

Proposals for new amending Regulations about the Classification, Packaging and Labelling of Chemicals: CHIP 3.2

This consultative document is issued by the Health and Safety Executive in compliance with its duty to consult under section 16(2) of the Health and Safety at Work etc Act 1974.

Comments should be sent to:

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to reach there no later than **4 July 2008**

The Executive tries to make its consultation procedure as thorough and open as possible. Responses to this consultative document will be lodged with the Health and Safety Executive's Information Centres after the close of the consultation period where they can be inspected by members of the public or be copied to them on payment of the appropriate fee to cover costs.

Responses to this consultative document are invited on the basis that anyone submitting them agrees to their response being dealt with in this way. Responses, or part of them, will be withheld from the Information Centres only at the express request of the person making them. In such cases, a note will be put in the index to the responses identifying those who have commented and have asked that their views, or part of them, be treated as confidential.

Many business e-mail systems now automatically append a paragraph stating the message is confidential. If you are responding to this CD by e-mail and you are content for your responses to be made publicly available, please make clear in the body of your response that you do not wish any standard confidentiality statement to apply.

Proposals for the Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2008

CONTENTS

CONSULTATIVE DOCUMENT

CONTENTS	i
PREFACE	ii
Acknowledgements:.....	ii
Why are we consulting you?	ii
What we would like you to do:	ii
What happens next?	iii
Making responses public:	iii
Feedback, queries and complaints:.....	iv
EXECUTIVE SUMMARY	1
INTRODUCTION.....	3
BACKGROUND.....	3
CHIP Approved Documents.....	4
The Dangerous Preparations Directive (DPD)	5
CHANGES TO THE DPD AND TO CHIP	5
The 2nd ATP	5
<i>Amendments to Annex II of the DPD.....</i>	5
<i>Amendments to Annex III of the DPD.....</i>	6
<i>Amendment to Annex V of the DPD.....</i>	9
Updates to the British, European and International standard specifications relating to child resistant closures and packaging.	10
Correcting minor errors in previous amendments to CHIP concerning the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004.	10
TRANSITIONAL PERIODS	10
IMPLEMENTATION DATE.....	11
COSTS AND BENEFITS	11
Simple competition assessment.....	12
Consultation with small firms – the small firms impact test	12
Impact Assessment.....	12
FUTURE DEVELOPMENTS - APPROVED SUPPLY LIST (ASL)	13
INVITATION TO COMMENT	13
APPENDIX I – RESPONSE FORM.....	15
APPENDIX II – BACKGROUND TO CLASSIFICATION AND LABELLING DIRECTIVES	20
APPENDIX III – LIST OF ORGANISATIONS & INDIVIDUALS CONSULTED	22
APPENDIX IV – DRAFT STATUTORY INSTRUMENTS	29
APPENDIX V - THE 2ND ATP TEXT	39

PREFACE

The Health and Safety Executive (HSE) would like your comments on proposals to amend the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002.

A response form is included at Appendix I at the back of this booklet to help you do this. Please feel free to circulate this consultative document more widely. You can download this document from the Internet on the HSE home page at:

<http://www.hse.gov.uk/consult/live.htm>

If you are reading this document on a computer screen and would prefer a printed version, it can be obtained on request. Furthermore, if you require a more accessible format, an Executive Summary is available in Braille, large print, disc, audio cassette or in another language. Please contact Paul Howarth at the address given below.

Acknowledgements:

HSE wishes to thank all those who have assisted with the development of these proposals.

Why are we consulting you?

HSE seeks to inform its decision-making by consulting a wide range of interested bodies and individuals. HSE believes that this will enable an open and transparent approach to decision-making, which is essential if policies and decisions are to have widespread ownership and reflect the needs and aspirations of the people they will affect. HSE then decides on the best way forward based on an interpretation and analysis of the results of this exercise.

