Advisory Committee on Toxic Substances Current Developments			*ACTS/27/2006*
Meeting date:	30 November 2006	**Open Govt. Status:**	Fully Open
Exemptions:	None		

HEALTH AND SAFETY COMMISSION

ADVISORY COMMITTEE ON TOXIC SUBSTANCES (ACTS)

Current Developments

1. Disease Reduction Programme: 2008 and beyond
2. Disease Reduction Programme Cancer Project: Overview
3. Disease Reduction Programme Skin Project: Hairdressing Campaign
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9. Existing Substances Regulation
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11. The Globally Harmonised System for Classification and Labelling of Chemicals (GHS)

1. Disease Reduction Programme: 2008 and beyond

The DRP Delivery Team is beginning to approach stakeholders within and outside HSE, to ask for help in developing the DRP plan for 2008 onwards. As part of this, they are hoping to meet ACTS Members informally in small groups, to seek views on plans and priorities in the context of what the health and safety system can support; where the resources of the system should be focussed for maximum impact; and on defining surrogate measures for monitoring and evaluation. The aim is to maximise efficency by beginning to outline a broad consensus for further discussion at the March meeting of the full Committee.

We are grateful for Members' contributions to this developmental work. If you have not yet been invited to take part in a meeting, we are likely to be in touch shortly. For further information or clarification please contact Lydia Harrison (lydia.harrison@hse.gsi.gov.uk; 0151-951-4624).

2. Disease Reduction Programme - Cancer Project

HSE, through its Disease Reduction Programme (DRP) is currently reviewing its priorities for chemicals including those that cause, or have potential to cause, cancer. The DRP cancer project has two main workstrands, work to look to reduce the number of deaths attributed to occupational cancers arising from exposure to chemical carcinogens and work to reduce the numbers of deaths from occupational cancers due to exposure to asbestos through work activities.

a) DRP Chemical carcinogens:

The DRP work on chemical carcinogens will provide an up to date review of the use, exposure and management of risks from occupational carcinogens in the UK. The review includes the available toxicological and hygiene information on more than 100 known or probable carcinogens with a view to enabling identification of those that appear to be most potent or are in wide use today. Information is also being gathered on the adequacy of workplace control measures for specific carcinogens. As well as helping to identify carcinogens of concern, this information will provide options for improving the control of carcinogens and baselines for evaluation. A major element of this work will be to improve HSE's evidence base on the current and future predicted burden of occupational cancer in Great Britain. HSE had already acknowledged the need to review its cancer statistics and has initiated a review of the current evidence base on the burden of cancer. This began in 2003 and continues under the DRP. A wide range of national and international experts are involved in this review. HSE plans to share and discuss all aspects of this work with stakeholders in 2007.

b) DRP Asbestos:

The DRP launched the asbestos 'don't take the gamble' campaign in September 2006. The campaign was targeted at the estimated 1.8 million workers who have spent some of their working lives in the building and maintenance trades. This was based on research showing that around 25% of deaths from asbestos-related disease occur in this group, and that these people are often unaware that they have been exposed to asbestos in their day-to-day work. Therefore, raising the level of awareness of the risks across the industry is fundamental to ensuring that the numbers of people suffering ill health from asbestos-related diseases in the future are substantially reduced.

The campaign involved targeted activity in trade and regional press, as well as highlighting the 'duty to manage' message via direct marketing information to over 80,000 dutyholders. All these aspects have been supported by HSE and Local Authority 'duty to manage' inspections and awareness raising events carried out throughout the year.

Future activities include evaluation of the above campaign which will provide basis and structure for a 2007 campaign. The HSE and LA 'duty to manage' initiatives will continue throughout 2007-08 with enforcement of regulation 4 a priority. Leading on from the publication of the 'asbestos essentials – task manual' on the new asbestos website, we will be developing a web based risk assessment tool for management of asbestos. To coincide with this new task sheets will be developed with sheets on textured coatings to be published soon.

c) Control of Asbestos Regulations:

The Control of Asbestos Regulations 2006 came into force on 13 November 2006 and will further strengthen controls to reduce asbestos exposure and increase employer and employee awareness of the presence of and risks from work with asbestos-containing materials to prevent further unnecessary deaths.

