

## **UK Government response to the EC Consultation on a draft GHS Regulation**

### **Q1. Contact details:**

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### **Q2. Location of headquarters:**

United Kingdom

### **Q3. Primary field of activity:**

Government (National)

### **Q4. Most relevant role of your enterprise:**

Regulation of Health and safety. Environmental issues, consumer protection and transport issues are also reflected in this response, which represents the views of UK Government.

### **Q5. Specify the number of employees in your enterprise:**

Not applicable

### **Q6. Percentage of annual turnover imported from outside EU:**

Not applicable.

### **Q7. Percentage of annual turnover exported outside EU:**

Not applicable.

### **Confidentiality statement:**

Yes, the contribution can be made public.

**Q8. At the World Summit for Sustainable Development in Johannesburg 2002, the EU Member States and stakeholders from industry and non-governmental organisations have endorsed the UN implementation plan to have the GHS operational by 2008.**

***Do you agree to implementation of the GHS in Community law by means of a Regulation replacing the current EU classification and labelling system for substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC)?***

The UK supports the implementation of GHS through a Regulation, subject to clarification and amendments raised in the answer to question 11. The UK welcomes the efforts from the European Commission in progressing the EU's commitment to GHS and the opportunity to comment on the draft Regulations and supporting documentation.

**Q9. After the entry into force of the GHS Regulation, companies will be allowed to apply either the current or the GHS criteria for classification and labelling during a transitional period. By the end of the transitional period reclassification and relabelling of substances and mixtures according to the GHS rules will have to be completed. The length of the transitional period is a trade-off between giving necessary time for companies to adapt to the new system and reducing the burden of applying a dual system. The GHS draft Regulation proposes 3 years after entry into force of REACH for substances and further 4 or 5 years for mixtures. The choice of the length of the transitional period for mixtures is further explained in the enclosed note by the Commission Services.**

***Do you agree to the proposed timelines? You are invited to give an answer for substances first.***

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

Sufficient time will be needed to allow for effective information campaigns to educate industry, users and consumers to the new terminology, pictograms and classification arrangements.

As currently drafted under Article 39, the provisions of this Regulation will apply according to when the REACH Regulation enters into force. If the REACH Regulation comes into force in April 2007, and the GHS Regulation comes into force in April

2008, this will mean industry will have 2 years, not 3 before the provisions apply to substances. This will mean that the GHS Regulation timescales will apply retrospectively, the UK is not clear if this is legally possible.

While a period of joint running of both current and new systems is expected, a prolonged arrangement would be costly to industry and should be avoided – for example providing both existing EU and GHS information on a single safety data sheet could be seen as unnecessarily burdensome and possibly confusing for end users.

The European Chemicals Agency will undertake considerable work in the initial years of REACH. There are concerns over the capacity of the Agency to cope with the introduction of both REACH and the requirements of this Regulation at the same time.

**Q10. The GHS draft Regulation does not propose additional hazard categories to those already existing in the current EU system, i.e. Directives 67/548/EEC and 1999/45/EC for supply & use, or needed for reasons of consistency with transport legislation**

***Do you agree that this is the right approach?***

The UK welcomes efforts to ensure that the new Regulation incorporates as much of the existing system as possible. We support the Commission's approach to limit the hazard categories in the new Regulation to those that are currently in use. We also support the extension of the new Regulation to ensure the continued inclusion of hazard categories that do not appear in GHS but are in usage throughout the EU – for example ozone depletors.

The UK requests that the Commission clearly identifies any provision that is not taken directly from either the existing legislation, or the UN GHS. This may be the case for several provisions (such as Article 5.6 and Article 7.4). The UK would like to understand the justification and rationale behind any new provision, before agreeing to an extension of scope.

**Q11. *Do you have any specific comments on the text of the draft proposal for the GHS Regulation?***

The response is broken down into the following sections:

- (i) Main concerns
- (ii) Explanatory Memorandum – detailed comments
- (iii) Whereas Clauses – detailed comments
- (iv) Article commentary – detailed comments
- (v) Annex I comments
- (vi) All Annexes

The UK may raise further detailed comments during the formal negotiations.

**(i) Main concerns:**

- **Legal base**

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

- **Role of Key Players**

**The European Chemical Agency** – the UK recognises the role of the Agency in dealing with classification and labelling. However, it is necessary to have a clearly defined role for the Agency, defining the scope of its authority, its powers, its commitment to acting within the timescales detailed in later Articles (8, 22, 24 etc), the appeals process open to Member States where disagreement exists or the Agency has failed to act within those designated timescales.

An example of where further clarification is needed would be the provisions in Article 24.2. It is not clear if the Agency will have any power to challenge the scientific data presented to it, and timescales for updating the inventory.

The Agency will also undertake considerable work in the initial years of REACH. The effective management of its increased role with the entry into force of the new Regulation will need to be a factor in negotiations on the transitional period.

**Industry** – As currently drafted the text is not consistent, or clear as to the role of all of those within the supply chain. The existing system places the same duty on all those in the supply chain to be responsible for ensuring the correct classification and labelling of chemicals. According to the proposed text this will no longer be the case, as retailers, for example, will not be responsible for ensuring the classification and label are up to date and correct. The Commission must clarify this issue, and be clear of its intention. For further details please see comments on ‘Article 4’ below.

- **Scope of proposed Regulation**

The UK would like further clarification on the intended scope of the Regulation to ensure a workable and effective system can be achieved. Currently there are two main areas of concern.

- (i) The extension of scope of the current system, with the Regulation proposing to now include 'articles'. Detailed concerns are explained in the description of Article 1 below.
- (ii) The requirement to classify and label chemicals depending on the future use of the chemical, rather than how it is placed on the market. The detailed concerns are in Explanatory Memorandum comments below.

There are also comments on Article 5.6, and Article 7.4.

- **Links to Other Legislation**

The UK welcomes the European Commission's acknowledgement of the impact of the GHS Regulation on Seveso-II, its commitment to amending it appropriately, and the substantial work on the impact on downstream legislation. However, the UK remains concerned that in practice, the impact on downstream legislation is not as straightforward as the report presents. The UK would therefore like to recommend that the Commission review the downstream legislation report and amend any down-stream legislation if there are unintended consequences, prior to the entry into force of this Regulation.

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

- **Transitional Period**

For further details of UK concerns please see the answer to Question 9 of the questionnaire.

- **Database / Inventory / Annex I of 67/548/EEC**

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

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

**Annex I of 67/548/EEC**

It is desirable to work towards an early resolution to the status of the classifications listed in Annex I, other than CMRs and respiratory sensitisers. The UK would welcome the detail in Annex I being retained by the new Regulation as far as possible, recognising the value of the harmonised classifications developed collectively over many years.

As drafted, the Annexes contain additional duties not covered in the Articles. This would appear to be an inappropriate use of Annexes, which arguable

should be restricted to “how” the substantive requirements in the Articles must be met.

### **(ii) Explanatory Memorandum:**

- **Page 7** - The UK welcomes the European Commission’s acknowledgement of the impact of the GHS Regulation on Seveso-II and its commitment to amending it appropriately. The UK would like to suggest that a technical filter should be added to the existing link between classification and application of the Seveso Directive to ensure that these controls are focused on circumstances where there is major hazard potential.
- **Page 16** – The description of ‘Article 7’ on- The UK seeks clarification, and the intention behind the provision to refine a classification depending on ‘the state/form it will be used’. Page 16 states: “Paragraph 4 allows a refinement of the classification, if the classification differs for different forms or physical states. In these cases, the form or physical state in which the substance or mixture is used or is supplied for shall be decisive, for example, phenol shall be classified for its more hazardous properties in the melted form if it will be used in that form.”

