKCPI and others stated *“the use of the generic term "supplier" could lead to confusion and misunderstandings regarding the responsibilities of 'each' actor in the supply chain. Downstream users have specific responsibilities under REACH that do not extend to classification and labelling. However, if a downstream user uses a substance to produce a mixture for supply they then become a manufacturer with C&L responsibilities. Legal clarification of the term "supplier" and associated responsibilities would be beneficial”.*
73. McBride on the other hand sought more *“specificity than just “supplier”.*
Downstream users can also be suppliers to those further down the distribution chain so further clarification is needed to avoid confusion and to apportion responsibilities and timing of actions with respect to classification & labelling”.
74. Two other respondents stated, respectively *“I fully agree with this as it places ownership on the "actors" to fulfil their obligations on risk assessment and registration, rather than the responsibility being placed on the primary supplier. Looking at downstream uses will result in higher quality safety data with improved relevance to the end users”, and “too much potential for misinterpretation or error”.*
75. BACS said *“although the practical implications of this are not entirely clear, we are inclined to think that this will mean more burden on our members”.*
76. Picon saw the role of the ‘distributor’ as being much reduced, saying *“having a "distributor" as an actor in the supply chain will present considerable difficulties. Many chemical distributor organisations are small and would not have the facilities or technical expertise to implement a change in classification. If this was in place there would need to be a reasonable time-frame for changes to take place as there could be considerable outstanding stock to be addressed. The manufacturer/importer/supplier is the most important link in the supply chain as they are responsible for the classification under REACH. They should be responsible for allowing the appropriate time-frame for change or requiring a product recall depending on the health, safety or environmental implications of any change”.*
77. Advanced Composites Group Ltd saw the proposal as a positive step forward and commented *“placing responsibility on all actors in the supply chain will hopefully generate a greater understanding of the rules and requirements under the regulations within the chemicals industry, however there will be the possibility of information being misrepresented, when inexperienced regulatory professionals are involved especially when the supply chain is lengthy, ie where complex formulations are involved. Communications through the supply chain will have to be vastly improved from its current standing and the demolition of confidentiality barriers will be an incredibly difficult hurdle to surmount. This is only going to be achieved by open communications, backed up with visible enforcement which is proactive rather than reactive”.*

78. National Starch and Chemical said *“we do not believe that Title II should be applicable to distributors since they will not have the information regarding formulated products to enable them to classify”*.
79. The Aromatherapy Trade Council also saw the proposal as being problematic for distributors, saying *“this attempt to separate roles in the supply chain in relation to classification is unnecessary. A hazard is an inherent function of a chemical. The person who supplies that chemical needs to classify the hazard and not the risk that is the job of the user of the chemical”*.
80. B&Q rejected the proposal, *“Article 4.4 - “a distributor, like B&Q, does not have sufficient information or expertise to ensure that the labelling or packaging is “correct”. For example, ensuring the label is correct would involve complete knowledge of the formulation, which we do not have as it may be confidential. If the word “correct” was removed, [B&Q] would be happy with the sentence [in Article 4.4]”*.
81. The Chemical Business Association echoed concerns about whether distributors possess the necessary expertise to carry out the duties currently assigned to them, saying *“the wording of article 4.4 imposes the responsibility for the correctness of package labels on distributors even when they only store and ship the packages. In the case of imports or re-labelling the distributor should retain such responsibility. However, in those cases where the label is not changed, the only legal responsibility of distributors should be to pass on the information downstream, as already raised by several Member States. In many cases there is no appropriate expertise to ensure that the information on the supplier’s label is correct.”*
82. One respondent suggested that *“products already in the supply chain should be excluded and distributors removed from the definition of a supplier, or some rewording of the text is necessary”*.
83. The British Coatings Federation (BCF) echoed the concerns about the competence of distributors to classify. The BCF added that this distinction was further needed when considering that “suppliers” had to “identify the relevant information” on hazards present. Distributors would, according to the BCF, for the most part, need to rely on the information provided by manufacturers and importers.

Current position

81. The UK continues to be involved in developing a more reasonable and proportionate duties for distributors, while ensuring levels of protection remain in place. The latest draft of Article 4, prepared by the UK and other Member States, removes from distributors the duty to classify. This means that distributors will rely on their manufacturers or importers to classify and advise them of the correct classification details for labelling and packaging. Distributors retain their duties to

correctly label and package remain in place, as is currently the case. In addition, a duty has been added requiring suppliers in a supply chain to co-operate.

82. The proposed re-draft is subject to agreement in negotiations.

Question 5: Will this split of roles and responsibilities help you in your business?

83. Responses:

No	x 12
Yes	x 3
Don't know	x 6
Not applicable	x 3
Not answered	x 9

84. The majority of respondents could see no benefit to their business from splitting the roles and responsibilities as proposed.

85. The CIA and one other respondent said *“our members will make, use and import chemicals to manufacture their substances and mixtures. Removing the role of the distributor to ensure that his products are suitably classified and labelled is only moving this responsibility onto someone else in the supply chain adding to costs for that specific company and reducing the benefits of having a harmonised system”*.

86. McBride said *“the majority of the raw materials we use are mixtures themselves. Clarification the role of supplier should help us at the bottom end of the distribution chain to get information earlier from those higher”*.

87. The Aromatherapy Trade Council added that the proposal introduced an unnecessary level of complexity, with no apparent reason for its basis. The ATC could see no any benefit from the proposal either.

Current position

88. Given the progress in negotiations these comments may no longer be applicable.

Question 5a: Which part of the supply chain best defines your role – manufacturer, importer, downstream user, distributor, professional user, other?

89. Few respondents answered this question, but those that did indicated:

<input type="radio"/> importer/downstream user	x 1
<input type="radio"/> consultant to distributors and manufacturers	x 1
<input type="radio"/> health sector employee using chemicals	x 1
<input type="radio"/> representative of manufacturers, importers, distributors, downstream users, retailers	x 1
<input type="radio"/> all categories above/ all or several functions	x 1

Question 6: Do you agree with the new proposed derogation for scientific research and development as described in Article 1.2(d)? If you don't agree, or partly agree please explain why.

Scientific research and development

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

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

92. Responses:

Disagree	x 4
Partly agree	x 7
Agree	x 11
Don't know	x 2
Not answered	x 9

93. Consultation responses indicated that there is full support to remove the qualification that unclassified substances used in research should be handled as though they had the severest hazards. The CIA said *"clarity is needed on what is required for R&D [Research and Development] samples where the classification is not known. This presents some real difficulties and could become an obstacle to trade. We would like to see the principle of "Caution - Substance not yet fully tested" reinstated and the incorporation of reference to "for use by professional users".*

Current position

94. In negotiations this provision has been amended such that substances and mixtures for research and development not placed on the market, are outside the scope of the Regulation provided they are used under controlled conditions in accordance with Community workplace and environmental legislation.

Question 7: If you classify chemicals now, do you think this Regulation introduces new obligations that are not in the current system?

95. Responses:

No, it doesn't	x 2
Yes, it does	x 17

Don't know	x 4
Not applicable	x 1
Not answered	x 9

96. Polartech said *“more products are likely to be classified (or more severely classified), but we have not assessed the proposals in sufficient detail in relation to our specific products to determine its full impact”*.
97. The CIA said *“In terms of new process, the introduction of GHS into the EU system will result in industry having to manage two systems in parallel for a number of years. This will result in an intensification of hazard and risk communication not only down the supply chain but also with consumers”*.
98. Another respondent echoed this view and raised concerns about Industry having to *“pick up the financial and resource burden for educating individuals and institutions in the supply chain”* as a result of *“the potential for enormous confusion”* resulting from a *“prolonged period of dual running between the existing system”* and the new one. The respondent added that the strain was already evident in coping with the introduction of REACH.
99. Both the CIA and the other respondent added, *“it is expected that a greater number of substances and mixtures will be considered hazardous under the new scheme due to the changes in calculation methods. Since downstream users and consumers have been handling the same products safely without hazard warnings, the new classification criteria may end up being disregarded in practice especially by the public”*. The CIA went on, *“the benefits of expanding existing requirements for child resistant caps and tactile labelling to additional classes of products remains questionable when balancing added safety benefits against the cost burden to industry and the limitation in accessibility to elderly people to some products”*.
100. A couple of respondents, including the UKCPI, highlighted the emphasis in the Regulation on the *“identification and evaluation of available data on the mixture itself or the substances contained in it. This in itself does introduce degrees of flexibility, which the cleaning products Industry has been made aware of. However, the ability to use this flexibility hinges on the availability of data and the expert interpretation of that data. In many cases neither the data nor the expertise is available and whilst the GHS Regulation allows new in-vivo (animal) testing to be carried out, subject to certain provisions, this approach is not an option for many detergent and cleaning companies due to animal welfare concerns. The net effect is that classification will rely on the summation method in the GHS Regulation. This will result in more severe and unjustified labelling and packaging for the majority of cleaning products”*.
101. Advanced Composites Group saw the Regulation as presenting *“considerable difference in the approach to classification based on hazard over risk”*.

102. Pick Quick Service Ltd saw problems in the replacement of the existing R and S phrase (so called Risk and Safety phrases). The respondent saw similarity between the existing phrases and their new GHS counterparts – hazard and precautionary statements – although the former were seen as easier to use. The respondent also stated that the new exclamation pictogram (!) did not have the same impact as the existing X, currently used for irritant/harmful.
103. The Aromatherapy Trade Council raised concerns on a related issue, suggesting that the Regulation could result in creating a *“precedent of over protective classification for novel chemicals where none existed before thereby potentially reducing innovation and competitiveness for no increase in consumer safety. If a chemical is classified by a supplier as if it is a carcinogen then it has to be treated as if it is or defence in law will be negated. Hence additional protective regimes equate to increased costs or reduction in development”*. The ATC also said the Regulation *“changes the concept of classification and labelling of hazard and conflates it with risk, thus creating the opportunity for confusion in terms”*. The ATC saw the identification of hazard as a *“precursor to risk assessment not a component of it. Complication creates confusion”*. Similarly, the ATC saw the proposed definition of a ‘supplier’ creating confusion and contradiction where none existed before and *“is a consequence of the conflation of hazard and risk”*.
104. One respondent saw the requirement of a supplier to *“identify all relevant information for the purposes of classification”* as *“unworkable as it is far too vague”*. The respondent did not support the requirement to *“notify the ECHA [European Chemicals Agency] of classified substances or mixtures placed on the market, as this introduces additional burden”*. Finally, the respondent, like PICON, called for a derogation for products already in the supply chain.
105. The LPG Association saw the new requirements as *“subtle”*, for example, *“the duty to mark a butane or propane cylinder “Warning - extremely flammable gas” rather than the current (“extremely flammable”)”*.

Current position

106. There seemed to be a certain amount of misunderstanding over this question. Many respondents chose to interpret the possible increase in the number of classified substances and mixtures as a new obligation. The obligation to classify has remained the same, although the new Regulation brings with it some new scientific criteria from which to do so. The duties to label and package also remain the same, albeit with adjustments to the terminology and some of the symbols (pictograms) used. Much of the concern appears to be borne of an unfamiliarity with GHS and concerns about a certain period of parallel running while industry migrates from the existing system to the new regime, rather than identifying significant additional obligations to those required under existing legislation. For example, while it is recognised that for certain sectors, most notably that of detergents and cleaning products, an increase in the number of classified products can be expected, the duty to identify all relevant data/information for classification forms part of the existing system.

107. However, since the Consultative Document was published, Industry has progressed with its understanding of GHS, the options and flexibilities provided by provisions such as the ‘bridging principles’, and how a more managed migration from the existing system to the new regime can be achieved. This improved understanding and, in some case, direct application of the new GHS based criteria for classifying existing products and formulations, is helping industry to better assess actual impact and the practicalities of implementation. The issue of child resistant closures and tactile warning devices is explored at paragraphs 122 to 131.
108. The concerns raised about the need for industry to run parallel systems while the migration from the existing system to the new one takes place, is understandable. However, a certain transitional phase is needed as switching to the new Regulation with no lead in time would be unworkable. Those involved with the supply, classification and labelling of chemicals are familiar with accommodating changes to classification, having done so for the CHIP Regulations for a number of years. While the Regulation brings in much bigger changes, the fundamental duties to classify, label and package remain the same. With an increased familiarity with GHS and the new Regulation, Industry is clearer on the value of the transitional period available.

Question 8: Would you agree that the obligations described in the labelling and packaging provisions in the Regulation (Title III and Title IV) are reasonable? If you disagree or partly agree, please explain why.