What we would like you to do:

We would like you to comment on these proposals by 4 July 2008. Please send your comments to:

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If you reply to this consultative document in a personal capacity, rather than as a post holder of an organisation, you should be aware that information you provide may constitute “personal data” in the terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the “data controller” and will process the data for health and safety and environmental purposes. HSE may disclose these data to any person or organisation for purposes for which it was collected, or where the Act allows disclosure.

You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected. Please note that all replies will be made public unless you specifically state that you wish yours to be made confidential.

Responses in electronic form are welcome. Many business e-mail systems automatically append a paragraph stating that the message is confidential. If you are sending your comments by e-mail please state clearly if you are not content for your response to be made public.

We have included a response form at Appendix I summarising the areas we would particularly welcome your views; it will also help us to analyse responses. It is not intended to restrict the scope of the comments: we would welcome any comments you wish to make on the proposal.

What happens next?

We will give full consideration to the substance of arguments in all responses to the consultation.

Respondents should be aware that most of the proposed amendments are the result of the second Adaptation to Technical Progress (ATP) to the European Directive concerning the classification, packaging and labelling of dangerous preparations (Directive 2006/8/EC). It should be noted that this ATP has already been agreed within Europe and the UK is required to implement it into domestic legislation. In practice therefore, there is little flexibility in how this can be done. Respondents may also wish to be aware that negotiations are presently underway in the European Council and the Parliament on a new EC Regulation to adopt in Europe the ‘Globally Harmonised System’ (GHS) for classification and labelling. When agreed, this will replace the existing EU system for classifying and labelling dangerous chemicals, including the Dangerous Preparations Directive. However, replacement will be progressive and in two stages to allow first suppliers of substances to convert to the GHS and then preparations. Under the present proposals this will take seven and a half years, ending 2015, when the Dangerous Preparations Directive will be revoked. In the interim, the UK is obliged to implement the 2nd ATP of the Dangerous Preparations Directive.

Making responses public:

To make our consultation process as transparent as possible we make the comments we receive available to the public at our knowledge centre in Bootle, Merseyside. Copies will

be made available at a small charge to cover costs, from the following address:

Knowledge Centre
Health and Safety Executive
1G Redgrave Court
Merton Road
Bootle
Merseyside L20 7HS

If you do not want your comments made publicly available please make this explicitly clear in your response.

Feedback, queries and complaints:

The Health and Safety Executive would also like to know what you think about the content and presentation of this consultation. Your views may help to improve other consultations. If you are not satisfied with the way in which this consultation exercise has been conducted we want to know, and we want to put things right. Please phone, or write to:

Robin Foster
International Chemicals Unit
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9th Floor South Wing
Rose Court
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London SE1 9HS

Tel: 020 7717 6990

We aim to reply to all complaints within 10 working days. If you are not satisfied with the outcome, you can raise the matter with the Chief Executive at the same address. You can also write to your MP to take up the case with us. Your MP may refer the matter to the Parliamentary Ombudsman who will investigate your complaint.