A chemical may be placed on the market in a different state to that which it will be used (and there could also be many intended and unintended uses), so the stated intention of Article 7.4 is problematic and open ended. Does this provision require suppliers to produce different classifications depending on all uses and physical states that it may be used in future? Annex 1, (p.3) states that: “The identification and evaluation of the information shall be based on the actual substance or mixture involved, i.e., on the substance or mixture, in the form and/or physical state as placed on the market”. The Annex 1 Statement reflects the approach adopted now under the existing EU system, and we are not aware of any provision in the GHS that would change it. Furthermore, 7.4 does not appear to be consistent with 1.1.1 of Annex I.

### **(iii) Whereas Clauses**

- **Page 28** (clause 21) – the reference to sensitizers in the third line should be removed as the hazard identification can be based on data for the mixture as a whole for this particular endpoint.

Editorial

- *Delete ‘s’ after mixture on line 2.*

- **Page 28** (clause 23) - the wording of the text leads to uncertainty, and does not reflect the text in Annex I. The concept that human data should “generally be given priority over animal studies” is too simplistic, and does not necessarily reflect the complexities of precedence of test data. The text could be re-written in line with sections 1.1.3.1.1 and 1.1.3.2.3 of Annex I.

- **Page 30** (clause 43) - the UK supports the provision allowing more than one Competent Authority per Member State, as this allows options for enforcement purposes. The UK has in place 'Devolved Administrations' for the home nations of Scotland and Wales.

**(iv) Article commentary:**

**Article 1**

**Article 1.1** - The UK would welcome clarification regarding the provision for now including 'articles' within the scope of classification and labelling legislation. Is it the intention of the Regulation to apply to all articles that contain either a dangerous substance or a mixture? Is it the intention to align the GHS Regulation with the GHS Transport legislation, or the REACH Regulation?

*- GHS Regulation and Transport*

In the 'Technical support for the preparation of Annexes for the draft EU legislation implementing the Globally Harmonised System for Classification and Labelling of Chemicals' Report by Milieu, page 26 states: "The definitions include the definition of 'Articles' from REACH. Three types of articles are included in the GHS criteria, which are not included in the current Directives on Classification and Labelling, namely explosive articles, pyrotechnic articles and aerosol dispensers (aerosols). Inclusion of these articles in the new Regulation therefore represents a widening of the scope of the legislation compared to the current provisions". If this is the intention, why is it not stated explicitly in Article 1.1?

*- GHS Regulation and REACH*

REACH does include provisions for substances in 'articles', but only those above a certain tonnage that have an intentional release (and retrospective unintentional release) (REACH, Art. 7 p.55-58).

As presently drafted, Article 1 has the potential to bring petrol within motor vehicles, gases in articles such as fridges, and laptop batteries into scope. Clarification is needed to ensure an appropriate application to 'articles' of the new Regulation. An unintentional extension of the Regulation to a far wider scope of 'articles' (than may have been originally envisaged) could result in significant cost to industry, with little or no gain to the environment or human health.

- **Article 1.2** - The UK supports the general principles but requests clarification regarding the removal of the derogation for munitions. In the existing system there is a derogation for the labelling elements of the legislation for 'munitions': Dangerous Preparations Directive 1999, Recitals (14) "Whereas, although

*munitions are not covered by this Directive...it is therefore necessary...to classify them and assign to them a safety data sheet...".* This is not the case for the GHS Regulation. Are munitions now intended to be within scope of the Regulation or was the derogation accidentally omitted from the text.

- **Article 1.2(e)** - the UK supports the derogation for scientific research and development, however, the conditions described in the text apply the highest possible standards, i.e. those for carcinogens and mutagens. This is over-precautionary, disproportionate, and may be very difficult to enforce in practice. Is it appropriate to specify requirements for use in a Regulation about classification and labelling? A better approach may be to develop the existing approach of labelling with “Caution, substance/mixture not yet fully tested”, and add “For use only in scientific research and development”?

## **Article 2**

- **Article 2** - Can the definitions be placed in alphabetical order to ease reference?
- **Article 2** - Definition is needed for the term “notifier”.
- **Article 2** - *REACH database* – this description should be removed as the REACH database will be taken out of REACH and become part of GHS (under Article 26 of GHS Regulation). This description and other references to the various databases and inventories should be aligned, as currently the descriptions could lead to some confusion.
- **Article 2** - Registrant - “under the REACH Regulation” is required at the end of the definition to clarify.
- **Article 2** – is there value in adding a definition of “consumers”? This may help to clarify the actual end-user as opposed to those who process the substance or article. For example, in the UK consumers and downstream users are terms often used to describe the same end-user.

### **Editorial**

- *The definition of Hazard Categories might read “Subdivision of class based on criteria”.*
- *‘Signal word’ - ‘word’ should also be in italics.*
- *Importer - ‘Importer’ should be in italics.*
- *Downstream user - ‘user’ line 1 should also be in italics and ‘preparation’ in line 3 should be replaced by ‘mixture’*

## **Article 3**

- **Article 3.1** – Strictly, there are no criteria for hazard classes, there are only criteria for hazard categories (which are within hazard classes). To clarify, the following text could be inserted to line 1 before ‘hazard class’: “any hazard category within a”.

Editorial

- *Article 3.3(h) and (i) - remove ‘systemic’ for these and all similar references in the text (this change has already been agreed at the UN level).*
- *Article 3.3(j) - remove ‘s’ from ‘hazards’.*
- *Article 3. 4 - add ‘s’ after ‘Part’ in line 1.*

**Article 4**

- **Article 4.2** - it is not clear how and when Annex VI will be populated and what will happen if there is a delay in the establishment of this Annex.
- **Article 4.3(a)+(b)** - the existing legislation requires all within the supply chain to ensure the classification and labelling of substances and mixtures is correct and up to date. This text removes the onus of the distributor to check if the classification and labelling is correct. Was this the intention of the Commission?

The UK is concerned that this is a weakening of the current controls of chemical safety (one of the main principles of GHS). In addition is this in the spirit of REACH (communication and responsibility up and down the supply chain)?

There are also concerns regarding old stock which has since been reclassified being sold with the old classification/label.

We have been made aware of concerns regarding the use of pipelines to supply chemicals (gas for example) not contained in a package. As drafted, the text would prevent these means of supply, as Article 4.3(a) requires manufacturers, importers or downstream users to package substances and mixtures. A derogation from packaging and labelling may be required for these forms of supply.

### Editorial

- *Article 4.1(b) - suggest replacing 'evaluated' with 'assessed'. The term 'evaluate' with reference to 'information on a chemical' under REACH has a different meaning to that described here. This may cause confusion therefore the term 'assess' is proposed instead (if agreed this will then have to be changed throughout the text).*
- *Article 4.1(c) – in line 1 the UK suggests replacing 'hazard information on' with 'hazard information for'.*
- *Article 4.2 -*
  - *Line 1, para 1, remove 'a decision on'.*
  - *Line 1, para 2, remove 'a decision on'.*
  - *Line 3, para 2, remove 'decision/'.*

### Article 5

- **Article 5.3** - the UK supports the REACH principle of limiting animal testing. However, the reference to Annex XI of REACH is confusing regarding the need to avoid animal testing. The first sentence of Article 5 states suppliers 'shall use, where possible, tests that do not use vertebrate animals'. The second sentence then states 'He shall consider generating information by means other than tests on vertebrate animals'.

The two conditions are not the same and may lead to confusion (the first is stating 'where it is possible to avoid' the second is to only 'consider avoiding').

The UK suggest the text should be amended to strengthen the limitation on animal testing, by amending the text accordingly:

Replace Article 5.3 with:

*'Where the supplier chooses to generate information for the purpose of hazard identification and classification, he shall generate information, where possible, by means other than tests on vertebrate animals, provided the conditions set out in Annex XI of the REACH Regulation are met'.*

- **Article 5.6** (and **Article 7.4**) - as drafted, this paragraph has the potential to significantly extend the scope of the classification and labelling system by seeking to call for a refinement or alteration to a classification depending on the differing forms in which it may be used after it has been placed on the market. The existing provision is to only test a chemical as it is placed on the market (DPD Article 3.1 for example).