109. Responses:
- | | |
|--------------|------|
| Disagree | x 8 |
| Partly agree | x 13 |
| Agree | x 7 |
| Don't know | x 2 |
| Not answered | x3 |
110. Polartech said in respect of Article 17.2, *“we believe universal language rules should be set in the regulation and not left to individual Member States in the interests of simplicity, clarity, consistency and uniformity”*. Also, *“we do not agree that there should be any label or packaging requirements that extend beyond the requirements in GHS”*.
111. The CIA, Glaxo Smtih Kline, and the Chemical Business Association all commented. Respondents expressed the following points *“a number of changes would need to be implemented to ensure the regulation works smoothly in practice”*. These were:
- inner & outer packaging labelling - the exemption under existing regulation
 - from outer packaging labelling where the inner packaging labelling is clearly visible i.e. shrink-wrap, etc has not been included in the new text. This will result in additional costs for industry where labels will now be necessary.
 - timeline for label updates -Article 33 expects labels to be updated "without delay". Some time should be allowed to take into account the length of supply

chains and stock holding/run-down. This could be achieved by requiring suppliers to act on information received from up the supply chain as soon as is practicable;

- given the large amount of new data expected to be generated by REACH activities and the requirement of suppliers to revise their classification as soon as they become aware of new information, it is expected that we approach a period of regular classification updates. This will have some significant impact on product formulators who produce mixtures, often containing a high number of individual ingredients.

112. A number of respondents raised concerns about small packaging. Comments were:

- *“the proposal leads to more labelling elements (pictograms, signal words, hazard statements and precautionary statements) than today. It may therefore be impossible to meet the requirements of Article 34 in the case where a package is either too small or otherwise unsuitable for attaching the required label”;*
- *“GHS labelling, particularly for mixtures will in many cases result in a requirement for more pictograms and hazard statements than at present. Responsible companies do what they can but they have to make a decision on what required information to leave off. This is a good opportunity for the EU to take the lead. I suggest that the limit should be 250ml under GHS. There is a good case for a second limit for very small packs below which very minimal labelling is necessary”;*
- *“Putting all the required chemical names on the label will cause considerable confusion and could present inordinate problems with complex mixtures. Under these circumstances a product could fall into several hazard classes and there would be problems fitting all the symbols on the label. This is particularly apparent as the new shape of the hazard label takes up a larger surface area of the label to achieve the same impact as the squares achieve on the current EU label. It would be preferable to have the “highest hazard” as is currently applicable to the EU label”.*

113. The Chemical Business Association also raised the issue of small packages and also commented on a number of other points:

- *the “transport regulations and supply classification have previously been separate due to the difficulty in bringing the two schemes together. GHS has attempted to achieve this unification. It is the CBA’s understanding that with the GHS classification of a hazardous substance for transport, that the existing transport diamonds would take precedence over the GHS transport pictograms. However two points subsequently arise:*

- *in a significant number cases the GHS classification is not compatible with the existing Transport classification in either in terms of Class indicated or severity of risk (>greater than Transport).*
- *GHS calls for pictograms to be used with signal words in a similar fashion to CHIP, however, transport diamonds do not come with signal words. Although the signal words should appear on the label it is not clear where these should be.*
- *the number of phrases to appear on the label with GHS is significantly higher than with CHIP, and the statements on precedence “are insufficient to indicate what phrases can be dropped to facilitate understanding and legibility for the user. This combined with the rules on how much space the pictograms must occupy present some difficulties”;*
- *the need for a “simple mechanism to be put in place in the EU that facilitates the update of the EU Regulation in accordance to the UN GHS amendments every 2 years without having to undergo a complicated regulatory procedure with scrutiny”.*
- *Article 33 – Updating information on labels – “the words ‘without delay’ in Article 33 should be deleted. They create uncertainty and do not take into consideration the complexity of the supply chains where some time will be needed in order to pass all the updated information to the last part of the chain so that all the labels may be properly updated”.*
- *the requirement for indelible marking of hazards has prompted many sectors of industry to utilise pre-printed packaging, to reduce the risk of markings becoming unreadable. Coupled with the fact that the supply chains for many products are very long means the words ‘without delay’ are imprecise and open to misinterpretation. Industry operates responsibly and communicates changes as swiftly as physically possible. Product recalls to repackage and label or over labelling of product will result in increased waste for disposal and potential safety concerns if the label were to become detached showing the old labels.*

114. Other respondents raised the following points:

- *“some of the pictograms in the GHS proposal are very, very vague, especially the one that shows a human torso with a silver star covering most of the chest area. The current REACH symbols are much clearer, why not use these inside of the red bordered diamond symbol used in GHS”;*
- *would a correlation table between existing R and S phrases and the new correlating hazard and precautionary statements be made available, citing current international Safety Data Sheets that use the existing CHIP symbols;*

- *the “absence of abbreviations (for example R20/21/22) for safety and risk phrases in the new proposed UN GHS does indeed require clarification. [The respondent] notes that it is proposed to have four hazard classes for ‘acute toxicity’: this we find excessive and will lead to confusion. Warning symbols need to be unambiguous and clear to advise the users”;*
- new pictograms will be introduced which do not express a clear and unambiguous meaning (for example, the exclamation mark- this is not a specific warning and refers to health hazards which could carry the same pictogram as other health hazards). *“Will pictograms carry additional information”?*
- *“the employment of a three digit code for health and precautionary phrases is bizarre; it implies that are numerous codes (i.e. nearly 999): the existing system of risk and safety phrases is much simpler employing only 2 digits”.*
- Invariably, bagged materials such as cement, gypsum plaster and other materials in dust form, are provided in paper bags which are prone to bursting open and leaking, exposing those handling them to a range of hazards including inhalation of the dust and injury to their skin. This problem is compounded by insufficient labelling. The manufacturer’s name invariably appears in very large writing across the bag, whilst hazards information is included in small print at the top of the bag where it is easily missed. It will also be appreciated that the people who handle these materials are not generally specialists in these materials and will be unaware of the hazards.
- The British Coatings Federation (BCF) expressed concern over the inconsistency between Articles 22 and 30 which were inconsistent in the number of precautionary statements required. The BCF highlighted that no such limits were included for the number of hazard statements that could be used.
- The BCF sought to have the ‘Supplemental information’ provisions included in the GHS to aid further harmonisation.
- The BCF also called for the small package limit to be raised from 125ml to 250ml.

Current position

115. As negotiations have progressed, many of these issues have been addressed and resolved.
116. The UK, working with a number of other Member States, has discussed a proportionate and practical approach to the labelling of small or awkwardly shaped packaging, without reducing the level of protection. The proposed

requirements on small packages have been rewritten to reflect both developments in the UN GHS and the existing EU provisions as adopted in Member States.

117. Article 33 – the words “without delay” have been replaced with “without *undue* delay” allowing suppliers to respond in a reasonably time frame and to reduce the need for product recalls.
118. The UK is playing an active role at UN level in re-assessing the number of precautionary statements available in GHS. It is recognised that there are too many statements and this has created difficulty in determining appropriate rules on precedence. Furthermore, the UK has successfully advocated a more flexible and proportionate approach whereby suppliers will have more scope to select the precautionary statements that are appropriate, and to combine them on the label in sensible ways.
119. Article 53 confirms the *regulatory procedure with scrutiny* as the procedure through which certain Articles in the Regulation and its technical annexes can be amended. The process itself is not open to negotiation as it reflects the agreed arrangements for the European Parliament’s scrutiny of new European legislation. The Regulation will be updated on a 2 year basis to align with amendments made to the UN GHS.
120. The pictograms form part of the detail of GHS which can only be amended at UN level. Few consultees have raised concerns with the suggested pictograms. Concerns may reflect an unfamiliarity with the pictures which, over time and following awareness campaigns, can be addressed.
121. The requirements on languages on labels has been tightened so labels have to be in the official language(s) of the Member State unless otherwise prescribed. In addition, the requirements for combined transport and supply labelling have been made more flexible and specifically address the ‘shrink-wrap’ situation where the outer packaging permits the labelling on inner packaging to be clearly seen.

Question 9: Do you agree with the extension of the provision for child-resistant fastenings and tactile warnings to cover the additional hazard classes and hazard categories listed (please see Title IV, Annex II Part 3 details of the hazard categories can be found at paragraphs 110-114 of the Consultation Document)? If you disagree or partly agree, please provide actual examples of products to demonstrate the possible cost and/or practical implications to support your reasons.

122. Responses:
- | | |
|--------------|-----|
| Disagree | x 8 |
| Partly agree | x 2 |
| Agree | x 9 |
| Don't know | x 7 |
| Not answered | x 7 |

123. Currently, child-resistant fastenings and tactile warning devices must be fitted to containers containing certain specified chemicals labelled as toxic or very toxic, or corrosive. The Regulation, in effect, extended the duty because under the GHS, the corrosive pictogram is required where, sometimes, under the present EU system, it is not. As a result, these new provisions may increase the number of consumer products having to be fitted with child-resistant fastenings or bear tactile warnings, particularly for certain cleaning products.
124. The CIA said *“we have some reservations over the extension of child resistant fastenings and tactile labelling to a wider range of products. The benefits of expanding existing requirements for child resistant caps and tactile labelling to additional classes of products remains questionable when balancing added safety benefits against the cost burden to industry and the limitation in accessibility to elderly people to some products. The application of such a system should remain in line with the existing classification and labelling system requirements”*.
125. The cleaning products sector has raised considerable concerns about this issue both in response to the Consultative Document and in discussions since. The UKCPI led comments, saying *“the industry [sector] is in the unfortunate position that due to the GHS classification criteria and the reliance on the conventional calculation method of the Dangerous Preparations Directive, products that historically would not have required child resistant closures (CRCs) and tactile warning devices (TWD) will require them. These products in the domestic sector would likely include, hand dishwash detergents, auto dishwash detergents, liquid detergents, heavy duty detergents (powders) and special cleaners. Only fabric conditioners, certain all purpose cleaners and glass cleaners would be exempt. Those products, oven, drain and toilet cleaners that have, under existing legislation, required CRCs and TWDs will continue to do so under GHS. The outcome of the EU GHS proposal is that consumers will not be able to differentiate everyday products like hand diswash from 'truly aggressive' drain cleaners, they would all be classified and labelled in the same way, regardless of actual product safety attributes and regardless of a history of safe use. In the professional sector, it would result in unnecessary use of personal protection equipment and give employees working with products the impression that the formulation may be unsafe, again in spite of a history of safe use”*. The respondents provided detailed examples illustrating their concerns.
126. Respondents went on to say, *“inclusion of serious eye damage would lead to the requirement to have CRCs and TWDs on many products (for example, most cleaning and detergent products) which currently do not require them. It is therefore critical that consumers be able to readily distinguish very hazardous products from other less hazardous products. Extending CRC and TWD provisions to products currently labelled as irritant is unlikely to improve consumer safety”*.
127. The British Cement Association said *“these requirements have been extended to substances and mixtures classified as "serious eye damage" which is not the case in the current EU legislation. This would mean that bagged cement*

would have to be sold in a container with a child-proof fastening and a tactile warning label and this is totally impractical. As stated by the European Commission, the aim of the proposed GHS Regulation is clearly to stay as close as possible to the current EU system. However, by extending the requirements to other hazard classes such as "serious eye damage", the EU proposal would significantly increase the use of special packaging provisions as many more products would be covered by these provisions and introduce a requirement that is not featured in the UN GHS".

128. Unite agreed with the proposed extension to additional hazard categories.
129. The British Coatings Federation echoed concerns raised about the cost impact of extending the current CRC and TWD provisions.

Current position

130. The UK has strongly questioned the aspect of the proposal that resulted in an increased scope of chemicals that would require CRCs and TWDs. This aspect of the proposal is out of line with the rest of the Regulation, where the European Commission has kept to the scope of the existing EU scheme as much as possible. There is no driver in the UN GHS for additional use of CRCs and TWDs.
131. At the time of writing, a UK proposal to bring the scope of products requiring CRCs and TWDs has been accepted in the Council. This amendment goes a long way to restoring the position under the existing EU system.

Question 10: Do you have any comments about how the Classification and Labelling Inventory will operate? (Article 43 refers)

132. Responses:
- | | |
|--------------|------|
| No | x 12 |
| Yes | x 10 |
| Don't know | x 2 |
| Not answered | x 9 |

133. Respondents indicated a number of practical and procedural concerns with populating the proposed Inventory.
134. The CIA said *"to ensure that the notification process remains manageable for both industry and European Chemicals Agency (ECHA), the CIA strongly encourages that notification to the Inventory should be solely limited to substances that are placed on the market at a quantity above 1 tonne per year, and are: subject to registration according to Regulation (EC) No 1907/2006, or are classified as hazardous on their own or in a mixture resulting in that mixture being classified as hazardous".* Without such qualification, *"substances and mixtures used for scientific or process oriented research and development for example will be included in this requirement in the absence of a threshold value for notification and this will further increase the already considerable administrative cost burden for industry and the ECHA".*

135. The CIA also said *“there is the possibility of a confusing situation arising where harmonised and unharmonised [industry self-classified] classifications will exist for the same material due to information found in different parts of the Regulation (ie. Annex VI and the Inventory). Industry would welcome some clarity over the procedure that will be followed when an amendment to the Annex VI inventory is required following the submission of REACH registration data, and which classification would take precedence should conflicting information be published on the Annex VI and classification and labelling inventories”*.
136. One respondent said *“the requirement to notify the ECHA, particularly for very small quantities and for small quantities of substance imported in mixtures is disproportionate. At the very least there should be a de minimis level”*.
137. PICON said *“it is essential that there is a uniform classification. The European classification is satisfactory and should be developed to include self classification. It is vital that this process is dealt with globally through representation at the UN”*.
138. Advanced Composites Group Ltd raised concerns about the time table for populating the Inventory saying it *“seems rather optimistic If we compare that the 40 years of the old regulations has managed to provide 8,000 ‘harmonised’ classifications and the expectation to provide the additional 92,000+ EINECS listed, polymers, small volume supplied products in 3 (2) years seems a little unbelievable. What are the fall back options? How are the conflicting classification going to be addressed? How long are these conflicts going to take to resolve? Who gets the final say?”*
139. The company went on to say *“the inventory timelines have to mirror REACH to prevent the reclassification scenario ideally with a time lag of 12-18 months to allow for the implementation downstream of these changes. I believe the underestimation on how these changes from REACH will impact down the supply chain cannot be addressed in the current timeframes set and will lead to massive non-compliance”*.
140. Seldon Research Ltd sought clarification as to what should actually be entered on the Inventory, saying *“it looks as though this inventory might include formulated products such as washing up liquids. I don't think this is the intention of the regulation, would create a significant workload and would not result in any benefit to anyone”*.
141. The Society of British Aerospace Companies (SBAC) said *“company priorities to identify substances and seek replacements will be strongly influenced by the REACH candidate list¹. The concern for SBAC members is that there are different international definitions of substances that are carcinogenic, mutagenic, reproductive toxins (CMRs), persistent/bioaccumulative/toxic (PBT) and Very*

¹ The REACH Candidate List is a list of substances created by the ECHA that will be studied for their possible inclusion as Substances of Very High Concern (SVHCs). SVHCs will be subject to authorization under REACH. What substances are included have yet to be determined at the time of writing.

persistent/very bioaccumulative (vPvB).” SBAC is concerned that, if the GHS system and the subsequent Regulation “aim to develop an international list of substances”, SBAC “believes that the GHS needs to define the list of CMR’s, PBTs and vPvBs as a matter of urgency and that no substances should be added to the REACH candidate list for authorisation until the GHS has reached agreement on these substances”.