EXECUTIVE SUMMARY

1. The Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP) need to be amended. This is necessary because Great Britain (GB) must implement into domestic legislation the 2nd Adaptation to Technical Progress (ATP) to the European Community's (EC's) Dangerous Preparations Directive (1999/45/EC). The Health and Safety Executive (HSE) will also use this opportunity to correct a few minor editorial errors and to clarify some requirements. These additional editorial amendments do not alter the existing requirements of CHIP.
2. This Consultative Document explains the proposals and seeks views on the amending regulations proposed by the HSE.
3. The CHIP regulations underpin Great Britain's chemical management framework. CHIP implements the EC's Dangerous Substances Directive, the Dangerous Preparations Directive, and the Directive on Safety Data Sheets. These Directives, through CHIP, place a number of duties on chemical suppliers which include ensuring that dangerous substances and preparations ("chemicals") are:
 - correctly classified (a process which identifies hazards to human safety and health and/or the environment);
 - labelled accordingly; and
 - appropriately packaged.
4. A further duty requires suppliers of dangerous chemicals for use at work to provide a safety data sheet. The changes to CHIP proposed in this consultation document do not affect these duties.
5. Published in the EC's Official Journal in January 2006, the 2nd ATP has been in the public domain for some time. We expect that many suppliers who may be affected by the changes required by the 2nd ATP are already aware of, and are preparing for, the changes to CHIP. These changes will result in some chemical suppliers having to:
 - re-classify certain chemicals;
 - change some product labels; and
 - change the information provided on the safety data sheets of certain products.
6. In addition, some suppliers may need to take account of any large quantities of these newly re-classified chemicals they have stored on site at any one time to ensure that they comply with the Control of Major Accident Hazard Regulations 1999 (as amended).
7. The HSE would also like your views on whether, in future, to continue to update and republish paper copies of the HSE's Approved Supply List (ASL) given that the EC now has easily searchable and up-to-date electronic databases available on the Internet. The ASL lists all the harmonised classifications and labelling requirements agreed at EU level.
8. HSE has a statutory duty to consult to seek stakeholders' views on these proposals. HSE believes that this enables an open and transparent approach to decision-making, which is essential if policies and decisions are to have widespread ownership and reflect the needs and aspirations of the people they will affect. The Board then decides the best way forward, taking into account an assessment of the results of the consultation.

9. The UK had to implement the 2nd ATP into domestic legislation by 1 March 2007. Owing to technical difficulties described later in this document, this was not possible. However, the need to implement is now urgent. The HSE is proposing an implementation date of 1 October 2008 to align with the Government's common commencement date for domestic regulations.

INTRODUCTION

1. On 23 January 2006 a European Commission Directive was published which changes the way that some dangerous preparations are classified, packaged and labelled. The amendment, known as the 2nd Adaptation to Technical Progress (or the 2nd ATP) was brought into European Community law through European Commission Directive 2006/8/EC. This needs to be implemented in Great Britain through amendments to the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (commonly known as CHIP 3).
2. There are also several minor editorial changes to CHIP 3 that the Health and Safety Executive would like to make to clarify existing requirements and correct errors; a minor amendment to the way in which the Control of Major Accident Hazards Regulations 1999 (as amended) is enforced is also proposed; as are minor amendments to the definition of the Approved Supply List (Eighth Edition) and the Approved Classification and Labelling Guide (Fifth Edition). These proposed changes will not alter the existing requirements on dutyholders.
3. The new Regulations will be known as the Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2008 (CHIP 3.2).
4. Please consider the proposals in this document and let us have your views. The section 'Invitation to Comment' on page 13 tells you how to respond, and the response form at Appendix I lists questions we would like you to consider. It is not intended to restrict the scope of the comments: we would welcome any comments you wish to make on the proposal.

BACKGROUND

5. CHIP implements several European Community (EC) Directives:
 - the Dangerous Substances Directive (DSD),
 - the Dangerous Preparations Directive (DPD); and
 - the Safety Data Sheets Directive (SDSD) (*see Appendix II for more details*).
6. Their purpose is to make sure that people are properly informed about the dangers of chemicals both at work and in the home. They also improve the Single Market by requiring all suppliers of dangerous chemicals to provide the same standard of information to their customers. The Directives (particularly the DSD) are frequently updated to deal with advances in knowledge about chemicals (this means CHIP has often been changed in turn). CHIP also implements some consumer protection labelling requirements from the Marketing and Use Directive (76/769/EEC).
7. CHIP is concerned with:
 - dangerous substances (chemical elements or compounds, such as mercury or sulphuric acid); and
 - dangerous preparations (mixtures or solutions of substances, such as paints, inks, cleaning fluids etc).
8. The term 'chemical' is used in this Consultation Document to cover both substances and preparations.

