**EXPLANATORY MEMORANDUM TO**

**THE CHEMICALS (HAZARD INFORMATION AND PACKAGING FOR SUPPLY) (AMENDMENT) REGULATIONS 2008**

**2008 No. 2337**

**1.** This explanatory memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions and is laid before Parliament by Command of Her Majesty.

## 2. Description

2.1 The proposed instrument implements in Great Britain European Commission Directive 2006/8/EC. This Directive amends Annexes II, III and V of Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparations ("The Dangerous Preparations Directive"). The revision updates how certain dangerous chemicals are classified, makes amendments to certain chemicals product labels and changes the information provided on the safety datasheet for certain products. Such updates are undertaken routinely in light of developing scientific knowledge. The proposed instrument also makes certain minor changes to the way in which the Control of Major Accident Hazards Regulations 1999 (as amended) is enforced, and makes minor drafting amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (the CHIP Regulations 2002)

## 3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 Regulations 3 and 6 of the Regulations correct minor drafting errors that have been identified in the CHIP Regulations 2002. Regulation 3 corrects a cross-reference in regulations 8A(4) and 9(2) of the principal regulations, and regulation 6 revokes amendments to the principal regulations that were made in error as they duplicate amendments already made in an earlier statutory instrument.

## 4. Legislative Background

4.1 These Regulations implement in Great Britain Commission Directive 2006/8/EC (known as the 2nd Adaptation to Technical Progress (2nd ATP), adapting the Dangerous Preparations Directive to technical progress for the second time. The Dangerous Preparations Directive, together with the Dangerous Substances Directive (65/548/EEC) and the Safety Data Sheet Directive (91/155/EEC amended by Directive 93/112/EEC), establishes a single market in the supply of chemicals in the European Community, and provides the starting point for risk-based controls on storage and use. All these Directives are implemented in Great Britain by the Chemicals (Hazard Information and Packaging for Supply) Regulations, known as CHIP. The current CHIP Regulations came into force on 24 July 2002.

4.2 The Dangerous Substances Directive and Dangerous Preparations Directives are updated routinely to reflect the latest scientific evidence and understanding of the

properties of dangerous chemical substances and preparations. The 2nd ATP is the most recent update of the Dangerous Preparations Directive.

4.3 The proposed instrument comes into force on 1 October 2008. The Transposition Note is attached (**Annex A**). The 2nd ATP was not submitted to the EU Scrutiny Committee (Internal Market) as it is a European Commission Directive, agreed through the 'comitology' or committee based EU procedures.

## 5. Territorial Extent and Application

5.1 This instrument applies to Great Britain.

## 6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## 7. Policy background

7.1 Directive 2006/8/EC, and consequently, these Regulations, revise and update the rules and procedures for classifying and labelling dangerous chemicals in the Regulations. They are important because:

a) they provide the basis for the information about the hazardous properties that manufacturers, importers and suppliers of chemicals have to provide to users in workplaces or in the home via labels and other means;

b) the presence of certain hazardous properties triggers specific control measures in health, safety and environmental legislation, e.g. storage of chemicals at major installations such as chemical refineries; and

c) they are central to the establishment of a single European market in chemicals, in which the British chemical industry plays a significant role.

7.2 It is in the interests of both business and of health and safety that the Dangerous Preparations Directive and the CHIP regulations contain accurate data. Adaptations to Technical Progress maintain this accuracy, are based on scientific evidence, and are agreed collectively by all Member States.

7.3 As a result of amendments to Annex III of the Dangerous Preparations Directive, which sets out the generic concentrations limits to be used for the evaluation of the hazards for the aquatic environment, it is possible there will be an increase in preparations classified as "Dangerous for the Environment". As a consequence, some premises storing significant qualities of these preparations, such as very large retail and wholesale warehouses, could be brought within scope of the Control of Major Accident Hazards Regulations 1999 (as amended). To ensure that enforcement of the provisions of the Health and Safety at Work etc. Act 1974 (HSWA) remains with the authority most familiar with that sector, Regulation 7 of these amending regulations amends the Control

of Major Accident Hazards Regulations 1999 to provide for the Health and Safety Executive to be the enforcing authority, for the purposes of HSWA, except in certain circumstances.

*Consultation*

7.4 The Health and Safety Executive undertook a consultation exercise between April and July 2008 on draft amending Regulations to implement the 2nd ATP, to correct minor errors in the principal regulations and to adjust the enforcement provisions of the Control of Major Accident Hazards Regulations 1999.

7.5 Invitations to comment were sent to over 6,600 individuals and companies with an interest in chemicals and a summary of the proposals and the Consultative Document were placed on the HSE website. This consultation exercise produced 62 substantive responses. A summary of the responses to the consultation can be found at **Annex B**. Overall there was broad support for the proposed approach to implementing the 2nd ATP. Four respondents mentioned perceived difficulties that may result should newly re-classified chemicals trigger the application of downstream legislation (see paragraph 7.3). This issue is not new; the classification of a chemical preparation could change for a great number of reasons. Adaptations to technical progress are numerous and routine and the chemical industry is used to managing such changes.

*Guidance*

7.7 Supporting guidance is not necessary as these amending regulations simply adjust the technical detail of the principal Regulations. As they do not introduce any new duties the existing guidance on the principal regulations is sufficient.

*Consolidation*

7.8 HSE is not proposing to consolidate this amendment with the principal Regulations at this time.

## 8. Impact

8.1 HSE has developed a proportionate short impact assessment template for assessing the impact of proposals with total costs below £5 million. HSE has assessed the impact of these regulations and a short impact assessment is attached for information at **Annex C** to this memorandum.

## 9. Contact

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**ANNEX A**

# TRANSPOSITION NOTE: THE CHEMICALS (HAZARD INFORMATION AND PACKAGING FOR SUPPLY) (AMENDMENT) REGULATIONS 2008

# DIRECTIVE: EUROPEAN COMMISSION DIRECTIVE 2006/8/EC of 23 January 2006, ADAPTING TO TECHNICAL PROGRESS, ANNEXES II, III, AND V TO DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS RELATING TO THE CLASSIFICATION, PACKAGING AND LABELLING OF DANGEROUS PREPARATIONS

## Introduction

The Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2008 implement Directive 2006/8/EC. This Directive adapts for the 2nd time the Dangerous Preparations Directive (1999/45/EC).

The Dangerous Preparations Directive sets out requirements to classify dangerous preparations and, where they are supplied, to package and label them according to their hazards. Here, 'classification' means the outcome of a systematic process that identifies the hazardous properties of chemicals, eg explosive, flammable, toxic, carcinogenic, corrosive, irritant, harmful to aquatic organisms etc. The classifications are based on scientific evidence and trigger controls on storage (including major hazards sites) and use of these preparations and products containing them.

Directive 2006/8/EC changes three of the annexes in the Dangerous Preparations Directive which are technical in nature and have been agreed by experts from Member States after full consultation, discussion and scientific inquiry. The changes do not affect the main legal duties but do adjust:

- The rules and procedures for classifying and labelling a chemical preparation containing carcinogens, mutagens or substances toxic for reproduction;
- The generic concentration limits to be used for the evaluation of the hazards for the aquatic environment; and
- The classification and labelling requirements for preparations containing ozone depleting substances;

The Directive also clarifies and makes more consistent specified warning phrases on labels for certain preparations.