The Regulations bring together the three previous sets of Regulations covering the prohibition of asbestos, the control of asbestos at work and asbestos licensing. Two approved codes of practice were published at the same time *(Approved Code of Practice Work with Materials containing Asbestos, L143, ISBN 0 7176 6206 3 and The Management of Asbestos in Non-Domestic Premises, L27, ISBN 0 7176 6209 8)*.

3. Disease Reduction Programme - Skin Project

Hairdressing Campaign

Hairdressers are more likely to develop work-related dermatitis than any other occupational group. One source estimates that more than 70% of hairdressers have some form of skin damage and that around 50% will develop dermatitis caused by their work.

Reducing dermatitis in hairdressers is one of the key aims of the Disease Reduction Programme and HSE is working in partnership with the LACORS, the Local Authorities, the NHF (National Hairdressing Federation) and HABIA (Hair and Beauty Industry Authority), to launch a campaign to tackle the problem.

The campaign will launch in the week beginning the 20th November and will run into December. Alongside advertising and PR-led activities, we have secured the support of Jo Hansford, the leading hair colourist in the UK. A direct mail shot will be sent to the majority of salons (we will be particularly targetting the areas where we know LAs are undertaking visits or other activities), highlighting the campaign and advising salon managers of simple steps that can be taken to reduce the risk of dermatitis.

Local Authority Inspectors are also visiting around 7000 salons across the UK, offering advice and information, as well as running seminars for local businesses. Campaign packs have been developed for distribution during these visits and seminars. They will contain a sample of gloves of the type we are recommending (i.e. longer length, smooth, non-latex), moisturisers, a checklist for salon owners, a myth-buster sheet (dispelling beliefs such as

'gloves snag hair', 'clients don't like gloves'), and a selection of campaign branded goodies such as appointment cards, fridge magnet etc. Inspectors may find it helpful to use the material to talk through the controls with the salons at their visits. A teaser leaflet for the campaign is now on the DRP/Skin pages of the Extranet, as well as a presentation that can be used in awareness raising sessions. A campaign site is currently under construction (www.badhandday.hse.gov.uk), which will have all the key messages, campaign imagery and some additional resources such as posters. The website will be launched to coincide with the campaign.

For more information on the campaign or if you have not yet ordered your campaign packs, please email skinproject@hse.gsi.gov.uk

4. Dermatitis In Catering

The DRP has three priority areas based on incident rates, number of workers within occupational groups and ease of intervention. These are work related skin disease, work related respiratory disease and work related cancer. Occupations with the highest incidence rates of work related contact dermatitis ('dermatitis' here after) have been identified from medical statistics. The hotel and catering sector has been identified as a priority group. The incidence rate for the hotel and catering sector is twice the all industry average and even this is likely to underestimate the true scale of the problem. Particular at-risk occupations within the sector are cooks and chefs, kitchen and catering assistants.

HSE's Dermatitis in Catering Project is looking to raise awareness of the issue and achieve behavioural change within the industry to effect a reduction in the number of cases of dermatitis. We are looking to raise awareness of the issue throughout the financial year 2007/2008. This will be done in a number of ways. The first approach is the direct awareness raising. Local Authority Environmental Health Officers will raise awareness of the issue and leave information for the employer/employees whilst they are inspecting work premises either as part of a food hygiene or health and safety visit. Similar awareness raising will also be carried out during HSE inspections at food manufacturing premises. The second approach is by working with our stakeholders to spread the message. The final strand is communicating the message through other routes such as the HSE website, articles in relevant trade publications etc. The catering sector and its workforce are large and diverse and we cannot hope to reach everyone and change behaviour in one go, so this is a step-by-step approach.

5. 2nd Adaptation to Technical Progress to the Dangerous Preparations Directive (1999/45/EC)

The 2nd ATP of the Dangerous Preparations Directive (2006/8/EC) was agreed on 4 November 2005. The implementation date is 1 March 2007. HSE originally planned to incorporate this ATP in CHIP at the same time as the 30th ATP of the Dangerous Substances Directive. However, given the uncertainty from the EC on when the 30th and 31st ATPs will be held (see latest developments below), and the potential consequences of the 2nd ATP the extension, to very low levels, of the generic concentrations limits (previously 25%) to classify preparations as *Dangerous for the Environment*, implementation has necessarily been delayed.

The 2nd ATP extends to very low levels the generic concentrations limits (previously 25%) to classify preparations as *Dangerous for the Environment*. The intention is to classify

products containing small quantities of powerful biocides (e.g. triclosan) that are typically present at concentrations around 0.1 to 0.5% in water based products such as standard emulsion paints and perfumes, and at higher concentrations (typically from around 0.5 to 5%) in products such as anti-fungal paints, wood preservatives, pesticides, etc.