This may result in: a move away from the understanding of classification as being based on the inherent hazards present; more than one entry for a substance on the Inventory depending on its use (some substances have multiple uses); different labels having to be produced for different end

users/purposes, thereby resulting in confusion and significant additional costs to industry.

The provisions in Article 5.6, and 7.4 also appear to be contradictory to those in Annex I, 1.1.1 which states:

*“The identification and evaluation of the information shall be based on the actual substance or mixture involved, i.e. on the substance or mixture, in the form and/or physical state as placed on the market”.*

Editorial

- Article 5.4 - remove ‘test methods’ from line 2.
- Article 5.4(a) - add ‘the’ at the start of text.
- Article 5.4(b) - add ‘of the’ before REACH Regulation.
- Article 5.4(c) – replace ‘for health or environmental hazards’ with ‘studies conducted according to’.
- Article 5.5 - line 2 ‘analyses’ should be replaced with ‘analysis’.

**Article 6**

Editorial

- Article 6 (a), second paragraph – insert at the start “However” to link and contrast with the first paragraph.
- Article 6(b)(i) – replace ‘ each Chapter in’ with ‘1.1.7 of’.

**Article 7**

- **Article 7.4** - the UK has a number of concerns regarding the inclusion of this provision. This is an additional provision to the current system and so far as we are aware, does not reflect a requirement of GHS (for further comments see Article 5.6).

Drafting legislation with references to specific examples (in this case phenol) does not appear to be appropriate.

- **Article 7.5** – As drafted, we are concerned that the provisions of the Annex will not be enforceable unless it is clearly stated that there is a duty to comply with the requirements in Annex I. A suggested replacement form of words is:

“Without prejudice to the general provisions of this Article, the further specific rules in Annex 1, Part 1 shall have effect”.

## Article 8

- **Article 8.1** - It is unclear why “two or more” notifiers or registrants are required for the classification of a substance to be adopted *prima facie*. Does this mean that if there is only one notifier/registrant that formulators do not have to pick up the classification?

More fundamentally, the provisions in 8.1 would appear to attract abuse by two or more industry parties seeking to impose on others a particular classification and so push others out of the market (with SMEs potentially at a disadvantage). Although another supplier can subsequently make a case to the Agency for a different classification, it is not clear whether this classification is also added to the inventory, or how the Agency resolves the differences when it has been notified of them. This could create a lack of transparency.

References to Article 76 (2) of REACH should be replaced by Article 26 of the GHS Regulation.

We understand that the Commission is considering transferring the whole of Annex I from DSD (67/548EEC) into Annex VI of GHS, if this is so the need for Article 8 may be lessened.

## Article 9

- **Article 9** – This is exactly the same text as paragraph 1.1.6.1 in Annex I, and covered by Article 7; and so arguably Article 9 is unnecessary and could be removed.
- **Article 9.2** - If Article 9 remains then Article 9.2 must be amended, to allow the provisions in Annex I to be enforced (for reasoning see comments for Article 7.5)

The text would have to be re-worded along the lines of:

*“Without prejudice to the general provisions of this Article, the further specific rules for the classification of mixtures in Annex 1, Part 1 shall have effect”.*

## Article 10

### Editorial

- *Article 10.1 - The final sentence should be replaced with, “As an alternative to the limits specified in Annex 1 Part 1...”*
- *The relevant sections of Annex I should be specified (not just referred to Annex I as a whole).*

## Article 11

### Editorial

- *Article 11.1 – the UK suggests replacing “evaluation”, line 1, with ‘assessment’. Also, replacing “evaluation of a human health or an environmental hazard according to Annex I if:” with “assessment of the relevant hazards if:”.*
- *Article 11, 2 – the UK suggests replacing “evaluation of a human health or an environmental hazard according to Annex I if:” with “assessment of the relevant hazards if:”. The current wording does not include the physical hazards, the suggested wording leaves it open to all hazards identified.*
- *Article 11, 3 – the UK suggests replacing “evaluation” with “assessment” in line 1. Also, replacing “that a re-evaluation of the hazard”, line 2, with ‘it’*

## Article 12

- **Article 12.1 (d) (ii) second indent** – the last sentence does not appear to make sense, in that multiple chemical names and generic names are not related. The text as it stands does not make sense. There is also a potential issue regarding confidentiality.
- **Article 12 and Article 17.5** – some concerns have been raised about the amount of information required on the new labels, particularly for mixtures. The principle concern is that the label will not be large enough to accommodate the new pictograms (which will take up more space on the label, as they will be a diamond shape rather than a square) and the longer hazard and precautionary statements. Representations have been made seeking an extension of the small package exemption (Annex 1 1.4.6).
- **Article 12.1 (a)** – some concerns have been raised to the UK Government about the use of the phys-chem transport pictograms in what is essentially a supply system. This may be a matter for an information campaign to explain why the transport and supply systems are being more closely aligned. Transport pictograms do not, of course, cover health and are highly selective in covering the environment. Also see comments on Annex I.
- **Article 12.1(g)** - Why is this requirement limited to the general public and not also provided where the substance or mixture is used at work?

### Editorial

- *General Rules* - for consistency with previous titles, “for the content of the label” needs to be added.
- *Article 12.1(c)* –add “es” at the end of “Annex” on line two.
- *Article 12.1(d)(i) and (ii)* - after each bullet (or dash) the words should start in lower case (example “one”, not “One”). In (i) insert a comma after “substance”. In bullet point 3, line 1, delete “neither”, and delete “n” from “nor”. Also insert a comma after “inventory” on line 2.
- *Article 12.1(d)(ii)* - first bullet point, insert a “;” after “mixture”. In the second bullet point replace “as” (2<sup>nd</sup> line) with “for”; replace “toxic” (2<sup>nd</sup> line) with “toxicity” and “corrosive or causing” (third line) with “corrosion or”; replace “mutagen” with “mutagenicity”; replace “carcinogenic” with “carcinogenicity” and “toxic for reproduction” with “reproductive toxicity; “replace “sensitising” with “sensitisation” remove ‘systemic’ from line 5 (at the UN level it has agreed that this will be now STOT, not STOST).
- *Article 12.1(f)(ii)* - add “es” at the end of “Annex” on line three.
- *Article 12.2* - delete “the” before “Annex I”.
- *Article 12.2 (a)* - replace “label element” with “hazard pictogram”.

### Article 13

- **Article 13.1** - The UK agrees with the general provisions in the text, however, additional work needs to be undertaken regarding the process. The timescales may also need further refining. The six-week timescale may be unworkable for industry, as, in our experience, they often require a decision in days. More specifically, does the six weeks include public holidays?

Will the existing list of generic names be imported into the GHS system? As drafted, the Regulation will require industry to re-apply to use existing generic names. The Regulation also requires payment for this process whereas the existing system does not. It would be helpful to see the development of Agency guidance on granting generic names, including those circumstances that will prompt the Agency to refuse a request for a generic name.

- **Article 13.2** – In order to allow enforcement of the provisions in Annex I, the text should be replaced with the following text:

*“The specific derogations from Article 12 contained in Annex 1, Part 1 shall have effect.”*

Editorial

- Article 13.1 - insert “of the” before REACH Regulation, in line 6.
- Article 13.2 - Give specific reference to the section in Annex I, as it stands it is very vague.

**Article 14**

- **Article 14.5** – is the text “Annex VI - harmonised” more appropriate for the safety data sheet rather than the label as only professionals and industry would need this information. It would mean little to consumers. Furthermore, the proposed text is arguably misleading, as only certain endpoints will be strictly harmonised. To note, due to the increase in space needed for the diamond pictograms, the space available for the label will already be limited.