Adaptations to technical progress (ATP) ensure that the provisions of the Directive are kept up-to-date, in line with developing scientific knowledge and the development and commercialisation by industry of new and innovative preparations. The regulations implement the 2nd ATP to the Dangerous Preparations Directive.

These regulations do what is necessary to implement the Directive, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply.

| Articles: | Objective: | Implementation: | Responsibility: |
|---|---|---|---|
| Article 1 | To implement the latest amendments to Annexes II, III and V to Directive 1999/45/EC, as specified in the Annex to Directive 2006/8/EC | Save where indicated below, by Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2008. They amend the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (S.I. 2002/1689, as amended by S.I. 2004/568, S.I. 2004/3386, S.I. 2005/1732, S.I. 2005/2571 and S.I. 2005/2092 (the "principal Regulations") which give effect to the provisions of the principal Directive.<br><br>Regulations 4 and 5 amend Schedule 3 and 5 to the principal Regulations. | The Secretary of State, by amending Regulations, save where stated below. |
| Article 2.1 | Member States to bring into force the laws, regulations and administrative provisions necessary to comply with the amending Directive by 1 March 2007<br><br>Member States to inform the European Commission thereof<br><br>Measures to contain or be accompanied by a reference to the amending Directive | As above, by Regulations 4 and 5.<br><br>In the Explanatory Note to the Regulations and in this Table | The Health and Safety Executive via UKREP |
| Article 2.2 | Member States to communicate to the European Commission the text of the main provisions of national law which they adopt | | The Health and Safety Executive via UKREP |
| Article 3 | Date of entry into force of the | No action required | |

| | | | |
|---|---|---|---|
| | amending Directive | | |
| Article 4 | The amending Directive is addressed to Member States | Action required as specified in this Table. | |

**ANNEX B**

**SUMMARY OF RESPONSES TO CD217**

**PROPOSALS FOR NEW AMENDING REGULATIONS ABOUT THE CLASSIFICATION, PACKAGING AND LABELLING OF CHEMICALS: CHIP 3.2**

## PROMOTION OF THE CONSULTATIVE DOCUMENT (CD)

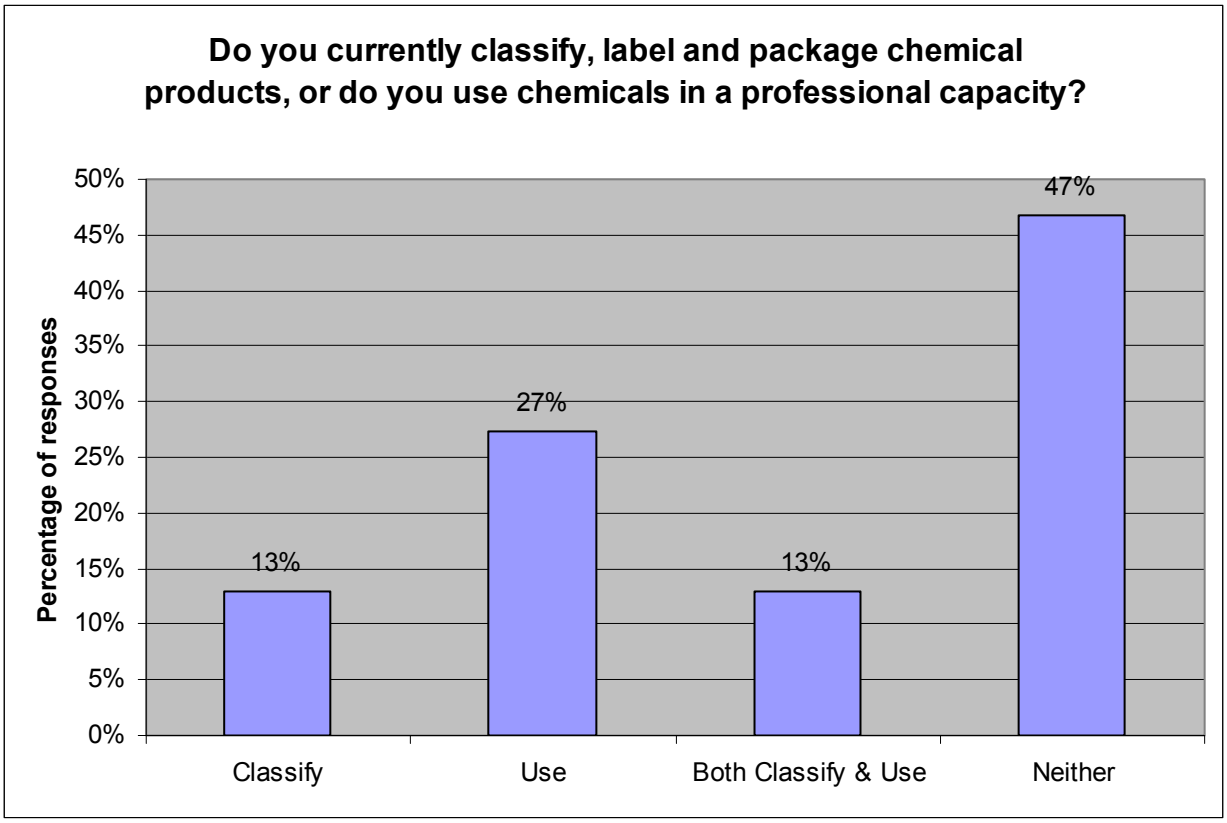
Over six thousand individuals and organisations with an interest in chemicals were invited to participate in this consultation through HSE's 'Web Community'. An additional six hundred individuals and organisation were invited to participate separately. The CD was also advertised prominently on the HSE website homepage.