142. SBAC went on to say *“UK companies will target resources and investment on identifying and replacing substances on the REACH candidate list. Once the GHS list is released it may demonstrate that some substances should have been given a higher priority and others that should not have been on the candidate list. In addition to the potential for causing considerable confusion, companies will have targeted resources incorrectly; this is exactly the type of confusion that the GHS system seeks to avoid. While this is an important development that industry welcomes, there is little use agreeing such a list a few years after industry has invested considerable resources in trying to identify substances on another list”.*

143. The British Coatings Federation (BCF) echoed the potential for confusion over the how the proposed Inventory would operate saying *“as agreed in REACH, GHS should follow the ‘One Substance, One Registration’ philosophy. It is not clear how the inventory and the harmonised classifications in Annex VI Part 3 will operate”.* The BCF indicated a preference for some kind of “identifying mark” to differentiate the two types of entries.

Current position

144. The practicalities of operating the Inventory, in parallel to Annex VI (list of harmonised classifications), and whether it is necessary to notify substances that are placed on the market in quantities of less than 1 tonne per year, remain subject to on-going negotiations.

Question 11: Do you agree with the transitional arrangements set out in paragraphs 70 – 74 of the CD? If you do not agree with the proposed timescales please provide details of a more suitable approach.

145. Responses:	No	x 14
	Yes	x 10
	Don’t know	x 6
	Not answered	x 3

146. Practical, workable arrangements for migrating from the existing EU system to the GHS criteria are essential, as industry will have to review and adjust, as necessary, the classifications and labels for the chemicals placed on the EU market. The Regulation proposes a two-stage process in which substances are re-classified first, over a 3 year period, and then mixtures over a further 4 ½ years. The potential advantages of changing over these longer timescales need to be balanced against the disadvantages, mainly in terms of cost, of having to run both systems during the transitional period. At the end of the transitional

period, the existing Dangerous Substances Directive (67/548/EEC) and Dangerous Preparations Directive (1999/45/EC), will be repealed in their entirety.

147. While the transition period outlined above was supported by the majority of respondents to last years' public consultation by the EC, including the UK, the benefits from aligning the start of the transitional period for the new Regulation with REACH (with an entry into force date of 1 June 2007) may, in practice, limit the time available to classify substances. If this approach is agreed, manufacturers and importers will need to notify its substance classifications and labels to the European Chemicals Agency by 1 December 2010, in effect, allowing two years for transition, rather than three.
148. The respondents were almost split evenly between those who saw the proposed timescale as too short and those that saw it as too long. Similarly, some saw the benefit in aligning the new Regulation with the timings in REACH, others saw this approach as unnecessarily limiting the time available to comply.
149. Polartech said *"whilst we broadly accept the transitional timetable, we have reservations about the requirement to classify substances both in accordance with 67/548/EEC and the new rules during the period 1 December 2010 to 1 June 2015. As all substances will have been classified under the new rules by 1 December 2010, we believe this should be the sole classification from 1 December 2010, and this would encourage a more speedy implementation for mixtures"*.
150. The CIA said *"Industry supports setting the transition period for substances to coincide with the deadline for the REACH classification and labelling inventory"*. However, the CIA went on *"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. In addition, the differences in the demands of REACH and GHS for Safety Data Sheets will place an extra burden on companies trading outside Europe, especially during the transition period, when both classifications are required to be included. It is clear that the proposed timeline is going to be challenging for companies. Support from competent authorities to ensure that the expectations of companies down the supply chain are appropriately managed will be key to help minimise the impact on manufacturing businesses"*.
151. The potential for *"confusion"* from the parallel running of the two systems was shared by Glaxo Smith Kline and one other respondent. The other respondent supported setting the transitional period for substances to coincide with the first deadline for the registration of phase-in substances under REACH.
152. The CIA was also concerned *"about the limited time industry might have in preparing for the proposed Regulation in terms of evaluating the regulatory requirements of substances and mixtures before the deadlines given in the proposal. By failing to do so, the transition period for substances will be shortened further as REACH has already entered into force, resulting in an ever-increasing cost burden for industry"*.

153. Finally, the CIA said *“the current proposal does not address the issue over the timeline of mixtures of mixtures reclassification. The transition 2015 deadline for GHS mixtures reclassification offers little scope for communicating any changes down the supply chain”*.
154. One respondent saw the proposed timescales as being particularly problematic for ‘end-user mixtures’, saying *“effective compliance will not be possible at the same time for mixtures which are end-user mixtures (e.g. retail and professional finished products) and for ‘intermediary mixtures’ or ‘pre-mixtures’ - used as raw material for finished products. Experience (Implementation of DPD) shows that for companies using a significant amount of ‘pre-mixtures’ in marketed formulations, about 3 years are required to ensure that information has passed through the supply chain and to update labels”*.
155. As a possible solution, the respondent suggests *“for finished products sold to the end-users, some additional time or a separate transition would be needed in order to allow for information to be passed on through the supply chain and to ensure effective compliance”*.
156. Another respondent focused on the impact of the proposed timescales on affected European downstream legislation – those related directives and regulations which use chemical classifications as a trigger for additional control measures. The respondent said *“the timescales may be sensible from the perspective of classification of substances, but there is no clear timescale for the application of derivative legislation such as COMAH² or Planning (Hazardous substances)³, which is particularly important given that the proposed regulation is direct-acting. For operators working under the Seveso II [or COMAH] regime, there is an additional requirement to classify substances and preparations against the new system whether or not they are intended for supply. Therefore there is more classification work involved than identified in the CD or the Regulatory Impact Assessment”*.
157. Concern about the impact on downstream legislation and the consequent changes needed to enforcement and training was expressed by ACPO in Scotland.
158. One respondent thought it unwise for transitional periods to be set before the entry into force date of the new Regulation was known, although the respondents supported the proposed 3 ½ years for substance classification.
159. McBride, a chemical product manufacturer, indicated practical concerns of relying on the timely classification of key ingredients (substances) to allow mixtures to be classified. Seldon Research Ltd and NStarch expressed similar concerns, NStarch saying *“for downstream industry there will be insufficient time to be in compliance by the end of the proposed transitional period. In reality, substance suppliers will most likely wait until the end of the substance deadline to*

² Control of Major Accident Hazards Regulations, implementing the Seveso II Directive

³

pass on their new classifications. This means that if you are using a formulated raw material in your formulation (a common case in the adhesives and sealants formulating industry), you will have to wait for your supplier to re-classify his material before you can start doing yours. It simply will not work in practice and we would wish for 6 years for mixtures”.

160. Advanced Composites Group Ltd saw the need to establish “a greater differentiation” between “classifying substances and preparations (mixtures) as this has been blurred under GHS”. The respondent said “as a practicing classifier, I am well aware of the different approaches required to fulfil these tasks. If this was an isolated regulatory change the timescales proposed would be adequate, however, running this along side the REACH implementation means we must follow the timelines REACH dictates”. The respondent was also concerned that “reclassification post-REACH be avoided at all costs. We must not forget that the key factor for this is workers understanding, this is a major move forward in the control in chemical supply not just a paper exercise. We cannot, even for a short time, end up with a system users of chemical products do not understand the associated hazards and risks. To invalidate all this hard work by rushing the GHS implementation into the proposed timescale is a big mistake which will dent consumer confidence, confuse and undermine the GHS goals. Staging the implementation for substances over the longer timeframe gives more time for the inventory to become established, which is key to the success of GHS, with quality, verified data and removes the lottery of classification which currently exists”.
161. Pick Quick Services Ltd said that GHS following so closely with REACH “would create intolerable financial burdens on small firms with limited finances and manpower”.
162. LP Gas Association said “LPG cylinders are reuseable and are returned, when empty, for refilling. The current life of a cylinder is in excess of 30 years. Regular requalification is required every 15 years. To avoid changes which would have no value, are environmentally damaging and costly we believe that marking on transportable pressure receptacles which complies with the Transport Regulations and the current Substances/Preparations Directives should be permitted to remain in service until the next statutory requalification. Article 4 or, possibly, Article 58 is the appropriate spot”.
163. However, the Society of British Aerospace Companies would like to see GHS introduced as soon as possible “because aerospace and defence companies are currently investing significant resources in developing materials to ensure employees and suppliers are aware of their obligations under the REACH regulation. It would be more preferable for industry to use the most up to date internationally recognisable symbols in the information that is being developed on REACH and so the GHS should seek to dovetail into these processes as much as possible. It is important that there is close correlation between REACH and GHS. Companies will begin to pre-register substances next year (2008) and the effect of bringing GHS in half way through the registration process, if the issues that SBAC has outlined are not addressed, could be delays in providing information on

datasheets, problems in defining uses, resources in appropriately targeted and considerable confusion and unnecessary cost incurred by industry”.

164. Unite said *“in relation to timescales for implementation, we would want to be sure that a balance is struck to ensure the introduction of a safe and comprehensive system and enforcing regulations are in place as soon as possible, whilst at the same time giving sufficient time to raise awareness and implementation of training of all workers affected”.*

Current position

165. As Industry has developed its understanding of the new Regulation, there has been a greater clarity in how it can better manage the migration to the new system. The alignment with the REACH timescales has been largely welcomed and the respective deadlines for classifying substances and mixtures are seen as more reasonable with a less pessimistic view on achieving compliance within the time scales available.

166. To assist with compliance, a recent proposal from the EC sets out a ‘period of grace’, allowing a slightly longer time frame for compliance for those products classified under the existing regime and already ‘on the shelves’ when the Regulation deadlines are reached. This has been welcomed by certain sectors (those supplying paints, coatings etc) as a helpful arrangement. Details remain subject to on-going negotiations but are presently an additional 2 years for both substances and mixtures.

167. The EC has already recognised the potential impact of the new Regulation on the Seveso II Directive on major accident hazards (implemented in GB through the Control of Major Accident Hazards Regulations 1999 (COMAH)). Seveso II uses chemical classifications as triggers for certain additional control measures. In view of the particular relationship between classification and Seveso II, the EC has initiated a separate review to assess in more detail the impact of applying the GHS criteria to the existing Seveso II Directive.

168. HSE provides UK representation at the European level meetings with responsibility for proposing changes to Seveso. HSE is currently working on options to amend the Directive in the context of the wider EU review. An objective of the review will be to minimise the impact of the GHS Regulation in terms of the interaction with COMAH. The review is expected to last several months and interested stakeholders have been invited to participate.

169. Negotiations remain on course for the Regulation to be adopted and enter into legal effect by the end of 2008, with the respective deadlines of 1 December 2010 and 1 June 2015 for substances and mixtures respectively, plus an additional ‘period of grace’ as in paragraph 166 above.

Question 12: The European Commission has produced a ‘Translation Table’ (Annex VII) to assist those that have already self-classified their chemicals under the current system to convert those classifications to the new system.

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

170. Responses:	Not helpful	x 1
	Helpful	x 15
	Very helpful	x 5
	Don't know	x 4
	Not answered	x 8

171. Annex VII of the new Regulation includes a ‘translation table’ to convert classifications made under the current Dangerous Substances Directive to the new GHS classifications. Where there is no direct one-to-one equivalent, the Annex has assigned the least severe classification and places a duty on the supplier to decide if a more severe classification is needed.

172. The table is designed to help manufacturers, suppliers and importers. The European Commission is proposing that suppliers can either use the translation table to convert their self-classified substances and mixtures (where possible) or require the supplier to re-evaluate the classification using the criteria in Annex I of the Regulation.