Editorial

- *Article 14.3 - replace “statements” with “indications”, as this covers pictures such as sunflowers, which may also be used to counter the classification and label.*

**Article 15**

- **Article 15.3** – it would be helpful to know if there are precedence rules where labelling is required under other legislation (not just transport rules).

Editorial

*In title replace “according to different legislation” in line 2 with “subject to other legislation”.*

- *Article 15.1 - remove “s” at end of “substances” in line 1*

**Article 16**

- **Article 16** - Clarification is needed about what is meant by the terms “without delay” and “receipt”. Does this mean immediately or when the supplier is first made aware of new data? Arguably suppliers are never directly in receipt of new scientific knowledge, since they are not sent original scientific papers. A better approach may be to put a duty on suppliers to keep up to date with new scientific or technical information that may result in a change to the classification and label and where it does so to require them to act promptly on the information. There would be no need to make an exception for biocides or

plant protection products, and this would cover the suppliers' duty to apply for a label change. In any event 16.2 appears to be a new and unnecessary provision.

There are practical considerations when updating labels. This can be a straightforward process but also a complex one depending on the complexity of the label, the size of the packages, the resources available to the supplier, the amount of stock remaining in different parts of the supply chain. There is also a question of who pays – what the costs would be, and the environmental impact – i.e., if the product has to be withdrawn, going to waste.

Editorial

- *Article 16.2 – remove 's' at the end of 'paragraphs' in line 2.*

**Article 17**

Editorial

- *Article 17.6 - delete "s" on the end of "one-twentieths" line 3.*
- *Article 17.7 - replace "particulars", line 1, with "information in Chapters 1-3" of Title III.*

**Article 18**

Editorial

- *Article 18.1 – delete 'label elements' inline 1.*
- *Article 18.4 – replace 'supplemental' with 'supplementary'*

**Article 19**

- **Article 19.2** - this provision contradicts Annex 1 (1.3.2.1). Article 19.2 states that in the case of a single package it should be labelled in accordance with the GHS Regulation in addition to those under the transport of dangerous goods.

Annex 1, 1.3.2.1, states that the transport labels have precedence for the same hazard, and need not be repeated on the same package. Consistency and clarification is needed.

Editorial

- *Article 19.1(a) - specify which 'Regulation' is being referred to (line 3).*
- *Article 19.1(b) - insert "goods" after "dangerous" on line 2. Specify which 'Regulation' is being referred to (line 3).*

**Article 20**

Editorial

- *Article 20.1 (b) - replace "must" (line 1) with "shall".*
- *Article 21,1 (c) – replace "must" (line 1) with "shall".*
- *Article 20.1 (d) - move "so" to after "designed" (line 1).*
- *Article 20.1 (g)(i) – replace with 'either a shape, design or any other indication likely to attract or arouse the active curiosity of children or mislead consumers, or'*
- *Article 20.1 (g)(ii) replace 'designation' with 'design'.*

**Article 21**

- **Article 21.1 + 2** - it is essential that this article is clear about what is intended to be transferred over from Annex I of 67/548/EEC to Annex VI of the new Regulation. As drafted, the Regulation suggests that all categories of carcinogen, mutagen and toxic to reproduction will be included in Annex VI.

The question remains, what will be the status of the remaining classifications in the existing Annex I? Would it be more appropriate if this provision stated that where an entry was transferred from Annex I to Annex VI it was done so in its entirety?

**Article 22**

- **Article 22.2** - Re-drafting the paragraph may make it easier for the two issues to be understood.
- **Article 22.3** - what would happen if the Agency could not adopt an opinion within 12 months? What are the consequences? Although 12 months is a good aspiration, a more flexible provision may be better. For example, industry may want some flexibility that would allow it to undertake more research.

### Editorial

- *Article 22; suggested redraft:*
  1. *Member State competent authorities may submit to the Agency proposals for harmonised classification and labelling for inclusion in Annex VI of this Regulation. Such proposals shall follow the format set out....*
  2. *Any supplier of a substance may submit to the Agency a proposal for harmonised classification and labelling for inclusion in Annex VI of this Regulation. Such a proposal shall be in accordance with...*

### Article 23

- Some concerns have been raised that the information requested as described in Section 2.1 to 2.3.4 of Annex VI of the REACH Regulation, if made publicly available, may constitute a breach of business confidentiality. The Commission must clarify that once collected, who will have access to the information.

### Article 24

- Article 24.1 (a) and (b) - See Article 23 above concerning business confidentiality. There needs to be clarity about which information the Agency intends to make public and which information will be held confidentially.
- **Article 24, 1 (c)** - what would happen if a substance was only partially classified in accordance with Title II (for example, very low tonnage chemicals with data on only one end point)? Does this narrow the covering of the legislation? – There is a chance that SMEs may also look at Annex I and the UN agreement and believe that the provisions only apply to larger businesses. The length and complexity of the provision may put off many SMEs.
- **Article 24.2** - the UK supports the general principle of allowing industry to update the inventory as new scientific data is produced. However, the UK would welcome further clarification on the process that the Agency will undertake when new evidence is submitted (both in terms of validation of evidence presented and workability issues regarding the timing of inventory updates).

How often will the inventory be updated? As there will be thousands of entries, and scientific data could be produced all the time, we are potentially looking at daily/weekly updates of the Inventory. How will this be managed? This could potentially be a major issue as the inventory could be very fluid, and change rapidly. This is in contrast with the sedate pace and conservative approach in the existing system. This could have massive potential impacts if industry is

expected to recall and relabel whenever there is a new classification on the inventory.

- **Article 24.3** - the text as written suggests that industry will have only 2 years (not the 3 as suggested in the consultation) for classifying and labelling substances, according to the dates in Article 23 (1) of REACH. The UK has concerns that this has the effect of applying the requirements retrospectively, which is not legally possible.

In addition, if industry were to comply with the Registration requirements of REACH within 1 year, it would have to re-classify and re-label under the GHS criteria soon afterwards. It would be clearer and fairer to state in the text the expected timescales for population of the inventory once GHS is in force.

Editorial

- *Article 24.1 - Line 3, replace the text with "...shall provide the Agency with the following information so that it can be included in the inventory in accordance with..."*

**Article 25**

- **Article 25.1** - the UK generally supports this principle. However, the UK wishes to see more clarification as to what "every effort" would constitute. The UK would like to know what would happen if two notifiers did not agree. We would also like to see more development of what the consequences will be for those not complying with this principle. The text may have more force if "reasonable" were inserted in front of "effort".
- **Article 25.2(a)** - the UK would like to understand why the Agency will need to receive all of the information that is set out in this provision. Clarification is needed on who will have access to the information once it has been collected. There may be confidentiality concerns if competitors were to have access to this information. It is the UK Government understanding that a formulator could, for example, use this information to identify the chemicals used and the process undertaken to create a competitor's mixture.

Editorial

- *Article 25.2 – line 1, insert 'within a reasonable period' after 'notifiers' - last sentence insert 'or registrants' after 'notifiers'.*

**Article 26**

- **Article 26.1** - rather than referring out to REACH, the Regulation text should explain which information will be freely available and which information will be kept confidential (then stating it complies with REACH).

- **Article 26.2** - the UK supports the provision for updating the classification and labelling inventory. However, the UK would like the timeframe and the process for the Agency updating the inventory clarified further. For example, will the Agency update the inventory as soon as it is informed, or will there be updates every one or two years? If the inventory were to be updated every time there was a new classification it could be updated on a daily/weekly basis. This could lead to major confusion and cost for those that have to enforce the Regulation and those that use the inventory to classify their mixtures (also see comments on Article 24.2).

### **Article 27**

#### Editorial

- *Article 27 – last sentence, should this be ‘authorities competent’ or ‘competent authorities’? We suggest adding before “legislation”, “European and Member State”; otherwise the duty on Member States is to ensure co-operation/co-ordination of all CAs worldwide.*

### **Article 28**

- The UK would welcome clarification on why the caveats in the current legislation have been removed. Was this intentional or an accidental omission? The UK would like to propose using the exact wording used in existing legislation. The removal of the caveats does not appear to have any validation.