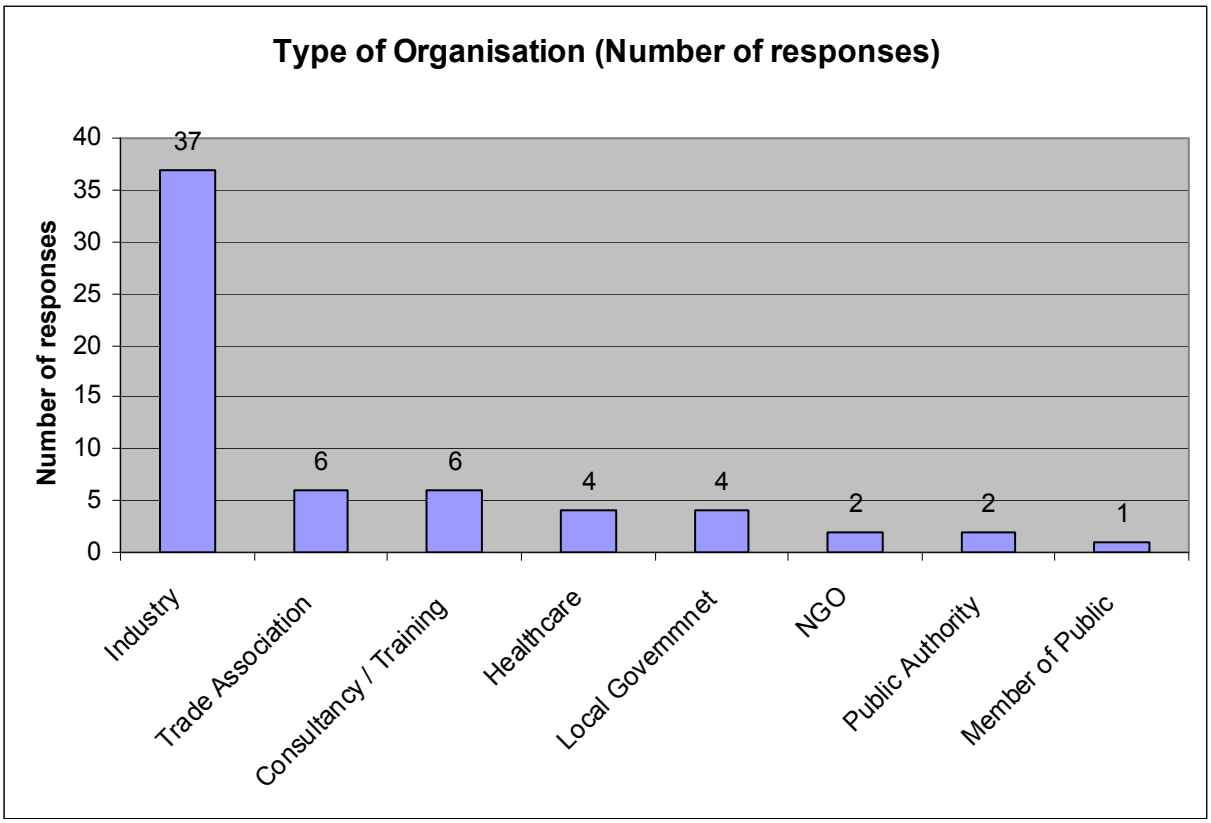
## PARTICIPATION

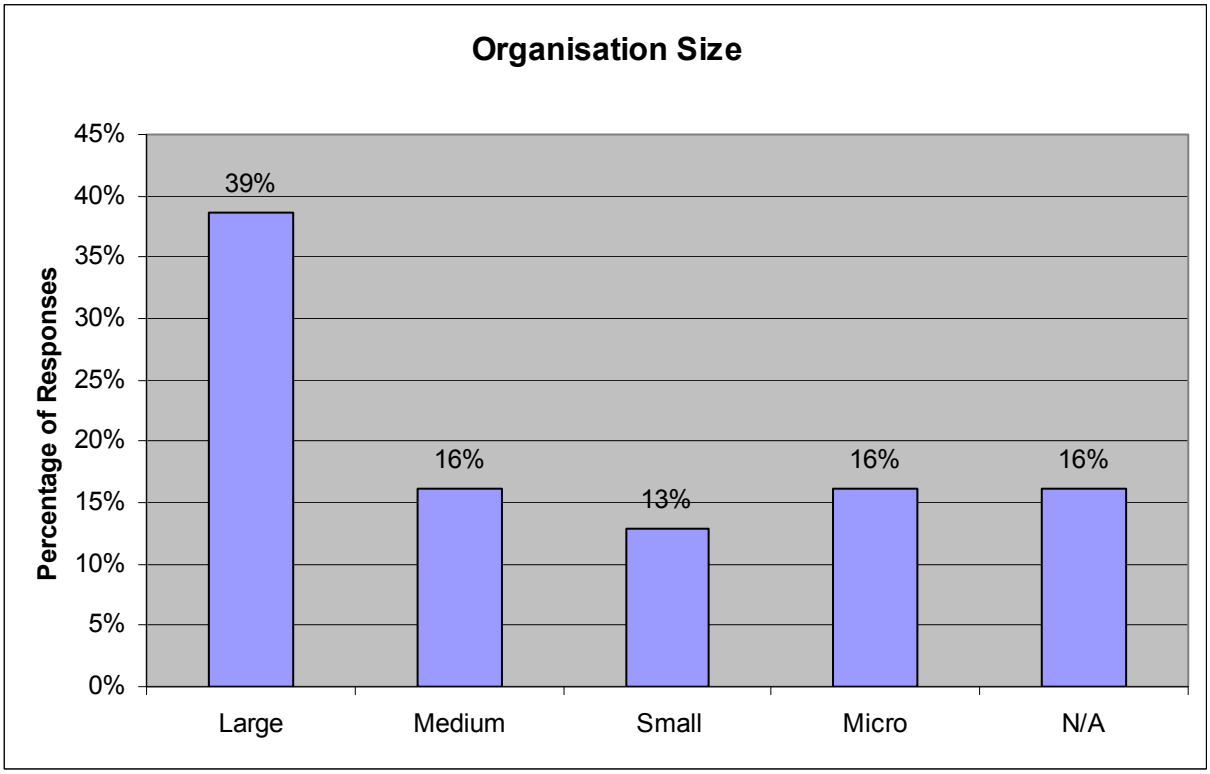
During the twelve week consultation period there were approximately five thousand eight hundred unique visitors to the HSE website where a summary of the proposals, and the downloadable CD were hosted (www.hse.gov.uk/consult/condocs/cd217.htm). Only one person requested a hard copy of the CD, the remainder were viewed online.

Sixty two completed responses containing substantive comments were received, as were three nil responses and one response which did not make substantive comments but was broadly supportive of the proposals. One response arrived a week after the consultation closed, but this was also broadly supportive of the proposals. 31% of respondents asked that their response remain confidential.

The profile of the 62 respondents who made substantive comments is below:

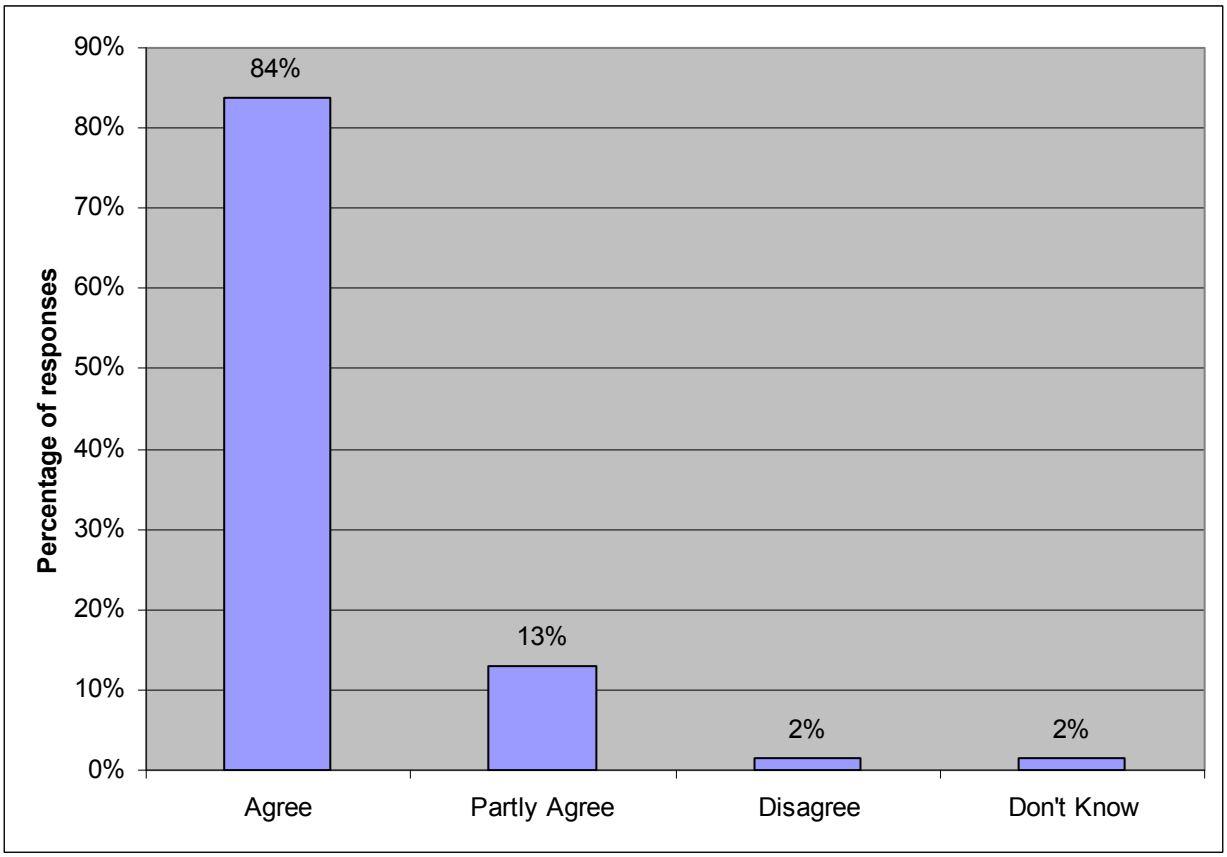



Type of Organisation (Number of responses)
Number of responses
40
35
30
25
20
15
10
5
0
37
6
6
4
4
2
2
1
Industry
Trade Association
Consultancy / Training
Healthcare
Local Governmnet
NGO
Public Authority
Member of Public


Organisation Size
Percentage of Responses
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
39%
16%
13%
16%
16%
Large
Medium
Small
Micro
N/A

**RESPONSES TO QUESTIONS RAISED IN CD 217**

**Q2 Directive 2006/8/EC (the 2nd ATP) needs to be implemented into legislation in Great Britain. This consultative document sets out a proposal to implement the 2nd ATP through amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002, (commonly known as the CHIP regulations). Do you agree with this approach?**




A large majority of comments received agreed with the proposed approach to implementation outlined in the CD, saying the approach was a 'sensible', 'simple', 'logical', 'obvious' and 'established method'. Consistency and harmonisation with the rest of Europe were mentioned often. Familiarity with the CHIP regulations, and the continuity of using them to implement the 2nd ATP were highlighted as being beneficial. Many respondents considered the CHIP regulations to be well known and understood by suppliers and users of dangerous chemicals. It was thought that bringing in separate provisions would be liable to confuse dutyholders.

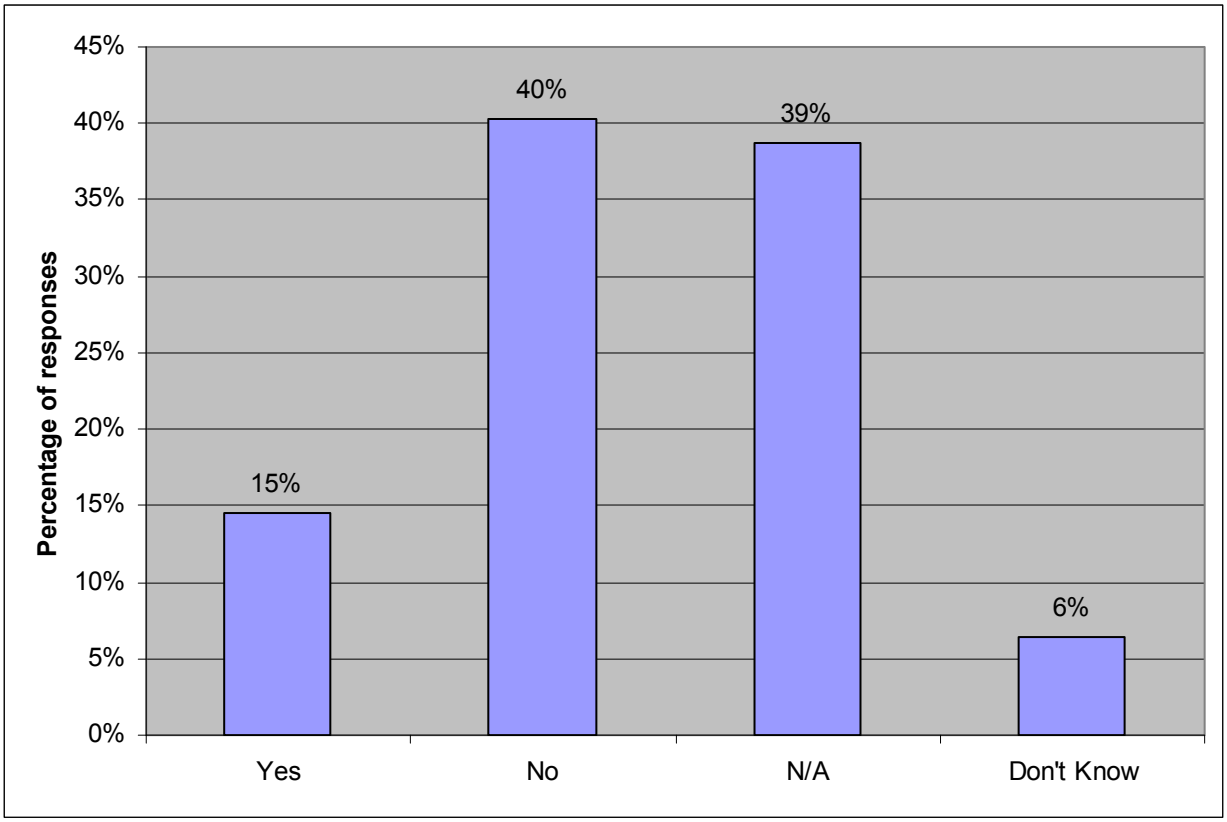
All trade associations agreed with the proposed approach. The Chemical Business Association stated that HSE had taken a pragmatic approach to implementation of EU Directives and noted that the HSE had investigated the potential impacts of the 2nd ATP thoroughly. The British Coatings Federation commented that harmonisation was needed across Europe whether or not they fully supported the changes. The Chemical Industries Association noted the commitment of the COMAH Competent Authority to taking a proportionate approach to enforcement for sites brought into the scope of the COMAH regulation by the changes imposed by the 2nd ATP.

Of the 13% who only agreed in part, one respondent's preference was for a consolidated set of CHIP regulations with all guidance updated and made freely available online. One respondent would prefer the regulations to be amended to provide more information on the health and environmental effects of the chemicals. Another questioned the impact of the Consultation,

having noted that HSE had stated in the CD that "*in practice there was little flexibility in how this can be done.*"

One respondent disagreed with the approach to implementing the 2nd ATP, considering the current legislation adequate.

**Q3 If you are a supplier or recipient of chemicals, do the proposed changes to the CHIP regulations cause you any specific problems – We are particularly keen to know of any issues related to changes to the generic concentration limits for preparations that are toxic to the aquatic environment (N, R50 or R50-53)?**




For the majority of respondents (79%) the proposed amendments were not considered to be problematic.