173. Polartech advised that *“this table may not be complete”* referring to more comprehensive table proposed by the European Chemicals Bureau in its document: TC C&L Document 33/07 of July 2007⁴.

174. The CIA expressed concern that *“although the provision of guidelines is appreciated, its use in real terms may prove difficult, as companies will still need to look at raw data to ascertain that the proposed classification is correct. In addition, it does not provide any guidelines when it comes to safety phrases. Only its use in practice will allow companies to determine how accurate and reliable the translation table is. The prospect of a wide use remains to be determined”*.

175. CIA members reviewed the R (or Risk) phrases contained in Annex VII and commented in detail. As these comments were technical in nature, they have not been reproduced here.

176. The CIA went on to say that *“the loss of many of the environmental warnings, which used to be available for use, is regrettable. The GHS phrases for environmental hazards do not appear adequate to cover the range and type of effects possible. This was also the case with the Dangerous Substances and Dangerous Preparations Directives but the process of extending the range of warnings may now be expected to be much slower due to the UN process, which may present some real problems in future”*.

177. PICON saw the table as *“absolutely vital”* although the respondent thought *“there should be more concentration bands to make classification more realistic”*.

4

178. One respondent saw the table *“in the light of the implications for Seveso II and COMAH”*. However, the table is seen to introduce *“additional complexity in how substance classifications are related to the generic substance categories in the Seveso II Directive”*.
179. Another respondent said *“the Translation Table will only be of limited use, since REACH looks at end uses to classify chemicals and the possible end uses for chemicals may not have been fully known at the time of classification”*.
180. Advanced Composites Group Ltd said the table was not sufficient to force those who provide deficient classifications to redress inadequacies.

Question 13: Where do you think guidance would be useful? What type of guidance or assistance will be helpful to you or your organisation in preparing for and complying with the new Regulation? Please also state your order of priority / importance.

181. The European Commission, Member States’ Governments (including the UK), industry and others (trade associations, and trade unions for example) will all have a role to play in providing guidance and assistance on what the Regulation is for, and what needs to be done to comply with its provisions.
182. The type of guidance/assistance sought ranged from:
- simplified, step-wise, concise, clear-language guide to classification and labelling;
 - a call for the introduction of Community level education programme for all ‘actors’ in the supply chain so that they can understand the meaning of the new Regulation;
 - guidance in the form of leaflets, brochures, workplace posters, advertisements in industry-related magazines/periodicals, customised by individual companies and trade associations, free of charge, to make the guidance relevant to sectors;
 - industry prepared Approved Codes of Practice;
 - guidance from the Competent Authorities (eg HSE);
 - clear guidance explaining the new classification criteria and other provisions of the new Regulation;
 - side-by-side comparison of the new Regulation with existing legislation;
 - guidance covering all aspects of the new legislation, relevant to worker health and safety;
 - on-line guidance and workshops around the country;
 - simple guide for each part of the supply chain and a web based version of a safety data sheet;
 - a call for much of the guidance to be free of charge;
 - general awareness leaflets, including for the general public;
 - basic training leaflets;

- classification ‘run-through’, examples of both substances and mixtures;
- separate documentation or segregation of information on classification of mixtures;
- a table that relates REACH and GHS phrases and symbols directly, accessible to all;
- guidance on the classification and labelling obligations during the transitional periods;
- guidance aimed at safety representatives; and
- guidance in all EU languages at Community level.

Downstream legislation affected by the introduction of the CLP Regulation

183. Since the publication of the CD, the European Commission (EC) has presented further information on the action it intends to take to ensure that the introduction of the GHS will have only minimal effects on the scope of downstream legislation controlling the use of chemicals. Some 22 pieces of downstream legislation refer in varying degrees to the classification of chemicals that, in many instances, will prompt additional control measures.

184. The EC confirmed that its policy is to keep the scope of downstream legislation the same under the present classification system, so far as possible. To do this, the EC has proposed two strands of action:

- a draft proposed Regulation and six proposed Decisions to amend certain Community legislation to align with GHS terminology, but to maintain the existing scope essentially unchanged;
- to review the remaining existing downstream legislation and to bring forward proposals for amendment over a longer timescale (around 3 – 4 years), consistent with the transitional periods in the new Regulation.

185. The choice between strands 1) and 2) appears to have been made by the relevant Commission Services responsible for the affected downstream legislation. For example, under strand 1), the EC has proposed the following:

- A Commission (EC) Regulation to amend the Detergents Regulation (648/2004) to change “preparations” to “mixtures” and to update references to existing legislation, such as the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (99/45/EC) to reflect the new Classification, Labelling and Packaging Regulation.
- A Commission (EC) Decision to amend the following Council Directives: Cosmetics (76/768), Toys (88/378), Volatile Organic Compounds (99/13), End-of-Life Vehicles (2000/96), Waste Electrical and Electronic Equipment (2002/96), and the Commission Directive on paints and varnishes (2004/42). The amendments will again replace “preparations” with “mixtures” and will make reference again to the new Regulation rather than current Directives.

186. While these proposals deal with some of the affected legislation, under strand 2) above, EC intends to review in more detail the other Directives that deal more directly with certain chemicals controls, including: the Plant Protection

Products Directive (91/414), the Biocides Directive (98/8), the Seveso II Directive (96/82), the Aerosols Directive (75/324) and the Chemicals Agents Directive (98/24), together with other occupational health and safety provisions such as the Carcinogens, and Mutagens Directive (04/37) and the Pregnant Workers Directive (92/85).

187. In the case of the Seveso II Directive, the review has already started. HSE leads for the UK and is playing a major role in this review, including engaging relevant stakeholders.

Regulatory Impact Assessment

188. The final Regulatory Impact Assessment, which reflects the comments submitted by consultees, appears at Annex B.

HSE, International Chemicals Unit
April 2008

**COMPLETE QUESTION SET – HSC CONSULTATIVE DOCUMENT No 213:
PROPOSED EUROPEAN REGULATION ON THE CLASSIFICATION, LABELLING
AND PACKAGING OF SUBSTANCES AND MIXTURES**

Question 1(a): Do you currently classify, label and package chemical products (in other words, are you a chemical manufacturer, importer, supplier, distributor or retailer) or do you use chemicals in a professional capacity? (please tick all that apply)

- I currently classify, label and package chemical products
- I currently use chemical products in a professional capacity
- I do neither of the above

Question 1(b): Type of organisation:

- A member of the public
- A representative of a trade association
- A representative of a trade union
- A representative of a non-governmental organisation (NGO)
- A representative of a charity/voluntary organisation
- Industry/business
- Other (please specify)

Question 1(c): Please select your industry sector

Question 2: Do you agree that the scope of the proposed Regulation should be limited to only those ‘building blocks’ of the UN GHS that most closely reflect the current EU classification and labelling system, together with elements of the EU system that are not covered by the UN GHS (ozone depletors)?

Question 3: Do you agree with the EC’s proposed new approach to classify chemicals according to their use/s (Article 5.1 for example), rather than classifying what is ‘placed on the market’ (as is the case now)? Please give your reasons, and details of any possible implications for your organisation. If you disagree or partly agree, please explain why.

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

Question 5: Will this split of roles and responsibilities help you in your business?

Question 6: Do you agree with the new proposed derogation for scientific research and development as described in Article 1.2(d)? If you don’t agree, or partly agree please explain why.

Question 7: If you classify chemicals now, do you think this Regulation introduces new obligations that are not in the existing system? If yes, please explain what you think these are.

Question 8: Would you agree that the obligations described in the labelling and packaging provisions in the Regulation (Title III and Title IV) are reasonable? If you disagree or partly agree, please explain why.

Question 9: Do you agree with the extension of the provision for child-resistant fastenings and tactile warnings to cover the additional hazard classes and hazard categories listed (please see Title IV, Annex II Part 3 details of the hazard categories can be found at paragraphs 110-114 of the CD)? If you disagree or partly agree, please provide actual examples of products to demonstrate the possible cost and/or practical implications to support your reasons.

Question 10: Do you have any comments about how the Classification and Labelling Inventory will operate? (Please see Article 43).

Question 11: Do you agree with the transitional arrangements set out in paragraphs 70 – 74? If you do not agree with the proposed timescales please provide details of a more suitable approach.

Question 12: The European Commission has produced a 'Translation Table' (Annex VII) to assist those that have already self-classified their chemicals under the current system to convert those classifications to the new system. How helpful do you think this 'Translation Table' will be in helping you comply with the new Regulation? If it will not be helpful, please provide details of further information you may require.

Question 13: Where do you think guidance would be useful? What type of guidance or assistance will be helpful to you or your organisation in preparing for and complying with the new Regulation? Please also state your order of priority / importance.

Question 14: Do you have any further comments on the draft Regulation that have not been covered in the questions above or on which you want to provide more information?

Initial Regulatory Impact Assessment

Question 15: The initial Regulatory Impact Assessment indicates that Option 3 (details below) is the preferred option. Do you agree that the UK should proceed with Option 3? Option 3 is to support the introduction of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (based on the UN GHS), and negotiate to make it as light-touch as possible, with the intention of avoiding any extensions in scope beyond the UN GHS 'building blocks' that most closely reflect the current system (with the continuation of any addition EU requirement that are not yet part of the GHS). If you disagree or partly agree, please explain why.

Question 16: Are the sectors and groups affected by the Regulation reasonably represented in the Regulatory Impact Assessment (Please see Sections 5.1 to 5.6 of

the RIA)? If you disagree or partly agree, please identify sectors that should also be considered and explain why?

Question 17: Based on your experience, do you think that the assumptions made in the RIA are reasonable? If you disagree or partly agree, please provide actual examples of products to demonstrate the possible cost to support your reasons. Areas that you may wish to consider include: staff training and familiarisation, IT systems (replacement or updating), reclassification of chemicals, re-labelling of chemical products, costs to downstream businesses, reviewing labels and safety data sheets, undertaking new risk assessments, customer/consumer education (Sections 5.11 – 5.17).

Question 18: 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.

Question 19: Do you agree that the benefits identified in the RIA are realistic? For example, increased trade opportunities outside the EU. (Sections 5.18 – 5.20). If you disagree or partly agree, please explain why.

Question 20: Are there any additional benefits that should be included? Please provide explanation for your answer.

Question 21: 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? Please justify your answer below.

Question 22: 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.

Question 23: In your view how well does this consultation document present the different policy issues involved in this matter?

Question 24: Is there anything you particularly liked or disliked about this consultation?

UK FINAL REGULATORY IMPACT ASSESSMENT (AFTER CONSULTATION) ON THE PROPOSED EUROPEAN REGULATION ON THE CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES (BASED ON THE UN GLOBALLY HARMONISED SYSTEM - GHS)

1. This is the final 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. The initial version of this assessment formed part of the Health and Safety Commission's published Consultative Document No 213, which sought comments on the proposed Regulation and its impact. 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 development⁵ objectives⁶.
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

⁵ **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

⁶ **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 Government Sustainable Development Strategy* (March 2005) www.sustainable-development.gov.uk/publications/uk-strategy/index.htm.

environmental protection from implementation of the UN 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 the facilitation of international trade, over the longer term, due to the lowering of technical barriers to trade. Despite the limited benefits for Europe, the UN GHS has political and industry support since its inception⁷. 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 2002⁸), in August 2006 the European Commission (EC) launched an Internet based consultation on a draft Regulation to adopt the UN GHS.
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. The new European Regulation will be directly applicable in the UK. Once the Regulation has been adopted at European level, the UK will only need to introduce limited supplementary legislation, including providing for enforcement and penalties for non-compliance. In addition, the proposal will, after a seven and a half year transitional period, replace a number of existing EU measures (Directive 67/548/EEC for example). In consequence, the repeal of several UK legislative instruments will be necessary, primarily CHIP (Chemicals Hazard Information and Packaging for Supply) Regulations⁹, which implement the existing European classification and labelling legislation. In the interim, a minor amendment of CHIP will be needed to accommodate the transitional arrangements.
10. 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 – 1907/2006 - (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.
11. 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 two European Directives, including 10

⁷ 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.

⁸ www.johannesburgsummit.org

⁹ For more information on CHIP please see: www.hse.gov.uk/chip

amendments and more than 30 adaptations to technical progress, with one Regulation.

2. BACKGROUND

12. 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.
13. 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*¹⁰ (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.
14. 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.
15. 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'

¹⁰ Safety Data Sheets (SDS) – are the primary tool for communicating reliable information (supplementing the label information) between suppliers of substances and mixtures and employers and workers using the chemicals. SDS contain information about the hazards and the recommended precautions that are essential to protect health, safety and the environment.

16. 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.
17. 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

18. 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.
19. 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, protecting people and the environment, and ensuring a fair and level playing field in the chemicals market across the EU.
20. 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) Regulations¹¹.
21. Examples of current EU labelling symbols, "risk phrases", and "safety phrases" are provided below.

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

¹¹ For more information on CHIP please see: www.hse.gov.uk/chip



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**

2.2 The UN GHS Agreement

22. The Earth Summit held in Rio de Janeiro in 1992 generated an international mandate, set out in Agenda 21 of the United Nations Conference on Environment and Development, to make available “a globally harmonised hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols”.

23. 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”¹².