### **Article 29**

#### Editorial

- *Article 29.2 - Insert “of the” before “REACH Regulation”.*
- *Article 29.3 - Insert “of the” before “REACH Regulation”.*

### **Article 30**

#### Editorial

- *Delete “provided for” in line 3.*
- *Delete “The” at the start of sentence 1, and the last sentence, starting on line 4.*

### **Article 31**

#### Editorial

- *Insert “hazard” before “category” in line 3.*
- *Replacing “concerned” with “relevant” may help clarity.*

### **Article 32**

- The 10 year retention period is consistent with REACH but is not part of GHS or the current system. Is this an appropriate time scale for both substances and mixtures?

#### Editorial

- *Article 32.2 - remove “to it” in line 3, after “substance or mixture”.*

### **Article 33**

#### Editorial

- *Replace the text with:*

*“Subject to the provisions of Article 34, Member States shall not prohibit, restrict or impede the supply of a substance and mixture within the meaning of this Regulation that complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation”.*

### **Article 35**

- The UK welcomes this flexibility offered by this provision.

### **Article 36**

- **Article 36.1** – which committee is being referred to here? If the committee is responsible for more issues than just classification and labelling there are concerns that these issues may be sidelined and overtaken by other demands.

## **Article 37**

### Editorial

- *Article 37.2(a) - replace 'Corrosion' with 'Corrosive' in the 7<sup>th</sup> bullet point.*
- *There are no "chapters" as such in Annex I.*

## **Article 38**

- Under the existing classification system the REACH text for selecting CMRs for authorisation is correct. However, if the proposed GHS Regulation text remains unchanged this will mean that all CMR substances that are now classified as category 3 will also have to be authorised. The UK believes this was not the intention of those drafting the text, and if left unchanged would massively widen scope. Therefore, Article 56 of REACH must also be amended. Article 56 should refer to those substances that are classified as Category 1a and 1b for carcinogenicity, mutagenicity or reprotoxic, not Category 1 and 2.

### Editorial

- *Article 38.3 - insert "REACH" in line 2 before "authorisations".*

## **(v) Annex I**

### **1.1.3.1.1**

This section seems to be out of place with section 1.1.3.2.3, both discuss the use of human versus animal data. It is necessary to stress that the quality of the human data is important and this is addressed in 1.1.3.2.3 but not 1.1.3.1.1.

### **1.1.3.3.1**

This new text has been included to cover note T from the 30<sup>th</sup> ATP but the text here does not reflect that note. Note T reflects the fact that a substance may be placed on the market in a form that does not have the physico-chemical properties as indicated by the classification in Annex I to 67/548/EEC. It then goes on to say that if results of appropriate tests show that the specific form placed on the market does not exhibit this property the substance should be classified in accordance with this test. As it stands paragraph 1.1.3.3.1 seems to be wider than this. This should be re-drafted in line with Note T.

### **1.1.4.1**

Beginning in this section, and then continuing throughout Annex 1, the phrase cut-off/concentration limit has been used. The same term has also been used in the

GHS. In terms of the EU Regulation we would recommend using only one term and in this context it may be better to use concentration limit.

#### 1.1.4.2.2 - Second and third bullet points

The terms 'substance in a mixture' and 'ingredient' have been used to mean the same thing. In other places in the text 'ingredient' has been replaced with 'substance in a mixture'. There should be consistency throughout the text.

#### 1.1.5

Line 3 states that the bridging principles are in each chapter, but this is not the case. They are given in section 1.1.7 of Annex I and then reference is made to this section in the individual sections of Parts 3 and 4.

##### Editorial

- Delete 'under each chapter in' and replace with 'in section 1.1.7 of'

#### 1.1.5 (b)

##### Editorial

- 1.1.5 (b) - delete the '.' before 3.7 on line 3  
- replace the word 'chapter' on line 3 with 'section'.

#### 1.1.5 (c)

Where it says 'for these hazards' it may not be clear which hazards this applies to. This should spell out carcinogenicity, mutagenicity or reproductive toxicity in accordance with sections 3.5, 3.6 and 3.7.

##### Editorial

- Replace the ';' with '.' after the word hazards.

#### 1.1.7.7

##### Editorial

- 2<sup>nd</sup> bullet under 'note that':  
In the sentence 'according to Article 11 (2)...' the '(2)' should be replaced with '(3)'.

#### 1.3.1.1

Editorial

- *Third paragraph, the sentence beginning ‘the label draws the attention of persons....’  
Insert ‘to’ after ‘attention’ on line 2.*

This sentence has been amended from Annex VI 67/548/EEC where there is no specific reference to the SDS but it just mentions other forms of information.

### 1.3.2.1

This paragraph is not written very well and it also contradicts Article 19(2) of this Regulation which states that a single package shall be labelled in accordance with this Regulation in addition to any label in accordance with the provisions on the transport of dangerous goods. Clarification and re-drafting are necessary.

### 1.3.3.1

Editorial

- *Line 2 – Replace ‘one-twenties’ with ‘one-twentieth’.*

### 1.4.2.2

Editorial

- *Line 3 – Replace ‘shall’ with ‘should’*

In addition, paragraph 1.4.2.2 is taken from Annex VI 67/548/EEC but this derogation has been extended to cover effects on the environment. Is this acceptable?

### 1.4.3.2

Editorial

- *Line 1 – Replace the second ‘shall’ with ‘should’ - In the GHS the word ‘should’ was used and this has been replaced with ‘shall’ in Annex I. In these paragraphs, however, the word ‘should’, should have been retained.*

### 1.4.3.1

The text has been taken from Annex VI 67/548/EEC but has been altered. As such, it no longer has quite the same meaning. It should read that although a substance itself is classified, if the form in which it is placed on the market does not present a hazard to human health or the environment then it need not be classified.

#### 1.4.4

Editorial

- *Line 1 – the word ‘and mixtures’ should be added after ‘containing substances’.*

#### 1.4.6.1

This section is based on Article 12.3 of 1999/45/EC, with some amendments. For example point (b) now applies to any quantity and not just small quantities. In addition it is not clear why there would be a need for a draft ATP for such things? It is unclear what the intention of this section is.

Editorial

- *1.4.6.1 (c) – Line 1, delete ‘either’*

#### **Table 2.1.1 – Criteria for explosives**

The following titles: explosibility, sensitiveness and thermal stability have been removed from the table but they have left the text that was under each of these headings. Without the headings it is not clear why they have referred to Test series 3 for the UN Manual of Tests and Criteria but then also specifically mentioned Test 3(c). The titles should be kept in the table as they detail why each series of tests are needed.

#### **2.1.3 – Pictograms.**

This comment is applicable to all of the sections regarding physical hazards.

The proposal is inconsistent in its use of pictograms. For all of the human health and environmental hazards the GHS supply pictogram has been used whereas for the physical hazards the transport pictogram has been used. This has been further confused as even here, in some hazard classes, a mixture of transport and GHS pictograms have been used for the different categories (e.g. section 2.1 on explosives).

#### **2.1.4.1**

Sentence beginning ‘For advice..’

It is not necessary to state this here, as all of this information has been included in Annex I – see footnote 55.

The 3 steps below this are given in the GHS but they are not part of the harmonised system. They are also inconsistent with other available information as they state that step 1 is to ascertain whether the substance or mixture has explosive effects using test series 1. The UN Manual of Tests and Criteria (10.3.3.2 and 10.3.3.3) states

that it is more appropriate to begin with test series 3 and figure 2.1.2 states that for classification purposes you should start with test series 2.