For the nine respondents who stated there could be problems, three (two trade associations and one chemical manufacturer) cited issues with the interface of CHIP with the COMAH regulation (as discussed at paragraphs 30 – 40 in the CD). These respondents stated that some water-borne decorative paints containing small quantities of biocides for in-can preservation, and some printing inks containing small quantities of photo-initiators, may have to be labelled as environmentally hazardous. It was thought that changes in classification for these products would result in the need to change packaging and labelling for affected products and may lead to increases in the cost of disposal of any waste of these products.

These three respondents agreed that, upon receipt of a new classification, manufacturers could reassess their inventory, or reformulate products, and then manage their storage volumes to remain below the requisite COMAH thresholds. Whilst this would result in administrative costs to business this was seen as an acceptable consequence of avoiding the direct and indirect costs of implementing the COMAH requirements at their premises. However, it was pointed out that some companies would be unable to reformulate products and therefore they may come within scope, or move tiers within, the COMAH regulations. One manufacturer stated that the way that

COMAH aggregates quantities of all qualifying chemicals against the tier thresholds would mean that any classification change for any product would impact on quantities of stored goods they could hold. Any classification change for any product stored in any quantity (even small amounts) could be problematic.

None of the respondents gave hard data (such as chemical names, specific products, quantities of product affected, and current proximity to COMAH thresholds) to improve or develop the appraisal of costs in the Impact Assessment (see question 5).

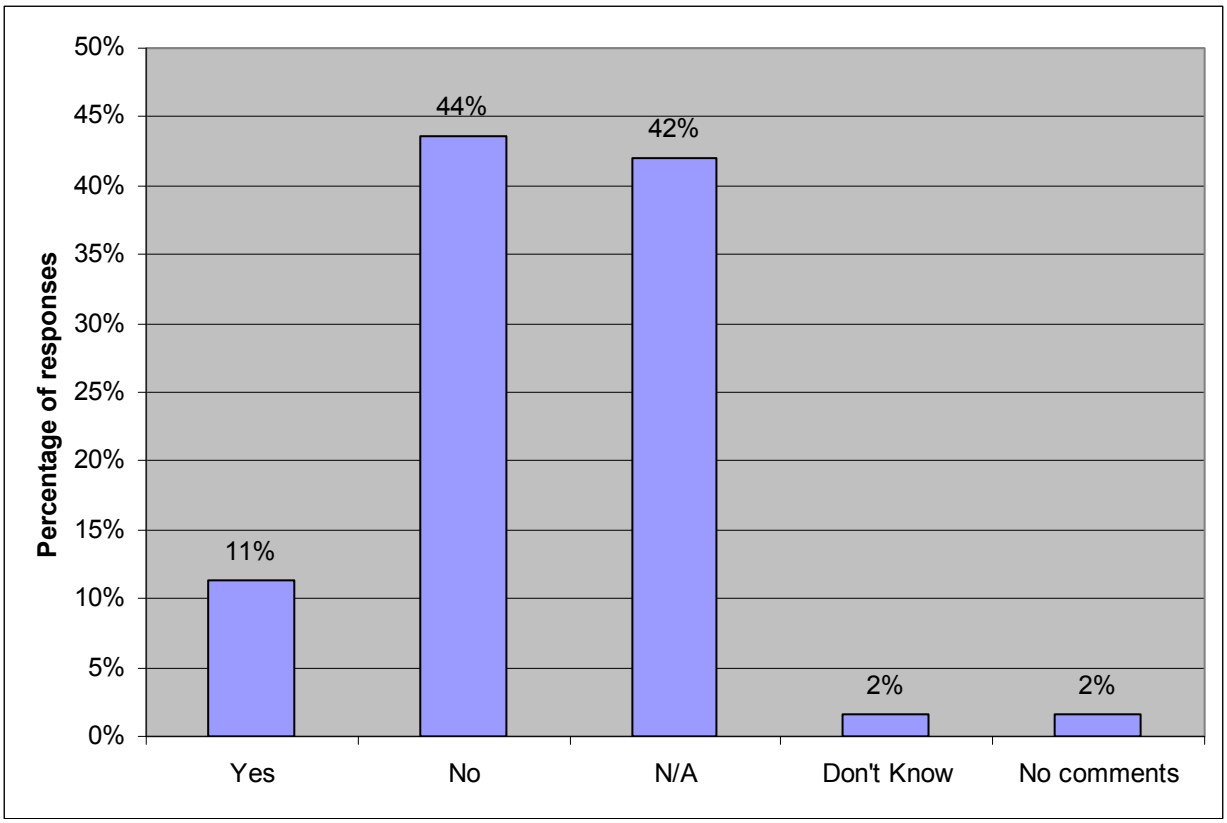
One trade association thought that the new regulations should include transitional provisions to give businesses time to comply with the new requirements. Another respondent was concerned about the time it would take for the new measures to be communicated throughout the supply chain. These respondents were keen that HSE apply pragmatic 'light touch' enforcement, to aid industry with compliance. In contract, one respondent was concerned that manufacturers would not comply with the new regulations swiftly and therefore they were concerned that products would be supplied to them incorrectly classified, labelled, packaged and with incorrect safety data sheets.

Three respondents mentioned difficulties with having to use LC50 and EC50 values to derive the classification of a preparation. One stated that the values were difficult to obtain from raw material suppliers, another stated that existing safety datasheets rarely provided this information. One respondent, whilst recognising the 'science-based' way of measuring the hazard, was concerned that a lack of ecotoxicity data would result in 'best-guess' estimates which could be mistaken by others as having been based on scientific tests. They suggested an including an obligation in the legislation to state if hazard data used to derive a classification had been estimated.

One respondent was concerned that HSE was not taking the opportunity to update the standards for child resistant closures and tactile warnings of danger (for the reasons discussed in paragraphs 48-50 in the CD). Leaving these unchanged sent the wrong message to industry, they said.

One respondent that did not consider the proposals problematic for their organisation still offered a possible difficulty for others – specifically, a possible increase in Hazardous Substances Consent approvals for chemicals Dangerous for the Environment affected by the proposal. They stated that it could take circa 12 months to gain Hazardous Substances Consent approval and, should a site come within scope of COMAH as a result of a product's reclassification, this may also have implications for Land Use Planning.

**Q4 If you are a person who works with chemicals (as an employee or self employed person) does the proposal present any specific problems for you?**




For the majority of respondents (86%) the proposed amendments were not considered to be problematic.

For the seven respondents who stated there were problems, one respondent from industry and the Chemical Business Association repeated their answers to Question 3, explaining that it may be more difficult for them/companies to operate their worksite below COMAH thresholds. Two respondents stated that they would find updating their product labels, safety data sheets, and revisiting their COSHH assessments problematic (although one acknowledged that many of their products had a short market life and much of this could work be done at the time of product replacement).

One micro-business commented that there was constant misunderstanding in the industry and a lack of training from HSE.

Of those who didn't consider the proposal problematic one respondent stated they would have to review information the held on various chemicals but that this would not be problematic as it didn't require a change in their current procedures.

**Q5 What evidence or data can you provide to improve or develop the appraisal of costs in our Impact Assessment?**

No respondent offered evidence or data to improve the appraisal of costs of the proposal. Several respondents anticipated costs in having to amend safety data sheets though respondents also commented that they expected the cost in terms of time and resource to be low. One respondent explained that there should be little incremental impact from having to revise safety data sheets as they should be reviewed, and if necessary updated, frequently anyway.
One respondent suggested that there could be costs associated with having to apply for Hazardous Substance Consent and the possibility of the application being rejected. They also

thought there may be knock-on effects from the possible increase in a site's Consultation Distance and Public Information Zone and from Land Use Planning/COMAH.