24. 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

¹² *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, second revised edition, UNITED NATIONS, New York and Geneva, 2007

also provides a basis for harmonisation of regulations on chemicals at national, regional and worldwide level, as an important factor to facilitate trade.

25. 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 basis¹³.

26. 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), 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.

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

- 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**

¹³ *Globally Harmonized System of Classification and Labelling of Chemicals (GHS)*, second revised edition, UNITED NATIONS, New York and Geneva, 2007

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

28. 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.

29. The EC 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 be required to lower protection levels. Of the available 83 UN GHS 'hazard categories' (these distinguish the severity of the 'hazard classes'), the EC is proposing to implement 77¹⁴. 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.

30. 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.

31. The most important similarities between the UN GHS and the existing EU system include¹⁵:

- Both systems provide for one holistic 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.

¹⁴ The proposed 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.

¹⁵ 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

- The UN GHS sets up a system of hazard communication that is equivalent to the EU system, 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.

32. There will, however, be some changes in classification within a hazard class. For example, for acute toxicity, the UN GHS had five 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 EU system there are three 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-wide¹⁶

33. 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 2002¹⁷). Furthermore, the pressures on industry who export chemicals worldwide to apply the GHS, are significant and strengthening.

34. Some countries have already put the necessary legal arrangements in place and require the GHS criteria to be applied when exporting to those countries. Anecdotal evidence from a couple of UK based companies indicates that the change to the GHS criteria had worked reasonably well, resulting in a much clearer understand of the practical application of the new requirements. Although limited, this suggests a positive outcome which can be shared to help with the more general migration to the new Regulation.

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

35. 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.

36. 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:

¹⁶ Information on the implementation of the GHS is available at:
www.unece.org/trans/danger/publi/ghs/implementation_e.html

¹⁷ www.johannesburgsummit.org

- 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.

37. 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. 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. The benefits section of this RIA will explore this further.

2.6 Future Amendments to the UN GHS

38. The UN GHS is continually being refined and amended through two-year work programmes 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

39. The EC has undertaken a study of the impact of the draft European Regulation on 'downstream legislation'¹⁸.

40. The EC's report was necessary because some 22 pieces of European legislation refer to, or are 'triggered' by, the Dangerous Substances Directive, and/or the Dangerous Preparations Directive in some way¹⁹. In anticipation of both these Directives being repealed by the proposed Classification, Labelling and

¹⁸ The term 'downstream legislation' means any piece of legislation that references 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). The EC study is available at: http://ec.europa.eu/enterprise/reach/ghs/ghs_sc_study_final110806.pdf

¹⁹ See Annex B (affected European legislation) for more information

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.

41. 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)).
42. The UK has welcomed the study, but remains concerned that, in practice, the impact on downstream legislation may not be 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.
43. Details of which European legislation will be amended within the draft Classification, Labelling and Packaging Regulation, or in associated measures or which will be amended in separate reviews are listed in Annex B. However, this approach does not consider that Directives are transposed at the national level by Member States. The effects of changes to Directives will need to be assessed at the national level. Details of the EC's proposals to amend some of this legislation, together with the latest position on the related reviews can be found in the section *Impact on European Legislation*.
44. HSE will be initiating 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

45. The new Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation – 1907/2006 - introduces a process under which hazard and safety data must be provided for all existing and new substances, providing a basis for classification and labelling²⁰.
46. 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).
47. 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

²⁰ For more information please see: www.defra.gov.uk/environment/chemicals/reach/index.htm

sheets (previously 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.

48. The draft Classification, Labelling and Packaging Regulation, amends the REACH Regulation to avoid any extension in the scope of the REACH due to the introduction of the draft Regulation.
49. 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 Regulation²¹.

2.8 Timing of the proposed European Regulation

50. 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 Community level rather than national level, the Member States called on the EC to come forward with a proposal to implement the GHS in the EU.
51. The EC is also aiming to minimise the cost of implementing the GHS Regulation, by aligning it with trigger dates in the REACH Regulation. For example, the date of 1 December 2010 is common to both Regulations to register the first tranche of phase-in substances under REACH and to complete reclassification of substances under GHS.
52. 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. It was first thought there would be a risk that the EU would be one of the first to legislate to introduce the GHS agreement and other major trading partners would fail to take up the GHS. However, this has not turned out to be the case, as many other countries, such as Japan, China and Australia, have made significant progress. However, it is highly unlikely that other major trading partners will

²¹ A copy of the Defra REACH RIA can be found at:
www.defra.gov.uk/environment/chemicals/reach/index.htm

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

2.9 Rationale for government intervention

55. 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 communicating 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.
56. 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.
57. As previously summarised, the EU already has a mature, well developed classification and labelling system for the transport and supply of chemicals, set out in EU Directives. However, there are currently, several different regulatory systems worldwide, for classifying and labelling chemicals. 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, reducing international trade in chemicals, and restraining competition in domestic markets. Therefore, there will be benefits in terms of increased international trade and competition, from implementing the GHS within the EU.
58. 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 developing countries. 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. Adopting the GHS as part of global sustainable development is consistent with the UK Government's policy on global health.
59. 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 transitional arrangements) the existing Directives. The choice of an EC Regulation is driven by:
- precedent of REACH, which is 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 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 EU level.
60. 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.
61. 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 are actively influencing the EU proposal further by fully engaging in the ongoing negotiation process.
62. 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.
63. 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.
64. The results of the EC Internet-based consultation, in 2006, also indicate that there is broad stakeholder support for the introduction of the GHS within the EU.

2.10 Importance of international trade

65. Data gathered by CEFIC (European Chemical Industry Council) in 2005²² shows the pattern of sales of chemicals from the EU chemical manufacturers, by country of destination. This data indicates that, for EU 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 EU accounts for the remaining 25% of sales.
66. According to data produced by the UK Chemical Industries 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

²² *Impact Assessment of Implementing the GHS: Work Package 1- Final Report, RPA, May 2006, p.7*

non-EU countries²³. 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).²⁴ According to data from the UK Chemical Industries Association, around two-thirds of imports, by value, into the UK are from within the EU, and approximately one-third are from outside the EU²⁵.

3. CONSULTATION

3.1. Consultation by the European Commission

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

68. All responses, including those from the UK Government and UK-based respondents, were published on the Internet²⁶.

69. 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.

70. 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 the 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.

71. A copy of the UK Government response can be found at: www.hse.gsi.gov.uk/ghs. The EC 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 is not lost, and to reinstate the current exemption for munitions from the classification and labelling requirements.

72. The EC 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

²³ For more information please see Table 3 in Annex 2.

²⁴ *ibid.*

²⁵ *ibid.*

²⁶ For more information please see: ec.europa.eu/enterprise/reach/ghs_consultation_en.htm

a very limited number of responses from stakeholders²⁷. 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 from UK stakeholders, and to improve the estimates provided by the reports produced on behalf of the EC. This RIA also takes, as appropriate, a UK rather than European perspective in assessing the impact of the GHS Regulation.

73. The EC published its formal proposal for a Regulation to adopt the GHS in Europe on 27 June 2007, together with its RIA. The proposal was taken up with enthusiasm by the Portuguese Presidency. By the end of its Presidency, Portugal had completed a first read through of all the Articles and initiated work on the extensive technical Annexes. In January 2008, the Slovenian Presidency announced its intention to seek a first reading deal with the European Parliament in May 2008. Negotiations are presently proceeding intensively to this end.

3.2 Consultation in the UK

Within Government

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

3.3 Initial stakeholder consultation

75. HSE alerted over 1500 UK external stakeholders to the EC's consultation, encouraging them to share their responses with HSE (after Germany, the UK had the highest number of responses per Member State).

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.

²⁷ *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.

77. An example of responses received by HSE is 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 organisations²⁸. In the statement Annex D) 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' 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 officials also produced a paper, and gave a presentation at the January 2007 meeting of the Small Business Trade Association Forum.

3.4 Formal stakeholder consultation summary

80. Consultation ran from 14 August – 2 November 2007 in the form of a Consultation Document (CD No 213), approved by the Health and Safety Commission. A copy of the HSC paper can be found at:

<http://www.hse.gov.uk/aboutus/hsc/meetings/2007/170707/c58.pdf>

81. The timing of the CD was determined by the publication of the European Commission's (EC) formal proposed Regulation on the Classification, Labelling and Packaging of Substances and Mixtures, on 27 June 2007 and the imminent start to Member State negotiations.

82. The CD was published on the Internet and was available as a hard copy on request. The CD included:

- an introduction to the classification and labelling of hazardous chemicals, covering both the current European system and the proposed international system, the Globally Harmonised System for the Classification and Labelling of Chemicals, known as 'GHS';
- the proposed European Regulation;
- the technical annexes to the Regulation;
- a draft initial Regulatory Impact Assessment.

83. The entire package ran to approximately 700 pages.

84. Written for as wide an audience as possible, both those well-versed in classification and labelling matters and those with a far more limited knowledge, the CD asked 24 questions. The questions were designed to establish a profile of

²⁸ 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).

the respondents, their specific involvement in the classification and supply of chemicals and the potential or anticipated impact on them – both financially and as benefits – of the proposed Regulation. The questions focused on key issues that had been highlighted in earlier consultations with stakeholders and the development of the UK's initial response to the EC's draft proposals in 2006, or were emerging from early Member State negotiations. These included:

- the proposed scope of the Regulation, moving from classifying the chemical as supplied, or extending classifications to take into account the uses of the chemical concerned;
- the role of the different 'actors' in the supply chain, especially the assumed competence and expertise of distributors to carry the same duties as manufacturers and/or importers;
- the proposed transitional period to migrate from the existing European system to the new one;
- the proposal to select only those elements (known as 'building blocks') of GHS that most closely reflect the existing European system;
- the proposal to extend those hazard classes (or end points) that would require child resistant closures and/or tactile warning devices.

85. The RIA invited respondents to comment on the assumptions made about the estimated costs and potential benefits of implementing the proposed Regulation in the UK. Where respondents challenged these assumptions, they were further invited to provide evidence and/or justification of any proposed amendments based on their experience of current classification, labelling and packaging activities and the anticipated changes.

86. The CD and initial RIA represented the latest part of an on going process of consultation. Consultation continues with HSE officials meeting representatives of industry and business sectors, as well as delivering numerous presentations both at UK and European level.

87. Where cost and benefit information was provided after the close of formal consultation, this has been incorporated in the revised RIA.

3.5 Summary and numbers of consultees

88. Overall, some 30,000 subscribers to HSE's web site were advised of the CD's publication, together with a further 3000 subscribers who have, in the past, indicated a particular interest in chemicals. A further 300 (approx) representatives of industry, business, academia, trades unions, trade associations and others, who have been invited to comment on regulatory changes to existing classification and labelling legislation were also invited directly to respond to the CD.

89. HSE officials have chaired an inter-departmental sub-group on GHS since mid-2006. The sub-group's members have been consulted fully on the draft proposal, its subsequent development into a formal proposal, the development of the initial Regulatory Impact Assessment (especially Better Regulation Executive), and the development and agreement of the UK negotiating strategy. The Devolved Administrations have also been consulted.

90. Small business representatives were particularly targeted. HSE officials delivered a presentation to the HSC's Small Business Trade Association Forum, to raise the profile of GHS, to alert members to the forthcoming proposal and to invite the trade associations to engage with HSE and other stakeholders. As a result, the Federation of Small Businesses expressed an interest and were invited directly to comment on the CD. Advice was also sought from the Small Business Service. Relevant trade associations and federations were invited directly to comment on the CD.

91. Respondents were invited to reply in whatever form best suited their circumstances. A reply form was included in the CD. An on-line questionnaire was also available.

92. A list of the questions from the initial RIA can be found at Annex A.

3.6 Number of responses received

93. Twenty-nine responses were received as follows:

- Industry/business representatives = 15
- Trade associations = 11
- Trade Union = 1
- Member of public = 1
- Academia = 1

94. Given the number of those consulted, this may seem a disappointing figure. However, HSE has either met or discussed the proposals with a number of industry representatives over the past year, and continues to do so. It may be, therefore, that many respondents were broadly satisfied or had little to add to the comments in the CD. A further Stakeholder Workshop was held on 19 February 2008, to bring stakeholders up to date with the latest developments in negotiations and to further comment on this RIA. The Workshop was well supported.

95. Other meetings have allowed many to express opinions and comments which informed the development of the overall negotiating strategy. Anecdotal evidence shows that the strategy has received the support of many in industry and there have been no objections to the way the UK has negotiated its interests.

3.7 Overall outcome of formal consultation

96. Since the CD and RIA were published, industry has progressed with its understanding of GHS, the options and flexibilities provided by provisions such as the 'bridging principles', and how a more managed migration from the existing system to the new regime can be achieved. This improved understanding and, in some case, direct application of the new GHS based criteria for classifying existing products and formulations, are helping industry to better assess actual impact. Follow up meetings with representatives of key sectors that have identified particular financial burdens resulting from the implementation of the new Regulation, have shown that costs may not be as high as originally reflected. However, it is recognised that certain sectors, most notably the cleaning products

and detergents industry, will be facing proportionately higher costs of compliance as a result of applying the new classification criteria.