9. CHIP requires suppliers of dangerous chemicals to:
- decide what types of danger (or hazard) their products present (known as ‘classification’),
 - package them suitably; and
 - provide information for their customers in the form of warning labels and safety data sheets.
10. CHIP is the foundation of Great Britain’s chemical control regime and affects other requirements on the storage, use and disposal of chemicals. For example changes to the classification of a chemical can make it subject to the “Control of Major Accident Hazards” regime (COMAH) or can trigger specific workplace controls for a carcinogen under Control of Substances Hazardous to Health regulations (COSHH).
11. The CHIP regulations directly mirror the provisions of the Directives listed in paragraph 5 and therefore need to change whenever the Directives change. This ensures that GB based chemical suppliers continue to enjoy the benefits of this single market and consumers across Europe receive the same information about the hazards presented by these chemicals.
12. The Directives (particularly the DSD and DPD) are frequently updated to take account of advances in knowledge about chemicals. Changes to the technical annexes to these Directives are called Adaptations to Technical Progress (ATPs).
13. European Member States agreed the 2nd ATP to the DPD in November 2005. The changes appear in European Commission Directive 2006/8/EC, which was published in the Official Journal of the European Communities on 24 January 2006. The text of this Directive appears at Appendix V. The 2nd ATP amends the technical annexes of the DPD in respect of certain labelling requirements; application of concentration limits for certain preparations; and adjustments to terminology used. The amendments have been agreed by Member States after full consultation, discussion and scientific inquiry where necessary.

CHIP Approved Documents

14. To help suppliers comply with CHIP there are a number of supporting documents.
- an Approved Supply List (ASL), which is the British version of Annex I of DSD. This lists EC agreed classification and labelling for many common substances (thus relieving the suppliers from the need to self classify them);
 - an Approved Classification and Labelling Guide (ACLG), which tells suppliers how to classify and label chemicals, which are not listed in the ASL. The ACLG implements in GB Annex VI of the DSD.
 - an Approved Code of Practice (ACoP) providing advice on the compilation of Safety Data Sheets.
15. The proposed changes described in this consultation document do not affect any requirements outlined in these documents.

The Dangerous Preparations Directive (DPD)

16. The European Council Directive on Dangerous Preparations (DPD) sets out the rules and procedures for hazard classification, packaging and labelling of dangerous preparations supplied in Europe (a preparation is simply a mixture of two or more substances). For health and environment effects, the hazard classification is usually based on the preparations ingredients and their respective concentrations. The technical content of the Directive is contained in a number of Annexes which are revised from time to time by means of European Commission Directives known as Adaptations to Technical progress (ATPs). The 2nd ATP to this Directive makes a series of changes to these rules and procedures, and makes some adjustments to terminology used to provide clarity, remove anomalies and improve the accuracy of labels.

CHANGES TO THE DPD AND TO CHIP

The 2nd ATP

17. The 2nd ATP makes changes to three of the technical annexes in the DPD – Annexes II, III and V. The amendments 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 parent Directive or the CHIP regulations. The text of the 2nd ATP is included at Appendix V of this consultative document for information.

Amendments to Annex II of the DPD

18. Annex II of the DPD outlines a conventional method that should be used for the evaluation of the health hazards of a preparation. The Annex provides the technical detail supporting Article 6 of the DPD.

19. The existing rules and procedures for classifying and labelling a preparation containing carcinogens, mutagens or substances toxic for reproduction require the preparation to be labelled with risk phrases (R-phrases) to indicate both categories 1 or 2 and category 3 classifications. For example:

A preparation containing a substance that is a category 2 carcinogen at a concentration above the concentration limit (default 0.1% by weight), and a substance that is a category 3 carcinogen above its concentration limit (default 1%) would be required to be labelled with both the following R-phrases:

- May cause cancer (R45); and
- Limited evidence of a carcinogenic effect (R40)

20. Similar difficulties would arise for preparations containing both categories 1 or 2 and category 3 mutagens, or substances classified as toxic for reproduction. Providing both R-phrases would send conflicting messages.

21. The 2nd ATP changes the rules and procedures for classifying and labelling such preparations. In these circumstances the preparation should only be labelled with the R-

phrase for the higher category – R45 in the example above, to avoid possible conflicting messages.