**Q6 Please describe, and if possible, quantify, any benefits of the proposal?**

A third of respondents provided a response to this question. Suggested benefits included:

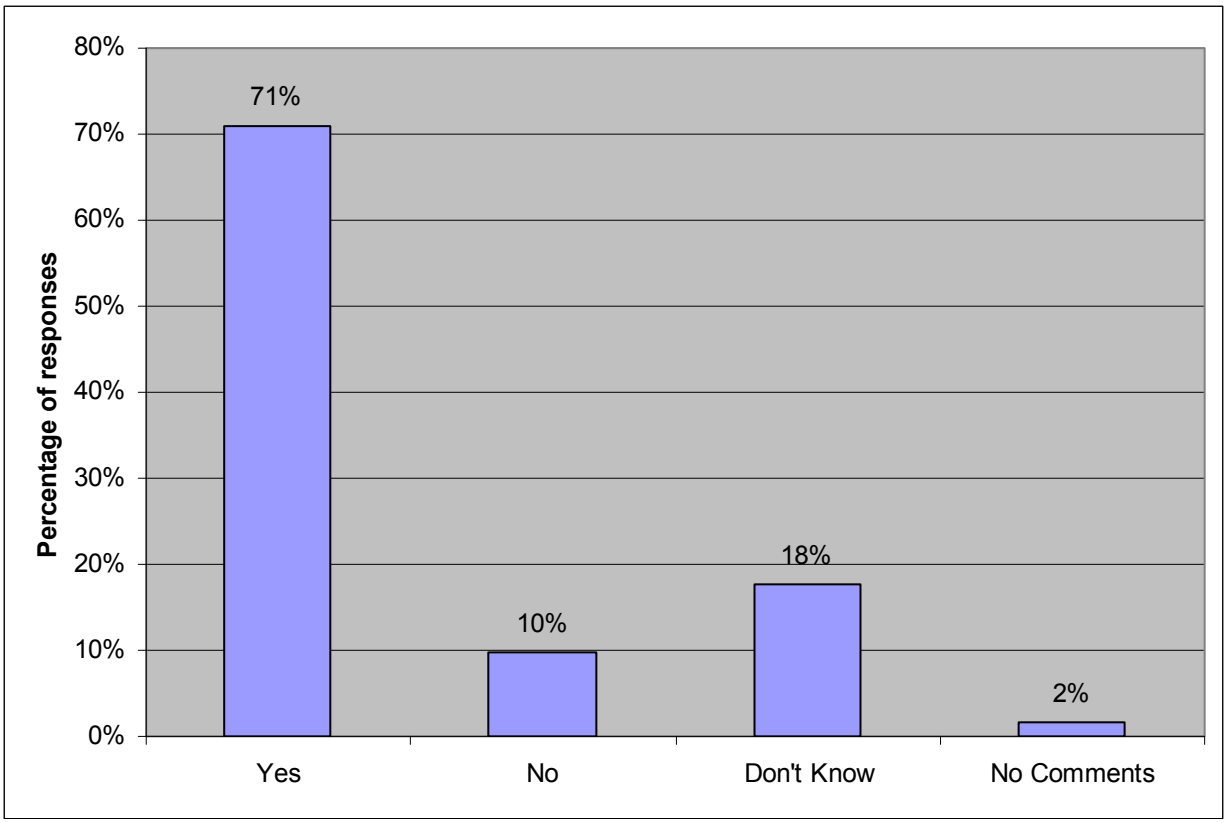
- harmonisation with the rest of Europe
- Improved consistency and a removal of anomalies in the way that chemicals are classified as toxic to the aquatic environment
    - an indirect benefit of this may be a reduction in the quantity of hazardous chemicals released into the environment as suppliers re-formulate or substitute for less harmful alternatives to avoid re-classification; or consumers choose not buy such products.
- More accurate reflection of the hazards in re-classified products thereby enabling users and emergency responders to better assess the risks of handling, use and disposal.
- The labelling of preparations containing carcinogens, mutagens and reprotoxins with the R-phrase for the highest category rather than multiple R-phrases would prevent confusion and may lead to better handling and use.

HSE's exploration of future options for the Approved Supply List were welcomed and seen as beneficial. IT was thought that the use of an electronic database could save businesses money as they would no longer need to by the Approved Supply List; a database would be easier to search; would reduce paperwork; and could reduce the burden on HSE to produce an updated document every few years.

One respondent welcomed the possibility of establishments that handle paints and solvents (such as DIY warehouses) being brought within scope of the COMAH regime and made reference to several major incidents (such as large fires) at these types of establishments.

No respondent was able to quantify the benefits.

**Q7 Do you think this Consultative Document and the Impact Assessment present sufficient information for you to be able to understand and comment on the proposals?**




Forty four respondents (71%) thought that the Consultative Document and Impact Assessment provided sufficient information for respondents to understand and comment on the proposals. Of those who answered yes, supplementary comments explained that the Consultative Document had been written in clear English, was comprehensive, and contained useful, relevant information that was easy to understand (although one respondent thought that it might be less well understood by those who did not work with chemicals).

Respondents stated that that document clearly described the objectives and contained reasonable explanations, suitable summaries and sufficient detail to aid understanding. One respondent commented that whilst technical in content, the CD did its best to explain the changes in a clear and logical fashion.

One respondent commented that, whilst the CD remained concise, it including all relevant data and documents. Little reference to other documents or websites was necessary.

Two respondents considered that it was clear that negotiations had been thorough and that introduction of the 2nd ATP appeared to have been given a great deal of consideration. The Chemical Industry Association welcomed the balanced approach of the HSE in ensuring that the regulation will have a manageable impact on industry.

Six respondents did not consider that the CD and Impact Assessment presented sufficient information for them to comment on the proposals. One respondent thought that the CD had not been written in clear English and had been difficult to understand. One respondent suggested further information on the health and environmental effects of affected chemicals would be helpful as they did not know how significant the effect of reducing the concentration of a chemical in a preparation could be. One respondent thought that a further breakdown of the costs related to the impact assessment should have been provided.

The Government Chemist thought it would have been useful if the CD had included a summary of how and when scientific stakeholders had been consulted during the EU phase, and a description of the steps taken to ensure the results of the scientific inquiry were evaluated on a sound scientific basis.

Few supplementary comments to this question were received from the eleven respondents who said they didn't know whether there was sufficient information in the CD and impact assessment. This may be because, in answer to earlier questions six had stated they neither classified nor used chemicals in a professional capacity and four had earlier stated that they were only users of chemicals.

**Q8 What are your thoughts / comments on the future of the HSE's Approved Supply List?**

Thirty eight respondents offered their views in response to this question, none of which opposed the introduction of an electronic version of the Approved Supply List (ASL). However, five respondents suggested that a paper version should continue to be published alongside any database or electronic version. Three of those suggested an acceptable compromise would be to have a printable version available as a free download from HSE's website alongside a searchable database.