97. A better understanding of how the GHS criteria is best applied, is key to an efficient and cost-effective migration from the mature and well-developed existing European system to the new regime. Negotiations both at European and UN level have indicated that, in some areas at least, some of the GHS criteria are not as sophisticated as the existing European system. It is this apparent 'weakness' that has led to some of the concerns about costs.
98. Overall, the proposals were supported, resulting in relatively few consultees commenting in any detail. Unfortunately where respondents did offer alternative costs, they were not supported by evidence, experience of re-classifications or how the new Regulation would incur costs in addition to those already assigned to existing classification, labelling and packaging processes. In those circumstances where the alternative costs were substantiated, these have been incorporated into this RIA. As a result, the assumptions originally made have largely remained the same.

4. OPTIONS

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

99. The EC 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.
100. This option would result in the UK not challenging the intention, scope and transition arrangements, or other aspects of the EC's proposals. Such an approach could lead to a significant extension in the scope and costs of the existing classification and labelling system.
101. Without input from the UK there could be areas where the EC 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'.
102. 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. In practice, other Member States have suggested extending the scope to include 'category 5' acute toxicity and to include a new classification and labelling criteria for substances and mixtures that are persistent, bioaccumulative and toxic (PBTs) and very persistent and bioaccumulative (vPvBs). This would have extended the provisions beyond the

existing EU system, something the UK Government would want to avoid without evidence of significant benefit and stakeholder support.

103. However, with UK input, these additions are being successfully resisted at this time in the negotiating process.

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

104. This option would involve opposing the introduction of the UN GHS as a Regulation in the EU, 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.

105. 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.

106. 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.

107. 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.

108. 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.

109. 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 key UK chemical trading partners are already having to use the UN GHS and take-up worldwide is likely to increase through 2008 and beyond in line with the political commitments made by world leaders.

110. Finally, such an option would mean that the UK turns its back on the political commitments it made at the Rio Summit in 1992 and at the World Summit on Sustainable Development in 2002. This would be contrary to broader UK international and domestic policy.

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

111. 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.
112. 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: labelling of small and awkwardly shaped packaging; classification duties of different actors in the supply chain, broadening the provisions to allow businesses to use generic names to help protect confidentiality (while maintaining safety); and, preventing unnecessary extensions to the provisions requiring child resistant closures and tactile warnings of danger on substances and mixtures supplied to the general public.
113. In addition we have highlighted the need for the EC to consider how it can assist SMEs with the introduction 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 European level.
114. 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

115. 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 affected groups: chemical manufacturers; downstream businesses; wholesalers; retailers; the public authorities; and retail consumers of chemical products.
116. Responses to consultation seemed to indicate some misunderstanding as to what constitutes a 'sector'. A number of respondents did not appear to correlate their own sectors with the descriptions offered, although their generic work activities were clearly included. For example, 'distributors' (such as retailers or wholesale distributors) were identified as being absent from the list, whereas in practice, such activities would be included in 'downstream businesses'; 'wholesalers'; and 'retailers'. Others either wanted to see their SIC sectors specifically included (although none were offered) or to have their specific speciality (eg office, hospital or school professional cleaners) listed.

117. One respondent commented that the figures given in the three highest employee bands in Table 1 (Section 5.2) were wrong and called for a “sizeable increase” in the number of companies reflected. The respondent also suggested that the number of companies covered by the sector dealing with paints, varnishes, coatings etc, would need to be increased by 10,000 if such companies were considered downstream users. However, no source information to verify these figures was provided.

118. A couple of respondents suggested that the sectors given should be aligned with those for the REACH Regulation. The sectors provided for in the initial RIA were those that have best reflected generic activities within the supply, classification, labelling and packaging of chemicals, and are broadly aligned with those roles identified by the new Regulation.

119. The original sector definitions and descriptors have, therefore, remained.

5.2 Chemical manufacturers

120. 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 band²⁹ (source: UK Business: Activity, Size and Location 2006 (Office for National Statistics³⁰).

Table 1: UK Chemicals Manufacturers

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
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	24.5	330	140	65	30	565

²⁹ 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.

³⁰ http://www.statistics.gov.uk/downloads/theme_commerce/PA1003_2006/UK_Business_2006_Optimized.pdf

mixtures						
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

121. All businesses that purchase and use chemical products will be potentially affected by the new 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.

122. Data regarding the value of intermediate inputs have been obtained from the Input-Output Supply and Use Tables 2004 (Office for National Statistics)³¹. The sectors that obtain at least 10%, by value, of inputs for intermediate consumption from the chemical manufacturing industry (SIC 24) are listed in table 2. Data regarding the number of businesses in each sector has been 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

³¹ http://www.statistics.gov.uk/downloads/theme_economy/Supply_Use_04_bb2006.zip

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

123. 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.

124. 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 new Regulation.

125. It should be noted the assumption that downstream business sectors are those that obtain over 10% of intermediate inputs, by value, from the chemical manufacturing industry (SIC code 24), 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 would be identified as “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 would be identified as “downstream businesses” in the chemical industry

126. 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

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

128. 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.

129. 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)	Number of large businesses (250 or more employees)	Total number of businesses

				employees)		
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

130. 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)³², 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

131. This includes groups within the public sector that will need to be aware of the new Regulation. 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.

5.7 Assumptions

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

133. The costs estimated for the implementation of the new 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 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.

³² <http://www.communities.gov.uk/index.asp?id=1156099>

134. It is not expected that the new 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 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 Regulation, compared with the baseline of the current classification and labelling system.
135. As the EC has selected the '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 scope of substances and mixtures covered by the new Regulation is broadly the same as the present EU system.
136. The EC has also undertaken a study to map out the possible impact of the proposed Regulation on European 'downstream legislation'³³. As the EC has committed to either amend this legislation within the Regulation or in other 'satellite' measures, or to review the affected legislation prior to the end of the transitional measures in 2015, it is assumed 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) in the context of a wider EU review. 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.
137. The EC has committed to 'translate' all of the current harmonised classifications (Annex I of the Dangerous Substances Directive – some 8,000 classifications³⁴) to the new GHS criteria. In addition, the EC has produced 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.
138. It was originally assumed that the new Regulation would not impact on current packaging costs (for example, the requirement to package with child-resistant closures (CRCs) and tactile warning devices (TWDs), as the aim of the new Regulation is to not extend or amend the existing provisions.
139. However, closer examination of the detailed text has shown that the proposal does extend the provision of CRCs and TWDs to additional hazard categories. This has been highlighted as attracting potentially significant costs if it were to be

³³ 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).

³⁴ According to the European Chemicals Bureau website

implemented, especially for the cleaning products and detergents sector. These costs have been incorporated into this RIA. Estimates of these costs can be found at Option 1A. However, this issue remains subject to negotiation and we are quietly hopeful of a reasonable outcome.

140. All cost and benefit 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.
141. In addition to the assumptions above, a number of further assumptions are made, and these assumptions are highlighted throughout the impact assessment.

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

142. The costs and benefits for option 1 are separated into two categories: transitional costs and long-term costs.
143. Transitional costs and benefits are the one-off costs and benefits associated with transition to the new Regulation. The EC'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 new Regulation.
144. 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 uncertain.

5.9 Transitional costs and benefits

Health and safety benefits

145. 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 associated with the changes to product labels. Conversely, there may also be a small increased risk to health and safety in transition, because of the uncertainty created from moving to a new classification and labelling system.
146. Internationally (external of the EU and other countries that already have developed chemical safety regimes), it is expected that there will be significant human health and safety benefits for those countries that currently have no or

rudimentary classification and labelling systems 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

147. 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 currently have no or rudimentary systems for classification and labelling and that adopt the GHS. As with international health benefits, this will be a benefit of the ECs 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

148. The introduction of the new 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 EC³⁵. This estimated average IT modification costs of around £1,700 for small / medium sized businesses and around £6,800 for large businesses³⁶. It is assumed that average IT modification costs for micro businesses are around £1,700.

149. 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. The responses received following consultation suggested these costs were underestimated, although no supporting evidence was presented to substantiate additional costs as chemical suppliers already have to use IT systems. One respondent suggested that the costs of modifying existing IT system to accommodate new labelling (and SDS) amendments were in reality some 2 – 3 times that given in the RIA. This suggested a range of costs as follows: **£3,400 to £5,100** for SMEs, and **£13,600 to £20,400** for larger organisations. Another suggested that the IT costs “were understated by an unquantified amount” but offered no further detail. Costs for colour printers were estimated at **£30,000** each. Associated software to accommodate new labelling designs were estimated as between **£15,000** and **£100,000**.

150. The estimated total cost to chemical manufacturers of replacing or updating IT systems is presented below. These are estimated by multiplying the estimated

³⁵ A copy of the RPA impact studies are available on the EC website:
http://ec.europa.eu/enterprise/reach/ghs_consultation_en.htm

³⁶ *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)

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
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

151. 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 training³⁷. 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 to be £20.72 per hour, based on the mean average wage for all employees in SIC 24 of £15.94³⁸ from the Annual Survey of Hours and Earnings (ASHE) 2006 (Office for National Statistics³⁹). 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 regulations⁴⁰.

³⁷ A working day is assumed to consist of 8 working hours.

³⁸ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

³⁹ <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=14630>

⁴⁰ 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.

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

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

152. No further substantiated information was forthcoming in responses to the Consultative Document on staff familiarisation and training costs.

Reclassification of Chemicals

153. 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.

154. 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.

155. 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.

156. 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.

157. 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 2005.⁴¹ Some respondents indicated that this figure should be revised to £2000 per substance but provided no supporting evidence for this alternative cost, nor explanation as to whether it reflected more complex or specialist substances. The original assumption, therefore, has been retained as a reasonable average cost of re-classification.

158. One respondent indicated that the required re-classification of substances and mixtures would result in a “huge amount of work” – the respondent’s company produced approximately 700 separate mixtures and products in the UK. As a result of implementing the new Regulation, the respondent estimated the classification and labelling costs to be **£1,700,000**, (**£1,360,000** relating to labelling changes implying that reclassification is only 20% of the total cost). While it would have been helpful to have seen a profile of how these costs were determined so the cost estimates could be more clearly substantiated, these figures actually support the estimates in the RIA for reclassification:

⁴¹ <http://www.hse.gov.uk/ria/chemical/chip2005.pdf> page 7.

1,700,000 (classification and labelling costs) – **1,360,000** (labelling costs only)
= £340,000

340,000/700 (no. of products) = **£485**, which is within the original range of £80 - £500.

159. A couple of respondents indicated that SMEs would, in many cases, have to 'buy in' the expertise to re-classify, so such costs could well be increased.
160. The cleaning products and detergents sector highlighted an additional area of potentially significant costs - the specific consequences of applying the new GHS criteria for skin irritation and skin corrosion to existing cleaning and detergent products. Cleaning products are classified currently under the Dangerous Preparations Directive primarily using the conventional calculation method. Calculation in GHS involves lower concentration limit values, meaning that more products may be classified or classified more severely. The sector raised concerns over the cost of this additional re-classification which, in a number of respects, may result in the added provision of child-resistant closures and tactile warning devices. These estimated costs of these provisions appear at Option 1A in this assessment.
161. However, the bridging principles provided in GHS, and the new Regulation, and other flexibilities offered based on existing evidence of the chemicals' safety and the application of expert judgement, should help to reduce the instances where these more severe classifications need to be assigned. This sector of the industry is reassessing their approach to classification and to the collection and use of the supporting data on which to base their decisions.
162. The total costs to businesses of reclassifying substances and mixtures are estimated in Tables 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.
163. 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 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	£4500,000
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

164. For an estimated small number of chemicals, reclassification 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.
165. 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 extreme 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.

Re-labelling of chemicals

166. Costs for reviewing and amending/re-designing labels were presented for re-labelling by the cleaning products and detergents sector. However, the sector's own Impact Assessment indicated that such labelling changes were already a relative frequent occurrence in the sector, responding to market changes, promotional activities and development in the concentrations of product formulations. The sector indicated that an average 'life-span' of a typical product label is between 18 months to two years. It is therefore assumed, that arrangements and facilities are already in place to accommodate label changes and the associated costs are already reasonably reflected in the original assumptions above, based on estimates made for previous CHIP amendments.

Cost of Stock Losses

167. 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.
168. One respondent following consultation referred to the "unquantified costs arising from stock write-offs when the new labelling scheme is established, unless the transitional period is sufficient (3 ½ years). The respondent did not indicate how this assumption differed to that already proposed for a transitional period, nor whether such costs could be reduced by managing labelling changes more effectively. Another respondent did estimate the cost of stock write-offs at **£200,000**, depending on the flexibility of the transitional period available.

169. However, as there will be a reasonable 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

170. 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. The HSE has already begun the process of alerting industry representatives about the need to start considering suitable, sector specific guidance, where necessary. See also the section on Guidance.

171. These costs to industry have not been estimated.

Cost of proposing new harmonised hazard classification

172. Annex VI of the new Regulation will incorporate all the existing harmonised classification that currently appear in Annex I of the Dangerous Substances Directive. As now, industry will be required to apply these classifications in full, when supplying the listed substances. While there are no new costs attributed to applying existing harmonised classifications, the new Regulation currently includes a provision to charge a fee where industry proposes a new harmonised classification entry for Annex VI. The level of this payment has not yet been suggested; but is not anticipated to be large.