In consequence, many more products such as emulsion paints will in future be classified and labelled as Dangerous for the Environment. However, another consequence (unintended) is that the provisions of COMAH will be triggered if such products are stored above the generic tonnage quantities specified for Dangerous for the Environment in COMAH. These quantities were lowered further in the 2005 COMAH Amendment Regulations (SI 2005/1088).

These latest threshold quantities could be exceeded in larger DIY stores, or in warehouses, bringing these premises into scope of COMAH. However, this is clearly anomalous – for example, the storage of 99 tonnes of the pure biocide would not attract COMAH, but storage of 100 tonnes of emulsion paint would do, even though the paint is mostly water and pigment, with only ½ tonne of the biocide (if present at 0.5%) distributed throughout the paint, which typically is stored in a large number of relatively small containers (10kg or less).

The problem was not recognised during the negotiation of the 2nd ATP by the EC, Member States or industry, but was raised just before the vote by the UK. We made a minute statement asking the EC to address the problem urgently by amending the Seveso II Directive. Some other Member States supported us. In fact the problem is one example of a bigger issue - the simplistic way the Seveso II Directive uses the classification system to trigger its requirements. HSE's HID is presently raising this issue with the EC and with other Competent Authorities for the Seveso Directive, with a view to amending Seveso II to introduce a 'technical filter' so only those sites with major hazard potential come within scope. The introduction of GHS should provide a further driver to amend Seveso.
Therefore, the 2nd ATP, if implemented as drafted, has the potential effect of many more sites falling within the scope of COMAH when, in reality, they would pose no major hazard threat.

We are currently working on a legal solution to this which will allow the implementation of the 2nd ATP, as written, but ensuring that the scope of COMAH is not extended unnecessarily. Once we have agreed within HSE, we will want to target a few industry contacts and ask for comment on our proposed solution. If comments are positive, we will then incorporate the solution into the formal HSC Consultation Document and then undertake the usual consultation exercise for proposed CHIP amendments.

We plan to introduce the 2nd ATP through the proposed Chemicals (Information Packaging for Supply) (Amendment) Regulations 2007 (subject to confirmation from HSE's legal advisers), or CHIP 3.2 on 1 October 2007; the next available common commencement date for implementation.

6. 30th and 31st Adaptations to Technical Progress to the Dangerous Substances Directive (67/548/EEC)

The latest information we have indicates a planned voting meeting for the 30th ATP on 16 February 2007. It is hoped that the EC keeps to its intention of holding the 30th and 31st ATPs close together. Recent intelligence suggests that the EC will suggest the same

implementation date for both ATPs. Depending on timing and the length of the implementation period for these ATPs, we envisage CHIP 3.3 coming into force on 6 April 2008, in line with the common commencement dates. CHIP 3.3 may also need to make other changes to CHIP to reflect the coming into force of REACH as a directly acting EC Regulation. For example, Regulation 5 of CHIP (safety data sheet provisions) can be revoked when Article 29 of REACH has direct effect.

7. 3rd IOELV Directive

The European Commission (DG Employment and Social Affairs) has begun moves to develop a 3rd IOELV Directive. This will resemble the 1st and 2nd IOELV Directives (2000/39/EC and 2006/15/EC), and will contain a further list of substances with indicative occupational exposure limit values.

Initial negotiations on the content of this potential Directive are being conducted in the forum of the tripartite Working Party on Chemicals in the Workplace, where an HSE official sits as a Government representative. As of October 2006, 13 substances are being considered for inclusion in a Directive. This list will grow as the European Commission considers further recommendations from its Scientific Committee for Occupational Exposure Limits (SCOEL). There are potentially another 14 substances in the pipeline.

HSE has already started to engage industry and other stakeholders in this potential Directive, through the medium of the Working Group on European Exposure Limits (WEELS). Once negotiations start in earnest, HSE will need to be informed about issues of reasonable practicability and measurability, to ensure that any eventual Directive can be implemented without difficulty.

8. Carcinogens Directive

The Carcinogens and Mutagens Directive (2004/37) consolidates the earlier Carcinogens Directive (90/394/EEC) and its subsequent amendments. The European Commission has put forward initial proposals to amend this Directive.