Comments in favour of replacing the paper version of the ASL stated that:

- The proposal to move to an electronic version was a sensible, practical prudent suggestion.
- Electronic databases were considered acceptable, adequate, and more user friendly than paper lists.
- Searching for information would be quicker and would facilitate better interrogation of data (for example searches could be performed on reference numbers, risk phrases or parts of chemical names etc.
- An electronic database would be easier and cheaper for Government to update.
- It would be easier to correct an electronic version if errors were found.
- Paper versions have a limited shelf life and are often out of date rapidly.
- A reduction in paper use would be good for the environment
- The current paper version of the ASL is expensive when only used for a few entries.
- One respondent was frustrated at having to buy a whole new edition when only a few entries get revised. Often the entries for chemicals used by their company remain unchanged.
- European Chemicals Bureau database (known as ESIS) was considered an example of a suitable replacement.

Those respondents who suggested that a paper version of the ASL should continue to be published alongside any electronic version said that many people would still find having a hard copy useful. The Chemical Business Association pointed out that not every company has internet access or the knowledge to manipulate or navigate a website. They suggested that many SMEs would be reluctant to access an electronic database and download or print a document because of the cost of stationary and consumables.

Several respondents suggested that a downloadable version of the full database should be available so that users could print a copy (or relevant pages) if they wished. One respondent

thought that such a download should include a mechanism to highlight any subsequent changes to that document for ease of reference.

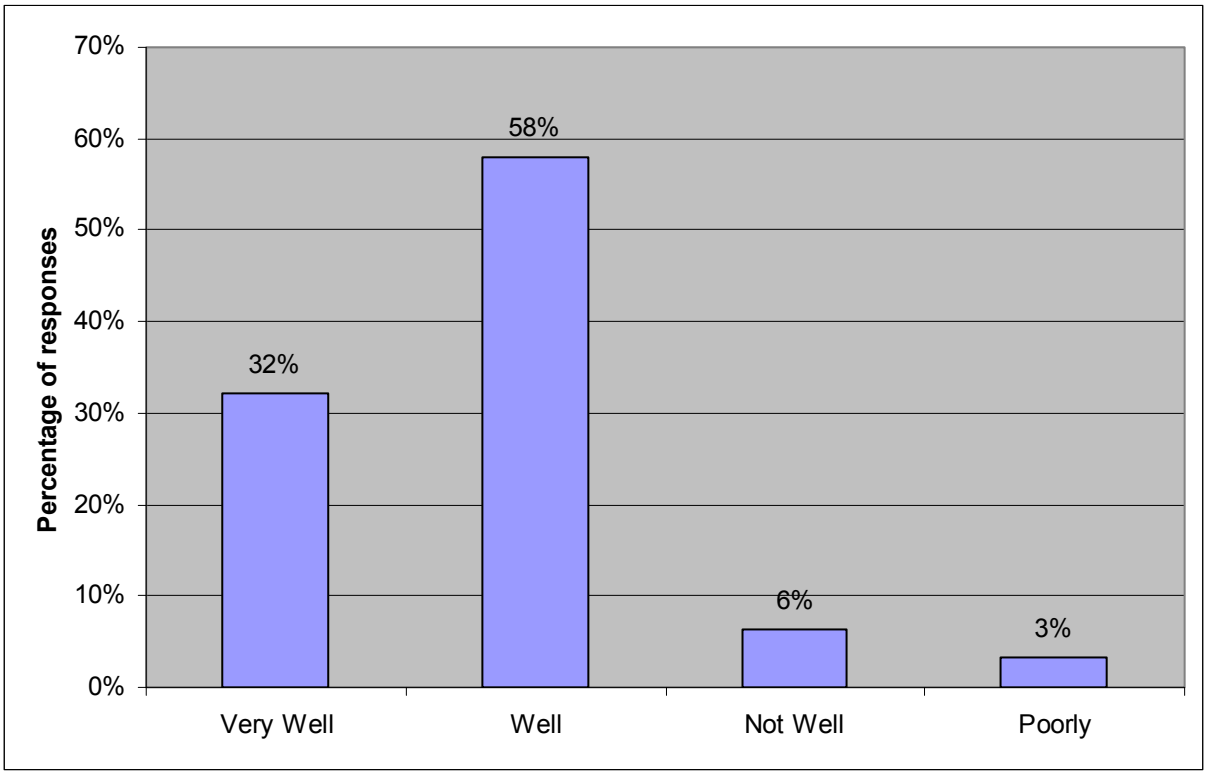
Two respondents said that any online database should be easy to locate on the internet and easy to operate. These respondents thought that the ESIS database was difficult to navigate. Two other respondents thought that the ESIS database lacked explanations of technical terminology, abbreviations, and notes that accompany certain chemicals.

**Q9 Are you aware of any further typographical errors in the current version of HSE's Approved Supply List (Eighth Edition) or entries that do not match the entries in Annex 1 of Directive 67/548/EC, as amended by subsequent ATPs?**

One respondent suggested that an entry for Dimethylaminoethyl acrylate (CAS number 2439-35-2) was missing from the Approved Supply List. However, HSE has checked and the omission is not a mistake. The reason why Dimethylaminoethyl acrylate is not in the ASL is because the substance does not have a harmonised classification and consequently is not listed in Annex 1 of Directive 67/548/EC.

The Government Chemist expressed concern that many of the entries in Annex 1 to Directive 67/548/EEC, which the ASL implements in the UK, are inaccurate or difficult to find or interpret. They considers that these problems reflect the way that Annex 1 has been developed over many years rather than being issues unique to Great Britain's ASL. They thought it would be helpful if Europe worked towards a harmonised naming convention for chemicals, and, in future amendments to Annex 1, improvements should be made to the accessibility, ease of reference, descriptions of isomers, listing of petroleum substances and consistent use of an ISO suffix for pesticides.

**Q10 In your view how well does this consultative document explain the issue and proposed changes to the CHIP Regulations?**



Ninety percent of respondents thought that the CD explained the issues and proposed changes to the CHIP regulations well or very well. Supplementary comments stated that the CD was concise, giving all the necessary information over just a few pages. It was thought that the CD did not contain unnecessary technical information, was well structured and laid out logically and allowed cross-referencing to be made between all relevant documents. One respondent described the CD as "a paradigm for others", another said that they were grateful for the care with which complicated amendments were explained. One respondent said that it was apparent that the introduction of the 2nd ATP had been given a great deal of consideration.

Nine percent of respondents (six respondents) thought that the CD did not explain the issues and proposed changes to the CHIP regulations well, or did so poorly. One supplementary comment was provided by a respondent in explanation of their answer. They thought that the CD did not contain enough detail and that some issues, such as the effect reclassifying a product as toxic for the aquatic environment may have on a business. For example, they thought that Hazardous Substance Consent applications and Land Use Planning had been overlooked.

**Q11 Is there anything you particularly liked or disliked about this consultation?**

Sixteen comments were received in answer to this question.

The layout of the CD and the format of the response form were liked, with respondents saying that both were easy to use and follow. One respondent thought that being able to comment online using a web-enabled form made doing so much easier. Several respondents liked that all the necessary supporting reference documents had been included as appendices to the CD, but one said they would have preferred separate documents to make it easier to compare. One respondent liked the "clarity and ease of the information style", another appreciated that the CD was not too large.