173. There is also a provision to create a 'Classification and Labelling Inventory' that will be maintained by the European Chemicals Agency (ECHA)⁴². The Inventory will be populated by the non-harmonised classifications determined by industry. There is not expected to be any additional cost for this provision.

5.12 Total Costs to Chemical Manufacturers

⁴² For more information please see: <http://ec.europa.eu/echa/>

174. The total quantified transitional costs to chemical manufacturers are presented in Table 8.

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

175. Downstream businesses have been identified as listed in Table 2. These businesses will incur costs in adjusting to the new Regulation. This analysis assumes that all downstream businesses would implement the 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.
176. 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

177. 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.
178. 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) 2006⁴³. The number of businesses in each identified industry is applied as weights. The weighted average wage per hour 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.
179. 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.
180. These assumptions were challenged by one respondent, who indicated the training costs were closer to £2000 per person, rather than the £250 estimate given above. However, the respondent did not provide any supporting justification for this assertion and the original assumptions have been retained.

⁴³ 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

181. Following the introduction of the new 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.
182. 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.
183. It is assumed that reviewing labels 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) 2006⁴⁴. The average cost of reviewing labels 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.
184. The estimated total cost of reviewing labels for all downstream businesses is shown in table 10.

⁴⁴ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

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

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

185. 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 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) 2006⁴⁵. 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.

186. 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

⁴⁵ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

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

Stock Losses

187. 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

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

Total Quantified Transitional Costs to Downstream Businesses

189. The total quantified transitional costs to downstream businesses are presented in Table 12.

190. 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	Costs to small/medium sized	Costs to large	Total costs to
--	----------	-----------------------------	----------------	----------------

	micro businesses	businesses	businesses	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
Total transitional costs to downstream businesses	£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

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

Staff Training and Familiarisation

192. 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

193. 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

194. 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

195. 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

196. 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

197. 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

198. 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

199. 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

200. 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.

201. The costs presented above for retailers are averages for businesses in the identified sectors, but, as previously highlighted, there are 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

202. 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 UK GHS Competent Authority has yet to be made; the outcome will, of course, have to be consistent with the Better Regulation agenda and the Hampton Review (2005)⁴⁶.

203. 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

204. 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

205. 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.

206. 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

⁴⁶ 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

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

207. 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.

208. 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) 2006⁴⁷. 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 products⁴⁸. 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

209. 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.

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

⁴⁷ All wage costs presented in this assessment are multiplied by 1.3 to include non-wage employment costs.

⁴⁸ 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.

211. One particular example has been raised to illustrate this point. According to the relevant industry sector, 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.
212. HSE has reviewed the possibility of this scenario and believes there are certain provisions in the GHS, including one that allows industry to present valid data to justify appropriate classification. In practice, the GHS is more flexible than the existing EU system in certain respects. The cleaning products and detergents industry continues to review the situation and accepts that it needs to revisit the evidence base and models that it uses now, and will use in the future under the new GHS scheme.

Long-term costs and benefits

Benefits

5.18 Trade benefits

213. The main economic benefits in the UK, from the implementation of the GHS, are expected to relate to international trade in chemicals.
214. Currently, businesses incur various costs in order to comply with differing chemical hazard classification and communication regulations worldwide. It is likely 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.
215. 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.
216. It is possible that more UK businesses than at present may be able to engage in trade outside the EU if a reduction in the costs currently associated with operating more than one classification and labelling system is achieved.
217. 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.

218. 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)

219. 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)

220. 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, 2006⁴⁹

221. 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 £2.71 million additional imports. This is equivalent to an increase in net exports from the European Union of approximately £1.39 million.⁵⁰ 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.

222. 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.

223. 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.

224. 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.

⁴⁹ http://www.cia.org.uk/newsite/industry_glance/facts_leaflet_2006.pdf

⁵⁰ . Exchange rate: 1 Euro = £0.67730 (Source: European Central Bank; 23rd August 2006)

225. Most consultees supported the assessment that the new Regulation will result in limited benefit to UK based chemical suppliers. Some consultees remained sceptical that a truly global system of classification and labelling would ever be achieved, citing the “inconsistent implementation of GHS in different countries” which “may lead to even more confusion and difficulties for industry than exist at present”. This was seen as a particular difficulty for SMEs, which were assumed to have limited experience of or involvement in extra-EU trade.
226. Different labels (and SDS) will “still be required to support sales in different countries” as a result of different jurisdictions selecting different building blocks in GHS. Although, on a more practical level, one respondent indicated that “opportunities to use multiple language labels will also be more limited as the level of [hazard] information to be provided on the label will become more substantial with the new system”. Some respondents were also reluctant to see any increase in international trade opportunities as a result of moving towards a common product classification – in the same way as there is no evidence that the existing non-harmonised systems are reducing trade opportunities, while one respondent suggested that benefits for “third world countries would have most likely been achieved had existing systems been applied to these countries”.
227. Timing was seen as key in the emergence of benefits, from increased trade opportunities or better management of chemicals especially in those countries with no current classification and labelling system.
228. One respondent saw GHS as supportive of “innovation and production improvement”. The re-classification of some substances “may help drive the introduction of greener production and greener chemicals”, although it was less likely to result in lower prices for chemicals.

5.19 Health and safety, and environmental benefits

229. 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 a consequence of implementation of the GHS Regulation.
230. 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. No comments were received following consultation on any further health, safety, environmental or other benefits, beyond those already commented on above.
231. 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 environmental health determinants including contaminated water and soil, and toxic chemicals (source:

Food and Chemical Safety, World Health Organisation, 2006)⁵¹. 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.

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

5.20 Other benefits

233. As the take up of the UN GHS increases, 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 initiative⁵².

5.21 Total Costs and Benefits of Option 1

234. 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

	Low	High
--	-----	------

⁵¹ <http://www.searo.who.int/EN/Section23/Section1001/Section1110.htm>

⁵² 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>

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>	<u>£600,000</u>	
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

235. 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 1A - 'Do nothing' - Adopt/accept EC's proposed draft Regulation without any negotiation – including proposals to extend the requirements for child resistant closures (CRCs) and tactile warning devices (TWDs) to an additional hazard category

236. This is a sub-option of the “do nothing” option, to reflect uncertainty regarding EC proposals to extend requirements for child resistant closures (CRCs) and Tactile Warning Devices (TWD) to cover an additional hazard category. Consultation responses suggested that together with the potential for increased costs for re-classification, the proposal to extend the need for CRCs and TWDs would be the most costly change of the new Regulation. However, as the proposed provisions do not form part of the GHS, there is currently uncertainty as to whether this change will be agreed. To do so would go against the EC’s original commitment that the new Regulation would reflect as far as possible the existing system, unless the GHS required otherwise.

237. This section estimates the additional costs of these requirements. These costs are in addition to the costs estimated for Option 1 above.

238. Affecting mainly the cleaning products and detergents sector, concerns noted in the consultation focused on the potential packaging changes resulting from the requirement to ensure packaging is fitted with CRCs and/or TWDs for substances/mixtures assigned the hazard category of ‘serious eye damage’ or are re-classified as ‘skin corrosive’ following the implementation of the lower GHS base concentration limits.

239. Follow up meetings with representatives of the sector, helped to provide more detail on the estimated costs. These were given as:

- Child Resistant Closures are between £20 per 1000 more than normal screw tops (double current costs) to £30 per 1000 more than flip tops (up to 4 times current costs)

- Child Resistant Closures / Tactile Warning Devices will be needed on at least all laundry, APC and washing up liquids (this is estimated to be approx 50% of the total number of chemicals products)
- Based on the assumptions that the extension of requirements for child resistant closures will generate additional costs of approximately £20 per 1000, and that the purchase of over 750 million caps per annum will be required, additional annual cost are estimated to be approximately £15 million per year.
- There will be a further cost associated with the testing of new child resistant closures. Assume 3 new variants, at £8k = £24k, 55 filling lines in UK, 50% affected = 28
- Capital costs for change parts to cappers @ £30k per line = £800k
- Development time for design and fitting changes = £5k per line = £140k
- 28 bottle mould cavities to adapt for TWD – total £16k = £450k.

Total for line changes: £1,415,000

- Laundry detergent is currently in cardboard skillets. A CRC requirement will mean a transfer to plastic bottles. At current production rates (assuming an existing bottle is acceptable ie no new packaging development), there will be a £10,275,000 annual packaging on-cost in UK

Total: £10,275,000 (applying the same principles to CE production figures).

- This option does not carry a certified CRC so there will be an additional cost of redesign and testing

Total: £16,000

- In UK, five current filling machines, including one recently purchased at a cost of £2,000,000 will not be capable of filling bottles so will have to be replaced

Total: £10,000,000

- Empty bottles will have to be outsourced or blown on site. Five machines would be needed to cope with current production at a cost of up to **£4,000,000** with the need for an additional building at an estimated further **£2,000,000** cost. The rate of filling bottles is significantly slower than that for skillets with major impact on labour efficiencies. It is impossible to cost this at present.

Total equipment cost: £16,000,000

- Plastic bottles represent a greater drain on oil resource, non-biodegradable waste problem and an increase in our packaging waste costs. There is development work ongoing on board cartons with plastic closures which could potentially be made child resistant but these are not at a point to be costed. For one site, the change to plastic would add 24000T plastic to landfill per annum (from 4600T biodegradable card).

**Total cost in waste packaging levy:
£380,000 pa****Overall estimate of costs of implementing the new Regulation in the UK:**

£20,000,000 in 1-off implementation costs
This is reduced to £1,700,000 if only labels and not packaging are affected

£17,000,000 in annual packaging on-costs

Total: approx £37,000,000

240. Another respondent indicated the following costs:

- CRC packaging for household products
- Loss of multilingual labelling
- Classification, labelling *[and SDS related Costs – these should be omitted as the costs fall under REACH compliance not GHS]*

For the UK, representing approximately 12% of the total EU market this is estimated to be:

- CRC packaging for household products: **£25,000,000** in equivalent annual value
- Loss of multilingual labelling: **£9,000,000** in equivalent annual value
- Classification, labelling *[and SDS related costs]* **£700,000** to **£1,300,000** in equivalent annual sales

Total estimated business costs in UK: approx **£35,000,000**

241. A third respondent suggested a total of **£39,000,000** for implementing the new Regulation in the sector, but no further information was provided.

242. It is reasonable to assume that these costs would be significantly reduced if the additional provisions relating to CRCs and TWDs were either removed or significantly revised.

5.23 Latest position on CRCs and TWDs in negotiations

243. The UK has strongly questioned the aspect of the proposal that resulted in an increased scope of chemicals that would require CRCs and TWDs. This aspect of the proposal is out of line with the remainder, where the Commission has kept to the scope of the existing EU scheme as much as possible. There is no driver in the UN GHS for additional use of CRCs and TWDs.

244. It appears that, in this respect, the Commission's proposal is a simple error. The use of CRCs is linked to the presence of the corrosive pictogram on the label. The Commission followed this principle in making its proposal, forgetting that under the GHS the corrosive pictogram is applied more widely than under the present system. This creates an awkwardness in reversing the error. Nevertheless, negotiations continue.

5.24 Option 2 - Oppose the introduction of the UN GHS

Benefits

245. 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.

246. 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.

247. The feasibility of this option would be dependent upon other EU member states also opposing the introduction of the UN GHS. To date, no member state has questioned their high level political commitment to adopting GHS.

Costs

248. 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.

249. 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. Already, UK firms are being asked to classify and label their products according to the GHS when they export to certain countries, such as Japan, China and Thailand. In this scenario, the chemicals industry in the UK, and other European Union countries would have to continue to classify under both 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.

250. 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.

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

251. Most responses supported Option 3, although a couple of respondents expressed some resistance to the addition of elements in the existing system that are, at least currently, not part of GHS. This relates to the intention of the EC to include ozone depleters within the scope of the new Regulation even though the hazard category does not yet appear in GHS. However, this approach is consistent with the EC's commitment to ensuring that there is no reduction in the level of protection currently provided following the implementation of the GHS and is supported by the UK. Furthermore, the inclusion of ozone depleters in the GHS is currently being considered at UN level and inclusion is likely to be confirmed in the near future.

252. The following sub-options have been identified as areas in which the UK could negotiate to achieve changes to the EC's current proposed Regulation. Further quantification of the costs and benefits of these areas will be dependent upon additional information regarding the ECs proposal and the outcome of negotiations.

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

253. The current draft of the new 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.

254. 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

255. 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 considerable.

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

257. This proposal is subject to active negotiation.

Derogations for scientific research and development

258. 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.

259. 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)⁵³.

260. Consultation responses indicate that there is full support to remove the qualification that unclassified substances used in research should be handled as though they had the severest hazards.

Gains for the UK under Option 3

261. As negotiations progress, we hope to make a number of gains beneficial to the UK. These include:

- A clarification of the duties of the different 'actors' in the supply chain. This is of particular importance to the role of 'distributors'. The term 'distributors' covers a wide range of businesses ranging from household names in retail to the corner shop. Their role can be very different from that of the manufacturer or importer and it is necessary to make this distinction clear in the duties of those in the supply chain. Many distributors will not have access to the necessary competence to determine whether or not classifications and labelling are correct. The UK continues to be involved in developing a more reasonable and proportionate duties for distributors, while ensuring levels of protection remain in place.
- A proportionate and practical approach to the labelling of small or awkwardly shaped packaging.
- Broadening, without loss of safety, the provisions to allow businesses to use a generic name where disclosure of the full identity of the substance would put at risk the confidential nature of the business.
- Removing extensions made in the proposal to the scope of the hazardous substances and mixtures supplied to the general public which have to be fitted with child resistant closures or fastenings, and tactile warnings of danger.