The decision logic that has been included for explosivity is flawed when used in the context of this Regulation. It is not part of the harmonised classification system and should not be included here. The problems with this logic have already been highlighted to the UN (ST/SG/AC.10/C.4/2006/5).

For other endpoints the decision logic has not been taken from the GHS and in some cases, flammable aerosols for example, a new table has been devised which make the criteria much clearer. Could this be considered for explosives?

## **2.2 – Table 2.2.2**

There is reference to pictograms when there is only 1 pictogram. This also applies to sections 2.4, 2.9, 2.10, 2.16 and 3.10.

### **2.3.4.1**

This section is not necessary. The information in the first paragraph has already been given in section 2.3.2.2. The second paragraph refers to the GHS decision logic, but as this has been summarised in table 2.3.1 there is no need to have reference to it, especially as it is not part of the harmonised classification system.

#### Editorial

- *Note to table 2.4.1 - '23,5%' should be replaced with '23.5%'.*

### **2.6.1**

#### Editorial

- *Replace '93 °C' with '60 °C', as 93 °C applies to Category 4 which has not been adopted.*

Footnotes 61 and 62 and sections 2.6.4.5 and 2.6.4.6.

These points are all related to transport and not supply. As such, why have they been included here?

### **2.8.4.1 - Second paragraph**

The decision logic has been included in the Annex therefore it is not necessary to make a reference to the GHS. Again this decision logic is transport based as it is taken from the UN Manual of Tests and Criteria.

### **2.9.4.1**

Editorial

- 2.9.4.1 – Line 2 - Delete 'production' or 'manufacture'. Preferably production.
- Add 'or mixture' after 'substance'.

**2.10.4.1**

Editorial

- Line 2 – Delete either 'production' or 'manufacture', preferably production
- Add 'or mixture' after 'substance'.

**2.11.2.1 (c) and (d)**

Editorial

- Line 4 - Add 'or mixture' after substance.

**2.13 – Table 2.13.1**

Editorial

- Add 'and mixture' after 'substance' on line 2 of each box.

**2.15- Table 2.15.1**

Editorial

- The hazard statements are incorrect. Replace with:
  - A – 'Heating may cause an explosion'
  - B – 'Heating may cause a fire or explosion'
  - C and D – 'Heating may cause a fire'
  - E and F – 'Heating may cause a fire'

**2.16 – table 2.16.1**

Editorial

- Add 'and mixtures' after substances in the title.

**3.1 – Table 3.1.1**

Editorial

- A number of the ' $\geq$ ' and ' $\leq$ ' signs have not appeared correctly.

**Notes to table 3.1.1**

Editorial

- Note (c) – Delete the second (c) on that line.

**3.1.3.3 (b)**

Editorial

- Line 2 - Delete ', , ' at the end of the line.

**Figure 3.1.1**

Editorial

- The line 'Test data on the mixture as a whole' should appear within the box and not with the title.
- Add ' $\leq 10\%$  or' after 'apply formula in paragraph 3.1.3.6.1. (unknown ingredients)'
- Add '(unknown ingredients  $> 10\%$ )' after 'apply formula in paragraph 3.1.3.6.2.3.'

**Table 3.1.2**

Editorial

- In the box relating to the classification category or experimentally obtained acute toxicity range estimate for the dermal route. The top value for Category 4 should be 2000 mg/kg and not 200 mg/kg.

### 3.2.2.2

#### Editorial

- *Line 1 - The '≥' and '≤' symbols have not appeared correctly.*

### 3.2.2.4

#### Editorial

- *2<sup>nd</sup> paragraph, line 4 - Reference is made to paragraph 3.2.1.6 but this paragraph does not exist in Annex I. Replace this with '3.2.2.5'.*

### 3.2.2.7

#### Editorial

- *Line 1 - To make it clear which table is being referred to add '3.2.2' after 'table' and remove 'the' from before 'table'.*

### Paragraph 3.2.2.7 and Table 3.2.2

#### Editorial

- *The '≥' or '≤' signs have not appeared correctly.*

### 3.2.3.1.2

#### Editorial

- *Line 7 - Insert 'to' between 'as avoid'*

Sometimes the section refers to skin corrosives Category 1 (as in the note to table 3.2.3) and other time it refers to skin Category 1 (paragraph 3.2.3.3.4). There is a need for consistency.

### Table 3.2.4

The GHS does not specify which subcategory the mixture should be classified in whereas Annex I states that Category 1A should be assigned. This is incorrect in the case of the classification of other corrosives (Categories 1A, 1B and 1C) ingredients for which additivity does not apply (third row). If the ingredient is classified in Category 1C then the mixture cannot be classified in Category 1A, likewise for Category 1B. The table should be amended to say Category 1A, 1B or 1C for this row.

### Notes to Figure 3.3.1

Editorial

- Step 3 - The '>' and '<' symbols are missing from the UN GHS.

### Table 3.3.2

Editorial

- The '≥' symbol has not appeared after iritis.
- Add 'and/or' after 'conjunctival redness ≥ 2.0'.

#### 3.3.3.3.4 – Line 12 and table 3.3.4.

Delete the reference to skin, when used with irritation, as this is incorrect and is not in the GHS.

#### 3.4.1.2

Editorial

- 2<sup>nd</sup> paragraph lines 2 and 4 (specialized and sensitized)
- 3<sup>rd</sup> paragraph lines 7 and 9 (standardized and sensitization)
- 4<sup>th</sup> paragraph line 2 (sensitized)

*In the above words replace 'z' with 's'*

#### 3.4.2.1

*Under the existing criteria substances and mixtures can be classified as causing sensitisation by inhalation if “the substance is an isocyanate unless there is evidence that the substance does not cause respiratory hypersensitivity.”*

This provision is not given in Annex I. Annex II (2.6) gives supplemental information which should be applied to mixtures containing isocyanates and states that such mixtures must carry the label “Contains isocyanates. See information supplied by the manufacturer.”

This does not address the issue of individual substances and does not convey the hazard posed by such substances either individually or in mixtures.

#### 3.4.2.2.4.1

There is reference here to a ‘Test Method Regulation’. This is the first reference to this in the text and it only appears in this section and in section 3.5 (3.5.2.3.3) regarding germ cell mutagenicity. Should this reference be removed?

#### Table 3.4.1

Editorial

- *The  $\geq$  symbols do not appear.*

#### Table 3.5.2

Category 1A/1B have been put together in 1 column in Annex I whereas in the GHS they appear as 2 separate columns. It may be better if 2 separate columns are also used in Annex I to emphasise that it is not Category 1A/1B but these are 2 separate subcategories

#### Table 3.6.1

Editorial

- *Note 1 - The  $\geq$  symbol does not appear.*

#### 3.7.3.3.2

Editorial

- *Line 2 - Delete 'label elements'*

#### Table 3.7.1

Editorial

- *The table should include the headings 'concentration limit triggering classification of a mixture as:' and 'Ingredient classified as:' as it does in the GHS.*

#### Table 3.7.1

Editorial

- *Note 1, line 3 - Replace 1% with 0.1% - see note 3 to table 3.7.1 in the GHS.*

In addition, the GHS says that if a substance classified in the additional category for effects on or via lactation is present in the mixture at a concentration  $\geq 0.1\%$  then a SDS would be required. This is not taken forward into Annex I. Several notes from the GHS have been combined into one note in Annex I, this may have led to the above error and omission.

In addition there is an additional note in Annex I which has just been called 'Note'. The 2 notes should be numbered accordingly.

### 3.8.1.7

Editorial

- *Line 3 - There is reference to table 3.8.1 but this table is not applicable to this particular paragraph. What should this reference be?*

### 3.8.2.1.1

Editorial

- *Line 3 - Insert '.9' after '3.8.2.1'*

### Table 3.8.1

Editorial

- *The '≥' and '≤' symbols are missing.*
- *The guidance value ranges for Category 2 via the oral route should be 2000 mg/kg and not C.*

### 3.8.2.1.9.4

Editorial

- *Line 5 - The ≥ symbol has not appeared.*

### 3.8.2.1.10.2

This paragraph discusses the use of human versus animal data and states that positive human data predominates over animal data. It is necessary to stress that the quality of human data is important.