The Commission's proposals are threefold:

- To extend the scope of the Directive to cover substances classified as Category 1 and Category 2 Toxic to Reproduction;
- To review the exposure limit values of the three substances in Annex 3 (benzene, hardwood dust and vinyl chloride monomer);
- To extend Annex 3 to include exposure limit values for additional carcinogens and mutagens (and potentially substances toxic to reproduction).

An additional proposal to include environmental tobacco smoke within the Directive has been quietly dropped.

As with all health and safety directives, the proposals have to undergo an initial procedure of two-phase Social Partner consultation, to ensure that employers and workers are in general agreement. The first phase of this consultation occurred in 2005 but HSE has yet to see a report of the results. The second phase is due to start shortly.

HSE had sight of the 1st phase consultation via the Cabinet Office (as a public sector employer), and commented accordingly. HSE also conducted a small-scale initial Regulatory Impact Assessment, contacting trade associations of firms using Cat 1 and Cat 2 reprotoxins. We received indications of those areas where the extension of the Directive would cause excessive additional costs to employers because of the more stringent workplace control regime required by the Carcinogens and Mutagens Directive. It was primarily industries using lead and its compounds who identified major problems.

In anticipation of the need to set exposure limits for carcinogens etc, the European Commission has recently organised a 1-day Workshop attended by a range of interested parties including HSE and members of SCOEL, at which presentations were made on various systems for setting such limits.

9. Existing Substances Regulation

HSE is half of the Joint Competent Authority (together with Defra) for the Existing Substances Regulation (ESR) (793/93), and acts as rapporteur for a number of substances on the ESR Priority List. This entails the development of a Risk Assessment for the substance in question, and, in certain cases, a Risk Reduction Strategy. The latter results in proposals to the European Commission for limiting the environmental, workplace health and consumer risks arising from the use of the substance. ESR will be taken into new procedures 12 months after the coming-into-force of REACH (April 2008).

There are a number of Risk Reduction Strategies still in the pipeline, for which the UK is rapporteur. The European Commission is anxious that as many of these as possible have completed and agreed Strategies before April 2008.

Current work on Risk Reduction Strategies focusses on two dossiers – trichloroethylene and hexavalent chromium oxides. In both cases HSE plans to submit draft Risk Reduction Strategies to a meeting of European Union Member States in December.

For trichloroethylene we are proposing the establishmemt of a voluntary agreement whereby the supply of the substance for metal-cleaning purposes would be restricted to those users who could demonstrate that they possess a closed system compliant with a European Standard.

The basis of the Risk Reduction Strategy for the chromium oxides (chromium trioxide, sodium chromate, sodium dichromate, ammonium dichromate and potassium dichromate) is a proposal for the development of an EU-wide occupational exposure limit and biological limit value, an emphasis on compliance with existing legslation, the promulgation of industry good practice guidance and the substitution in decorative plating of the hexavalent oxides with trivalent substitutes, where this is possible.

10. Prior Informed Consent: A new Regulation concerning the export and import of certain dangerous chemicals

HSE is the Designated National Authority for the European Regulation (304/2003) that implements UK obligations under the Rotterdam Convention (PIC). In November, the European Commission expects to produce a proposal revising Regulation 304/2003/EC concerning the export and import of certain dangerous chemicals. HSE will lead negotiations for the UK.

The 2003 Regulation had a three-year review clause, which allows Member States to make changes in light of practical experience. This coincides with the European Court of Justice's decision in January that the Regulation's Treaty base should be broadened. There are no legal implications because the existing Regulation remains in force.

In 304/2003/EC, the European Union went beyond the requirements of the Rotterdam Convention, resulting in additional burdens to industry. Early drafts of the proposed amended Regulation indicate that the European Commission intends to align the new Regulation more closely with the Rotterdam Convention, altering a process that has caused industry undue expense and frustration.

Although the new Regulation will act directly on Member States, we will still have to prepare new Enforcement Regulations that will allow HSE and HM Revenue and Customs to continue to enforce this Regulation and will re-appoint HSE as the Designated National Authority (the Competent Authority).

11. The Globally Harmonised System for Classification and Labelling of Chemicals (GHS)

At the May meeting, we confirmed HSE as Government lead on GHS and explained the European Commission's (EC) plans for a summer consultation on its intended Regulation implementing GHS in the EU. Planned timings slipped but the EC launched its Internet based consultation on a draft proposed Regulation on 21st August, inviting replies from industry, individuals, organisations and Governments alike. The consultation will ran for only 8 weeks.