Four respondents thought that the CD was too long, although two of those said that they could not see a way to shorten it because of the technical content and the necessity to explain the proposals adequately. Two respondents thought that the CD was not written clearly enough; one thought it repetitive; one thought that the CD did not provide enough guidance on the information HSE was seeking; and one respondent thought that the questions asked were closed and tailored so that HSE would receive the responses it wanted to hear. One respondent thought that implementation of REACH and GHS should have been explained more extensively.

**Q12 Do you have any other comments on the proposal not covered by this form?**

Two respondents mentioned that reclassification of certain preparations may result in businesses requiring Hazardous Substances Consent, with one respondent concerned that planning authorities would not be as pragmatic as the COMAH competent authority.

One respondent thought that it would be difficult to communicate the amendments to small and medium sized enterprises; another respondent asked that the chemical hazard control regime be kept simple otherwise it would be ignored.

**Paul Howarth**
International Chemicals Unit
Health and Safety Executive
AUGUST 2008

## SHORT IMPACT ASSESSMENT

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| **Description of the intervention:** | The Second Adaptation to Technical Progress of the Dangerous Preparations Directive (DPD) has been formally adopted as Commission Directive 2006/8/EC (commonly known as the 2nd ATP). This has to be implemented into National Legislation to fulfil our Treaty obligations as an EU Member State. The 2nd ATP makes changes to three of the annexes in the DPD which are technical in nature and have been agreed by experts from Member States after full consultation, discussion and scientific inquiry where necessary. The changes do not affect the main legal duties set out in the DPD or in the UK's Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (commonly known as CHIP), amendments to which will implement the 2nd ATP.<br><br>The 2nd ATP changes the rules and procedures for classifying and labelling a chemical preparation containing carcinogens, mutagens or substances toxic for reproduction; changes the generic concentration limits to be used for the evaluation for the hazards for the aquatic environment; adjusts the classification and labelling requirements for preparations containing ozone depleting substances; and clarifies and makes more consistent the specified warning phrases on labels for certain preparations.<br><br>There are also several minor editorial changes to CHIP to clarify existing requirements and correct errors which do not alter the existing requirements. | | |
| **Objectives:** | The objective of the regulatory amendments to CHIP is to implement the 2nd ATP into National Legislation to fulfil our Treaty obligations as an EU Member State. The 2nd ATP contributes to ensuring that the system for classifying and labelling chemical preparations is updated to reflect the latest scientific knowledge. | | |
| **Calculation of costs:** | **Familiarisation cost**<br>**Updating labels for CMRs**<br>These costs are calculated based on an estimated **65** preparations having to be re-labelled at a cost of either £**155.70** or £**519** per label @ 2007/08 prices.<br>*(Costs have been uprated from 2006 estimates of £150 or £500 per label)* | | **£min**<br>Lower Estimate **£10,121**<br>Upper Estimate **£33,735** |

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| | **Amending SDS for CMRs**<br><br>These costs are calculated based on an estimated **65** preparation's SDSs having to be amended at a cost of either £**156.24** or £**357.12** each @ 2007/08 prices.<br><br>*(Costs have been uprated from 2004 estimates of £140 or £320 per SDS)* | | Lower Estimate<br>Upper Estimate | **£10,156**<br>**£23,213** |
| | **Updating labels for aquatic toxicity**<br><br>These costs are calculated based on an estimated **2,500** preparations being re-labelled at a cost of £**155.70** or £**519** per label @ 2007/08 prices. | | Lower Estimate<br>Upper Estimate | **£389,250**<br>**£1,297,500** |
| | **Updating SDS for aquatic toxicity**<br><br>These costs are calculated based on an estimated **2,500** preparations having to have their SDS amended at a cost of £**156.24** or £**357.12** each @ 2007/08 prices. | | Lower Estimate<br>Upper Estimate | **£390,600**<br>**£892,800** |
| *Indirect cost* | **Estimated four businesses becoming COMAH lower tier**<br><br>Based on estimated compliance cost per site of £**182,752.50** each @ 2007/08 prices.<br><br>*(Costs have been uprated from 2006 estimates of £177,000 per site using the GDP Deflator).* | | | **£731,010** |

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| *Indirect cost* | **Estimated two businesses moving from COMAH lower tier to upper tier**<br><br>Based on estimated cost of £**436,747.50** per site [i.e. the difference between estimated compliance cost of being lower tier (£182,752.50) & upper tier (£619,500)] @ 2007/08 prices.<br><br>*(Costs have been uprated from 2006 estimates of £177,000 per lower tier site and £600,000 per upper tier site using the GDP Deflator)* | | | **£873,495** |
| | **Updating labels for ozone depletors**<br><br>These costs are calculated based on an estimated **80** preparations having to be re-labelled at a cost of either £**155.70** or £**519** per label @ 2007/08 prices. | | Lower Estimate<br>Upper Estimate | **£12,456**<br>**£41,520** |
| | **Updating SDS for ozone depletors**<br><br>These costs are calculated based on an estimated 80 preparations having to have their SDS amended at a cost of £**156.24** or £**357.12** each @ 2007/08 prices. | | Lower Estimate<br>Upper Estimate | **£12,499**<br>**£28,570** |
| | **Costs to Government** | | Lower Estimate | **£23,874** |

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| | **Regulators & others**<br><br>These costs are based on the estimates for investigating complaint/incident and associated work examining safety report etc at one COHAM site at 2007/08 prices | | Upper Estimate | **£56,052** |
| | **TOTAL COSTS:** | | Lower estimate (if no sites fall within COMAH) | **£848,955** |
| | | | Upper estimate (if four sites fall within COMAH lower tier and two upper tier: | **£3,977,894** |
| **Impact on industry (including any effect on the Admin Burdens Baseline):** | All costs are admin costs. | | | |
| **Benefits (quantified where possible):** | Health – there may be more careful handling of carcinogenic, mutagenic or reprotoxic chemicals owing to clearer labelling. It is estimated that, on average, each reduced case of work related ill health causes overall savings of £7,500 per annum There may be reduced rates of skin cancer through decreased solar radiation due to better identification and disposal of ozone depleting substances. A recent study[1] estimated the average cost of each case of skin cancer at £20,000.<br><br>Environmental – The 'ozone depleting substances' and Aquatic Toxicity' amendment will enable duty holders to make an informed choice between a product containing harmful preparations damaging to the environment and less harmful alternatives. Customers may move towards the use of products less likely to damage the environment or may use and dispose of products more carefully. Some manufacturers may choose to reformulate preparations that cause environmental damage.<br><br>The main benefit to GB is the continued improvement to the Single Market by requiring all suppliers of dangerous | | | |

[1] Morris, S., Cox, B., and Bosanquet, N. (2005) *Cost of Skin Cancer in England Report*, Imperial College London

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| | chemicals to provide the same standard of information to their customers. The improvement will be beneficial to GB industry both domestically and in trade with other EU Member States. |
| **Consultation:** | This approach has been discussed with HSE's Chief Economist and the Better Regulation Team. |
| **Chief Economist's comments:** | |
| **Recommendation:** | That based on proportionality, a full impact assessment is not produced. |

**Signed:** Philip Agulnik **Date:** 21 February 2008
**HSE's Chief Economist**

**Ministerial Sign-off**

***I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.***

Signed by the responsible Minister:

William D.McKenzie, ……Date: 1st September 2008