### 3.8.2.2.1

Editorial

- *(a), Line 1 and (d), Line 5 - Insert 'o' to make oedema not edema.*

### Table 3.8.2

Editorial

- *The table should include the headings 'concentration limit triggering classification of a mixture as:' and 'Ingredient classified as:' as it does in the GHS.*

### 3.9.2.4

Last sentence says 'Evaluation shall be based on all existing data, including peer-reviewed published studies and additional acceptable data'. What is acceptable data and to whom should it be acceptable? The GHS text says 'data acceptable to regulatory agencies'.

### 3.9.2.9.9

Editorial

- *Line 6 - The '≥' is missing.*

### 3.9.2.10.2

This paragraph discusses the use of human versus animal data and states that positive human data predominates over animal data. It is necessary to stress that the quality of human data is important.

### Table 3.9.1

In the text of paragraph 3.9.2.9.6 it states that classification in Category 1 is justified when effects are seen at or below the values indicated in table 3.9.1. It may be useful to reflect this in the table by inserting  $\leq$  before each value so that this can be seen at a glance. This also needs to be taken into consideration in table 3.9.2 where the values should be  $>$  the lower limit. At the moment something exhibiting toxicity at the lower limit could be classified in either Category 1 or Category 2.

### Table 3.9.3

Editorial

- *The table should include the headings 'concentration limit triggering classification of a mixture as:' and 'Ingredient classified as:' as it does in the GHS.*

### **Sections 3.2 and 3.3 - Skin corrosion/irritation and serious damage/eye irritation**

Concerns have been raised to the UK Government on the potential increase in the number of mixtures classified for skin corrosion/irritation and serious damage/eye irritation under the draft Regulation.

It is the UK government's understanding that the methods described by the Regulation (taken directly from the UN GHS) are significantly different to the methods currently used and could, if applied literally, lead to the classification of more mixtures for such end points. The criteria, as presented in Annex 1 lack clarity and could lead to confusion amongst some classifiers.

This may lead to a real, or perceived drop in the protection in human health, as it would appear that mixtures such as washing up liquid will be classified and labelled the same as an oven cleaner. The concern of the UK is that consumers will then not be able to differentiate between products that can be potentially dangerous and hazardous from those which present far less danger. This could lead to consumers treating mixtures, which do require careful handling and precautionary steps (such as some oven cleaners), then being treated the same as mixtures they have previously used which do not require such care (such as washing up liquid).

There are also potentially large implications and costs for industry, as if a mixture is classified more severely it may become within scope of other legislation, and this may cost industry more to comply. For example, there may be additional costs/limitations associated with advertising.

#### **(vi) All Annexes**

The UK would wish the Commission to clearly identify when it has taken provisions directly from the UN GHS and from existing legislation, compared to amended, or additional requirements. Where the Commission has amended or inserted additional requirements to the UN GHS the UK would like to understand the justification behind the decision.

#### **Q12. The costs and benefits of implementing the GHS have been assessed in the RPA / LE impact assessment study.**

***On the basis of the cost items identified in this analysis, do you think these GHS implementation cost estimates are generally plausible?***

The UK welcomes the work undertaken in assessing the costs and benefits of implementing GHS in the EU, and thanks the RPA for the prepared impact assessments.

However, the UK believes that, while offering a starting point, the impact assessment alone should not be used as the basis for estimating the anticipated costs or benefits

of the tabled draft proposed Regulation. The UK has several reasons for making this statement.

### **Assumptions**

The assessment appears to be based on two broad, but potential flawed, assumptions: that the UN GHS will be implemented across the world at broadly the same time as the EU; and, that UN GHS will be implemented across the world in exactly the same way.

While the UK accepts that other jurisdictions are aiming towards the 2008 timescale, it is very unlikely others will use exactly the EU timescales (3 years for substances, plus 4/5 years for mixtures). The study makes no reference to, and gives no global context to what the other major trading partners of the EU chemicals industry are planning. This global context must be provided.

In addition, due to the 'building block' approach it is highly unlikely other jurisdictions will be implementing GHS in the same way as the EU, especially since jurisdictions will be allowed to choose the blocks they wish, and keep additional provisions which go beyond the UN GHS agreement.

The impact assessments takes these assumptions as a given (without evidence to back this up) and the costs and benefits reflected are assessed against this background.

### **UN GHS vs draft Regulation**

Secondly, the assessment focuses on the implementation of the complete UN GHS agreement *not* the draft Regulation (which sensibly chooses not to implement all the building blocks, and keep other provisions not in the UN GHS agreement). The impact assessment was completed in May 2006 but the draft Regulation was not completed until August 2006. Therefore the UK Government is concerned the assessment does not estimate the costs and benefits of the actual draft Regulation.

### **Evidence Base**

The estimates given are based on responses from a very limited number (only 16 responses from across all 25 Member States). It is not clear how representative this sample is of the sectors, or the size of companies, most likely to be affected by the Regulation. This raises doubts as to the robustness of the costs and benefits given.

### **Other costs**

The costs as presented do not include other major costs which must be included in the final impact assessment. The cost for Member States, and industry to educate consumers is not referred to at all in the study. There are likely to be significant costs across the EU for educating consumers when the pictograms and the hazard statements are changed.

The full impact on the cost of redesigning all labels has also not been taken into consideration. The RPA study, for example, states that if the classification of a chemical remains the same under GHS the impact will be minimal. However, even if the classification is unchanged the pictograms and hazard statement may change. Many of the new pictograms, as proposed, will be in colour, and the diamond shape of the pictograms will require more space on labels, which is likely to cost time and money for industry to redesign. This impact on all the above needs to be explored more fully.

The costs arising from the impact on other downstream legislation needs to be looked into more thoroughly. The RPA study does not look into the impact on downstream legislation in any great detail, dismissing the impact as minimal at an early stage. The UK recommends that this be done as soon as possible.

The UK would also welcome further work to calculate the cost of any possible dual running of the existing system, and the new proposal during the implementation period. There could be costs for running two IT systems in parallel for example.

### **Scenarios**

The impact study is based on 4 scenarios, but it fails to consider the potential cost/benefit for another potential scenario, which should be considered for completeness.

Scenarios considered:

- 1, GHS is global, with the EU lagging behind
- 2, GHS is global and simultaneously implemented
- 3, GHS is global with the EU implementation delay for partial REACH implementation
- 4, Fragmented global system (status quo)

The additional scenario that should be costed is if the EU were to implement the UN GHS and all other major trading partners failed to implement it.

The UK understands that the Commission has given an undertaking to produce a Regulatory Impact Assessment which will support the draft Regulation itself. The UK welcomes this commitment and would encourage an early circulation of this assessment.

The UK recognises that the full benefit from the UN GHS will only be achieved in the EU when the EU's trading partners (globally) adopt GHS themselves, thereby moving towards a standardisation and harmonisation of classifications and supporting hazard communication for each substance and mixture. But such circumstances are some years away, particularly if some jurisdictions are delayed in implementing GHS or if they select different Building Blocks than the EU (and continue with additional requirements outside the scope of GHS).

**Q13. It is expected that harmonised criteria for classification and labelling all over the world will benefit trade in chemicals with non-EU countries (EU exports and imports into the EU): companies incur less trade-related costs as they no longer will have to spend time and resources to deal with different criteria for classification and labelling. Table 2 in the RPA and London Economics study summary shows that the GHS implementation costs are on average relatively small.**

***On the basis of your experience, do you agree with the consultants that these costs will be outweighed by the trade-related cost savings of the GHS?***

We doubt that the costs of implementing GHS in the EU will be balanced by the trading benefits in the short to medium-term.