Assistance for SMEs to comply with the new Regulation

262. The UK has already highlighted the need of the EC to consider how it can assist SMEs with the introduction of the new GHS Regulation. The UK will continue to have a dialogue with the EC to ensure the needs of SMEs are considered at a European level. See the sections below on *Guidance* and *Other Guidance Tools*.

Impact on other European legislation

263. 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).

264. Since the conclusion of formal consultation, the EC has published information on the action it intends to take to ensure that the introduction of the GHS in the

⁵³ <http://www.statistics.gov.uk/pdfdir/erd1106.pdf>

EU will have only minimal effects on the scope of downstream legislation controlling the use of chemicals. Some 22 pieces of downstream legislation refer in varying degrees to the classification of chemicals that, in many instances, will prompt additional control measures.

265. The EC confirmed that its policy is to keep the scope of downstream legislation the same under the present classification system, so far as possible. In order to do this, the EC has proposed:
- a) a Commission Regulation to amend the Detergents Regulation (648/2004) to change “preparations” to “mixtures” and to update references to existing legislation, such as the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (99/45/EC) to reflect the new Classification, Labelling and Packaging Regulation; and
 - b) a Commission Decision to amend the following Council Directives: Cosmetics (76/768), Toys (88/378), Volatile Organic Compounds (99/13), End-of-Life Vehicles (2000/96), Waste Electrical and Electronic Equipment (2002/96), and the Commission Directive on paints and varnishes (2004/42). The amendments will again replace “preparations” with “mixtures” and will make reference again to the new Regulation rather than current Directives.
266. These proposed amendments are limited to indicating references and terminology. The costs for the adjustments indicated above are expected to be minimal.
267. In addition to the action taken above, the EC has announced that the relevant services will review the other affected Directives controlling chemicals, including: the Plant Protection Products Directive (91/414), the Biocides Directive (98/8), the Seveso II Directive (96/82), the Aerosols Directive (75/324) and the Chemicals Agents Directive (98/24), together with other occupational health and safety provisions such as the Carcinogens, and Mutagens Directive (04/37) and the Pregnant Workers Directive (92/85).
268. The EC is taking advantage of the long transitional period to complete these reviews. Such reviews are sometimes to the advantage of the UK: for example, HSE 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) in the context of this wider EU review.
269. In terms of changes arising from adoption of the GHS, the outcomes of these reviews cannot be predicted or costed at this stage. However, the stated intention of the EC remains no change in scope as a consequence of the adoption of GHS.
270. 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 on classification and labelling. However, any changes to domestic implementing legislation, as a result of the action taken by the EC, are expected to be minimal, if needed at all. No costs are anticipated.

5.26 Other Uncertainties for all 3 options

271. A considerable number of uncertainties have been identified, in this impact assessment, in estimating the costs and benefits of the new 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 high level political 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 their existing systems, which go beyond the requirements of the GHS (although at this stage this is highly likely as currently those countries with extensive existing systems are following the EU approach and introducing the GHS sections that most closely resemble their existing systems). In this case, the potential initial trade benefits of the GHS would be limited.

5.27 Interaction between REACH and GHS regulations

272. When considering the impacts of the new Regulation it is important not to double count the costs associated with the REACH Regulation (Registration, Evaluation, Authorisation (and Restriction) of Chemicals)⁵⁴, for example any costs attributed to the amendment of safety data sheets. 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.

5.28 Review and re-classification

273. Currently all substances and mixtures are either self-classified, or have a harmonised classification 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.

274. 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.

275. 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 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.

5.29 Safety data sheets

⁵⁴ For more information please see: www.defra.gov.uk/environment/chemicals/reach/index.htm

276. Costs relating to the review and revision of safety data sheets are not included here as they reflect REACH compliance costs, not those relating to the new Regulation.

5.30 Assisting stakeholders to comply with the GHS Regulation

'Translation' Table

277. 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.

278. 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.

279. 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'

280. 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. To assist with the transitional arrangements, and to provide one source of harmonised classification, this Annex will also include the content of the existing Annex I of 67/548/EEC. The existing Annex I will be repealed when the new Regulation comes into force. The classifications under the existing EU system will be deleted at the end of the transitional period.

281. 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, respiratory sensitisation or for other effects on a case-by-case basis.

'RIP 3.6: Guidance on Classification and Labelling under the Globally Harmonised System'⁵⁵

⁵⁵ For more information please see: <http://ecb.jrc.it/reach/rip>

282. 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).
283. 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.
284. As part of this work, RIP 3.6 aims to produce guidance on classification and labelling under the GHS. The work on this RIP is well under way with good participation by industry and Member States. Costs of familiarisation with this guidance are included in the costs to business of familiarisation with the GHS Regulation, which are estimated above.

Other Guidance/Tools

285. For its part, the EC has already announced its plans to prepare various guidance and compliance tools – some specifically for small businesses – to assist chemical suppliers and users with the migration from the existing system to the new regime. These include an on-line tool.
286. Compliance tools for small firms are recognised as being of particular importance. The European Chemicals Bureau (ECB), under commission by the EC, has already started some of this work under the banner of the Commission's RIP 3.6 project. Alongside this, DG Enterprise is working on two proposals: a tool to assist those that already have a basic knowledge of the current system but do not know about GHS. This will cover the basic procedures and principles of the new Regulation and will be available in a downloadable document and web site via the ECB site. Secondly, a training/interactive tool on GHS will also be developed and made available through the ECB web site. Work has not yet started on this element of supporting compliance guidance.
287. Consideration is still being given on how best to target and educate consumers to the forthcoming changes. Industry is seen as needing to play a key role here as sectors know their respective customer profiles and can more accurately assess the level and type of awareness tools needed.
288. The UK Government will also work the EC, 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 EC, 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.

289. Until it is clear what level of detail these European guidance and compliance tools will provide, whether they easily translate into different sectors, and the extent to which they ultimately meet the necessary understanding and training needs of those affected by the new Regulation, it is difficult to speculate on the more specific costs involved. The RIA already estimates staff training costs, together with more general familiarisation costs for public authorities and others (Table 14 refers).

6. SMALL FIRM IMPACT TEST

290. 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. Consultation responses supported the conclusion of both the EC's Impact Assessment (dated 2006) and the UK initial RIA that the introduction of the new Regulation is likely to have a disproportionate impact on SMEs, from both practical implementation costs and/or the 'buying in' of necessary expertise. However, other than the generic costs offered elsewhere, no specific cost impact was provided for a small or medium sized business/organisation.

291. Engaging with representatives of small firms and/or appropriate trade associations has proven difficult. Later follow up requests or meetings have helped to raise the profile of GHS and the new Regulation, but specific detail on costs has remained difficult to establish. Efforts are continuing to push the new Regulation onto the small firms' agenda.

292. The estimated total costs to micro businesses and small and medium sized businesses, associated with the GHS Regulation, therefore remain unchanged and 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

293. 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

294. 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.

295. The competition assessment undertaken for the partial Regulatory Impact Assessment of the REACH Regulation⁵⁶ 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.

- 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)

⁵⁶ Defra (2006) "REACH Partial Regulatory Impact Assessment after Common Position"
<http://www.defra.gov.uk/environment/chemicals/pdf/reach-partialria-commonposition.pdf>

296. 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

297. 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 chose 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.

298. 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.

299. Responses to consultation indicated a certain lack of understanding as to what would either positively or negatively affect competition. One consultee saw no impact if the Regulation was “subject to proper/consistent application and enforcement throughout the EU”, Others saw the introduction of the new Regulation as having a negative impact on competition as smaller players “were put at a disadvantage” but no further substantiating detail was provided.

300. The cleaning products and detergents sector indicated a similar concern stating that if concerns in relation to increased re-classification were not resolved, the new Regulation would “severely penalise large companies – as well as small”, as in future, the sector would be dominated by a few very large multinational companies.
301. Another respondent saw the introduction of the new Regulation (and GHS more generally) as “opening the flood gates to outside competition” with non-EU suppliers “utilising the knowledge database assembled by the EU”, even though this is one of the core aims of the GHS.
302. The essential oils and aromatherapy sector, however, welcomed the proposed introduction of GHS and saw a harmonised system of classification and labelling as a key element in reducing barriers to trade and increasing the opportunity for competition through a reduction in import restrictions.
303. No specific detail was provided to support or justify these concerns about market competition, therefore the assumptions made in the RIA remain.

8. ENFORCEMENT, SANCTIONS AND MONITORING

304. HSE will draft UK legislation in order to allow the Enforcing Authorities to enforce the new 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 five years on the results of the official controls, and other enforcement measures taken. Drafting will begin after the Regulation has been adopted.

9. EVALUATION AND MONITORING

305. As the new Regulation has a lengthy transitional period, no plans are in place to evaluate its impact until the run up to two key milestones: 1 December 2010, the date from which all substances should be classified according to the new GHS criteria; and, 1 June 2015, the date from which all mixtures should be classified according to the GHS criteria. Evaluation is expected to involve chemical suppliers, enforcing authorities and downstream users, through both existing stakeholder networks and those established for evaluation purposes. There after, evaluation is expected to fit in with the duty of Member States to report back to the ECHA every five years on enforcement controls and actions taken.

10. IMPLEMENTATION AND DELIVERY PLAN

306. The Regulation is intended to come into full legal effect throughout the United Kingdom on 1 June 2015. The Regulation will be agreed through the co-decision procedure and will apply directly in all EU Member States. Certain provisions relating to the classification of substances will come into legal effect on 1 December 2010; the remaining provisions relating to the classification of mixtures will come into legal effect on 1 June 2015. However, the transitional measures

allow duty holders to classify and label substances and mixtures before these dates if they wish.

307. The Regulation will be enforced by HSE and Local Authority Inspectors.
308. The Regulation will, over the period above, repeal and replace existing UK legislation dealing with the classification, labelling and packaging of chemicals: the Classification (Hazard Information and Packaging) for Supply Regulations 2002, as amended, and the Classification (Hazard Information and Packaging) for Supply Regulations (Northern Ireland) 2005, as amended.
309. Once in place this Regulation will become part of the general portfolio of health and safety regulations to be enforced in a proportionate way in line with Health and Safety Commission's (HSC's) enforcement policy statement.

11. POST-IMPLEMENTATION REVIEW

310. 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 and amendments will be subject to negotiation.

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.

Annex A**Questions from the initial RIA (question numbers relate to the order in which they appeared in HSC Consultative Document No 213):**

Q 15. The initial Regulatory Impact Assessment indicates that Option 3 (details below) is the preferred option. Do you agree that the UK should proceed with Option 3? Option 3 is to support the introduction of the Regulation on Classification, Labelling and Packaging of Substances and Mixtures (based on the UN GHS), and negotiate to make it as light-touch as possible, with the intention of avoiding any extensions in scope beyond the UN GHS 'building blocks' that most closely reflect the current system (with the continuation of any addition EU requirement that are not yet part of the GHS). If you disagree or partly agree, please explain why.

Q 16. Are the sectors and groups affected by the Regulation reasonably represented in the Regulatory Impact Assessment (Please see Sections 5.1 to 5.6 of the RIA)? If you disagree or partly agree, please identify sectors that should also be considered and explain why.

Q 17. Based on your experience, do you think that the assumptions made in the RIA are reasonable? If you disagree or partly agree, please provide actual examples of products to demonstrate the possible cost to support your reasons. Areas that you may wish to consider include: staff training and familiarisation, IT systems (replacement or updating), reclassification of chemicals, re-labelling of chemical products, costs to downstream businesses, reviewing labels and safety data sheets, undertaking new risk assessments, customer/consumer education (Sections 5.11 – 5.17).

Q 18. 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.

Q 19. Do you agree that the benefits identified in the RIA are realistic? For example, increased trade opportunities outside the EU. (Sections 5.18 – 5.20). If you disagree or partly agree, please explain why.

Q 20. Are there any additional benefits that should be included? Please provide explanation for your answer.

Q 21. 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? Please justify your answer below.

Q 22. 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.

Annex B

Affected Downstream European Legislation⁵⁷

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.

European legislation that will be amended within the proposed 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

⁵⁷ 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 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:

there is no reduction in the level of protection for people, or the environment, compared to the existing classification and labelling system;

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;

the final Regulation provides a practicable, workable system, incorporating the experience from operating the existing classification and labelling system;

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;

transitional arrangements for migrating from the present system to GHS are practicable and workable;

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)

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

CD No 213 Annex C

LIST OF RESPONDENTS TO CONSULTATIVE DOCUMENT No 213

Advanced Composites Group Ltd
Pick Quick Service Ltd
British Coatings Federation
Chemical Industries Association
Chemical Business Association
UK Cleaning Products Industry
McBride
N Starch
British Association of Chemical Specialities
Glaxo Smith Kline