HSE has initiated a wide-ranging consultation via the Internet, involving other Government departments, the devolved administrations, industry, trades unions, trade organisations,

non-departmental government bodies, small business associations and others. Altogether, HSE approached over 1500 stakeholders. We encouraged consultees to reply to the EC's consultation, and asked that they share those responses with us to better advise and inform our negotiating position. HSE also hosted a workshop for interested stakeholders on 25 September. The event was participative and allowed stakeholders (and Government) to share perspectives on the proposed Regulation, discuss issues, identify changes and develop alternatives where the text presented difficulty. The event was welcomed and well received.

HSE officials continue to work closely with colleagues across Whitehall on the detail of the proposed Regulation and its supporting documentation. We chair a specialised group of those that have a key interest in the proposed Regulation. DTI, DEFRA, the Environment Agency, the Scottish Environment Protection Agency, HM Treasury, Better Regulation Executive, Small Business Service, Department of Health, the Local Authorities Co-ordinators of Regulatory Services, and Northern Ireland, are among those represented.

The short consultation period also indicated the EC's wish to progress quickly with the Regulation in order to secure a text to allow an entry into force date of 2008 and to align the new Regulations with the proposed REACH Regulation. The year 2008 is an ambitious target. Early indications are that the EC is seeking a First Reading deal on GHS between the European Parliament and the Council. The Germany Presidency (Jan – June 2007) is known to be supportive of GHS and keen to progress formal negotiations and a First Reading Deal is possible.

Working with OGDs and others, the HSE developed a full response to the draft Regulation. The full UK response appears at Annex A.

HSE, Departmental officials, Ministers and the Devolved Administrations have agreed that the UK negotiating strategy should be supportive of the introduction of GHS in the EU, provided certain policy principles are in place. Details of these policy principles can be found at Annex B.

Efforts are now turning to the development of an initial Regulatory Impact Assessment.

The EC is expected to submit its formal proposed Regulation for inter-service consultation on 6 November. Consultation is expected to run until 24 November. The EC will then review comments from the other DGs. The EC hopes to achieve formal adoption and publish its formal proposed Regulation in the Official Journal between 8 – 21 December. It is hoped that the EC's awaited regulatory impact assessment will accompany the published Regulation. Formal negotiations are expected to start in January 2007. The Germany Presidency (Jan – June 2007) is known to be supportive of GHS and keen to progress formal negotiations. This being the case, a First Reading Deal is possible.

We will keep Members up to date with developments.

Annex A

UK GOVERNMENT RESPONSE TO THE EC CONSULTATION ON A DRAFT GHS REGULATION

Q1. **Contact details:**

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UNITED KINGDOM
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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 rational 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" (2nd line) with "for"; replace "toxic" (2nd 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 7th 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 30th 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

- 2nd 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 s*entence 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 ^{o}C' with '60 ^{o}C', as 93 ^{o}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 '≥' and '≤' 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 '≤ 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

- *2nd 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

- *2nd paragraph lines 2 and 4 (specialized and sensitized)*
- *3rd paragraph lines 7 and 9 (standardized and sensitization)*
- *4th 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 ≥ 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 ≥ 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 ≥ 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 ≤ 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 arsing 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.

- **<u>SEVESO II Directive</u>**

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.

Annex B

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

The UK's negotiating position is supportive of the introduction of GHS in the EU provided that:

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

(b) GHS is adopted in such a way that the new system aligns, as far as possible, with the existing system for both supply and transport;

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

(d) the interface between GHS and REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals – the new chemicals regulatory system successfully brought to common position by the UK during its Presidency last year) is coherent;

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

(f) any consequential changes to the scope of 'downstream' controls on chemicals are proportionate and appropriate.

The above principles seek to ensure the proposed Regulation will strike the right balance between maintaining the benefits of the long-established and well understood EU system and securing the wider global benefits of sustainable development and simplification of world trade.

Very broadly HSE considers that the proposal gets the balance about right. However, HSE's analysis has identified a number of drafting, technical and procedural points within the draft Regulation that the UK's response and subsequent negotiations will seek to clarify or resolve. The UK's principle aim is to agree with Member States and the European Parliament a workable system for the EU under GHS, and a sensible, timely migration from the current system to the new one.