### **Cost/Benefit mismatch**

As a representative of national Government, we have no direct involvement in the trade of chemicals. However, from our reading of the impact assessment, it is our understanding that any potential cost-savings that may result from increased trade opportunities will only be available to those companies that are engaged in trade outside of the EU's Single Market (estimated as 25% of the EU chemicals market trade).

Therefore, any cost-saving will be open to a relatively small part of the market, likely to be dominated by larger companies that have the resource to operate internationally. Implementation costs, however, will be demanded from all companies, having a disproportionate impact on SMEs.

An initial discussion with a sample of UK industry representatives indicated support for this position and a limit to any new trade opportunities being identified as a result of the proposed Regulation.

The UK suggests that any analysis of cost-savings in relation to trade benefits needs to be appropriately qualified (clearly identifying who will benefit, and who the impact will disproportionately fall upon) and are not suggestive of benefits open to all.

### **Assumptions**

As stated above for the answer to Question 12, the UK has a number of major concerns over the assumptions made in producing the figures in the impact assessments.

The assumption that other jurisdictions will implement the UN GHS in exactly the same way as the EU is flawed (based on evidence of how other jurisdictions plan to implement the UN GHS).

The 'building block' approach (and the agreement to allow other requirements beyond GHS to continue) mean that at this stage industry will have to continue to have different classifications, labels and Safety Data Sheets for different jurisdictions, as they do now. GHS will be a major step towards the harmonisation of classification

and labelling systems, but the assumptions of the study are far too simplistic. The UK agrees that as the classification and labelling systems become more aligned (as most jurisdictions are likely to pick up many of the building blocks) the cost and time taken to comply with different systems will be reduced, but the UK questions the optimistic picture given by the impact assessment.

**Q14. Do you have other specific comments on the RPA / London Economics impact assessment study?**

Specific comments on the impact assessment:

- Study summary Section 6 - The UK would welcome more robust data on the number of substances/mixtures that are produced/traded by SMEs compared to larger companies. The impact study has made assumptions in this respect and supporting evidence is needed.
- There appears to be a lack of valuation of the benefits in savings of trade-related costs to EU chemicals companies compared to the value of potential benefits that would be lost if the EU did not adopt GHS. The UK would welcome a valuation as far as is possible. Better data on potential savings in trade-related costs are needed as the stated data is based on a limited sample of businesses.
- Table 2 – the data here is based on an estimation of the number of EU chemicals businesses involved in international trade. The RPA assessment estimates 6800 European based chemicals businesses engaged in the international trade of chemicals but they may be a certain level of uncertainty attached to this assumption. Varying this assumption would effect the estimates given and may suggest a greater or lesser total for those companies that could benefit from GHS.
- From the work that has been completed, is it possible to analyse whether or not there are any business characteristics that would influence potential costs? Similarly, are there any (identified) types of business that can expect to carry a higher proportion of the costs? Is it fair to read across from the existing system and say that the coatings or solvents sectors, for example, can expect to see heavier compliance costs.
- There does not appear to be any specific costings of administrative burdens. Is it possible to reflect such costs?

**Q15. The analysis related to EU “downstream” legislation examines potential effects of the proposed GHS Regulation on the various EU downstream acts which refer to the current system of classification and labelling. The analysis suggests that potential effects could be minimised by modifying the references to the classification criteria in various acts without changing their scope.**

## ***Do you agree with the findings of this analysis?***

The UK welcomes the analysis provided by the Commission Services of the potential effects of the proposed Regulation on the EU's downstream legislation.

- *SEVESO II Directive*

The UK welcomes the European Commission's acknowledgement of the impact of the GHS Regulation on Seveso-II and its commitment to amending it appropriately.

The UK would not wish to go beyond the current scope of SEVESO II, and there is a risk that would happen if the Directive were aligned with the GHS classifications. The UK offers the following comments on the Commission's downstream proposals for SEVESO II.

The work done by the Commission appears to limit the impact of the changes of the GHS Regulation on SEVESO II with regard to substances.

The draft regulation acknowledges that the position regarding preparations (GHS terminology 'mixtures') is unclear. Clarification is needed as it could bring more sites into SEVESO with implications for how regulators would regulate effectively a greater number of sites and the increased burden on industry. The UK wishes to withhold judgment on the impact on SEVESO until further work has been carried out.

- *Explosives*

With regards to explosives for example, the proposals maintain the status quo since the industry uses the UN classification to determine SEVESO limits and it would be unlikely to bring more companies into the Seveso regime. However, there are other concerns relating for instance to the terminology in the proposals.

Unstable substances are those that are too unstable to package for transport. They are usually manufactured and used soon after manufacture. These substances include pure nitroglycerine, explosives which are used to initiate explosives or are used in detonators and fuses for weapons such as bombs and shells, or explosives which are too unsafe to produce on a commercial scale or used for experimental purposes.

It is not clear what is meant by unintentional explosives as it is not mentioned anywhere in UN GHS, or existing legislation. The UK would welcome clarification.

- *Solvent Emissions Directive*

The UK's reading of pages 140-145 of the Study which is dealing with the Solvent Emissions Directive, suggests that the EU and GHS definitions for most risk phrase solvents mentioned in the Directive are the same and therefore the changeover to GHS will have no effect.

However, the threshold for classification of R60 and R61 as a reprotoxic toxicant is 0.3% in GHS compared with 0.5% in the Directive. The document, therefore, seems to suggest that this will only have a theoretical impact, but the reasoning for this is unclear.

If there were solvents between the 0.3 and 0.5% thresholds, these would surely be newly caught by the changeover, with the effect that the more stringent provisions of Directive in relation to R60 and R61 would apply.

- Batteries Directive (2006/66/EC)

The recently agreed Batteries Directive has capacity labelling requirements? Will these be affected by the proposed GHS changes?

- Ecolabel

The Ecolabel scheme is voluntary (page 63 of the Study) but the document refers to the Ecolabel "legislation". It is also not clear why the Ecolabel criteria being is set out in a different category from the other types of downstream legislation which will be affected by GHS (i.e. the European Ecolabel - other European labels are not mentioned).

On page 73, the Study states: "Currently, detergents as well as other consumer products are also subject to particular eco-labels which are applicable in some Member States, e.g. the Nordic Swan (awarded in the Nordic countries). One of the criteria to get the respective eco-labelling is based on the absence of product or ingredient classifications. For example, the Nordic Swan labelling would not be granted if the products were classified under EU legislation. This means that the GHS might disqualify a product also for the award of further eco-labels. Concluding, potential effects of the GHS could be due to additional substances and / or mixtures classified under GHS. The corresponding final products would consequently disqualify for the Community eco -label and other national eco -labels as far as the latter require the absence of product or ingredient classifications."

However, this is not clear. Ecolabel criteria are regularly updated and revised, and could and would simply need to be adapted when the GHS came into force. This could be a significant exercise, but the introduction of GHS should not be delayed on that account, given that the Ecolabel has the status of a voluntary scheme.

- Packaging Directive

Is the proposed Regulation likely to affect the Packaging Directive?

- Other Legislation

The UK Government is concerned that the full impact on all downstream legislation remains to be assessed. The UK is concerned that if the proposal remains on course for entry in 2008, Member States and the Commission may not have sufficient time or resource to amend all affect legislation prior to entry into force.

The study on the effects on the downstream legislation contains a number of examples where a “statement is not possible” written next to the conversion charts which describe the potential effects on the numbers of chemicals that will become in/out of scope (for example p.97 of the study).

The impact assessments accompanying the proposal also fail to adequately assess the full impact on downstream legislation. The studies quickly dismiss the impact on all downstream legislation (apart from Seveso II) without reference to evidence.

The UK would also like to raise the concern that it is not just Community-wide legislation that must be amended, but Member States also have national legislation that reference the current classification and labelling legislation.