22. Tables VI and VIA of the Annex II of the DPD, have been amended accordingly. Therefore these changes need to be reflected in the corresponding tables at Schedule 3, Part II of CHIP. (The new tables appear on pages 32 - 33 of Appendix IV).

Amendments to Annex III of the DPD

23. Annex III of the DPD outlines a conventional method that should be used for the evaluation of environmental hazards of a preparation. The Annex provides the technical detail supporting Article 7 of the DPD.

24. Most amendments to Annex III of the DPD concern Part B(I), which sets out the generic concentration limits to be used for the evaluation of the hazards for the aquatic environment. These relate to preparations that contain substances that are classified as very toxic to the aquatic environment and assigned the Risk phrases R50 or R50-53, i.e. N, R50 or N, R50-53.

25. Where such substances are listed in Annex I of the DSD, specific concentration limits can be applied in order to avoid an underestimation of the hazard present. These can be set at very low levels, for example 0.0025%. However, where substances have been self-classified (in accordance with Article 6 of the Dangerous Substances Directive) and provisionally assigned R-phrases R50 or R50-53, the generic concentration limits given in Annex III to the DPD apply.

26. For example, triclosan is listed in Annex 1 of the DSD with low specific concentration limits (e.g. $\geq 0.025\%$ and $< 0.25\%$ for N:R51 - 53), and preparations containing it are classified as “very toxic to the aquatic environment” at concentrations above 0.25%; whereas preparations containing other biocides not listed on Annex 1, but potentially equally as potent as triclosan, would only be classified as “very toxic to the aquatic environment” if present in concentrations above 25%.

27. Industry representatives, principally from those who manufacture or formulate biocides, made representations to the European Commission that this inconsistency created a distortion in the relevant markets and threatened legal action.

28. The European Commission responded by proposing extended, generic concentration limits (GCLs) for deriving the environmental classification of a preparation containing a substance classified as dangerous to the aquatic environment. The GCLs are based on lethal concentration or environmental concentration limit values (LC_{50} or EC_{50}) of the substances. This ensures consistency between the aquatic environmental classification of preparations containing any substance, whether or not listed in Annex I of the DSD, because the concentration limits applied will always be based on LC_{50} or EC_{50} , for the substance(s) concerned.

29. The 2nd ATP, therefore, replaces Table I of Annex III of the DPD with new Tables 1a and 1b. It also amends Table 2. These changes are reflected in the proposed CHIP amending regulations by replacing the corresponding tables at Schedule 3, Part III of CHIP with new Tables 1a, 1b and 2 (see page 34 of Appendix IV).

30. These changes resolve the perceived issue of market distortion, but they lead to other consequences:

- it will no longer be possible to derive the health and environmental classification of a preparation just from the classifications of the ingredient substances and their concentrations in the preparation. For the endpoint of aquatic toxicity it may now be necessary to refer also to eco-toxicological data on the constituent substances; and
- extending the default concentration limits in this way means that many preparations such as water-based paints and perfumes, containing small quantities of powerful biocides, may now have to be classified as “Dangerous for the Environment”.

31. Extending the default concentration limits in this way (and thereby possibly increasing the numbers of preparations classified as “Dangerous for the Environment”) may have implications for premises where such products are kept e.g. where they are manufactured, canned, packaged, stored or sold. Strict application of the existing criteria in the Control of Major Accident Hazards Regulations 1999 (COMAH) (as amended) would trigger application of those regulations if these products are stored above generic qualifying quantities. These quantities were lowered in the 2005 COMAH Amendment Regulations (SI2005/1088) and are:

Dangerous for the Environment	Quantity in tonnes	
	Lower tier	Upper tier
(a) R50 (with or without R53)	100	200
(b) R51 – 53	200	500

32. The COMAH regulations implement the SEVESO II Directive on preventing and mitigating the effects of major accidents. COMAH applies where threshold quantities of dangerous chemicals identified in the regulations are kept or used. As well as listing specific dangerous substances that will cause COMAH requirements to be applied (if the threshold quantities are reached); it also lists certain CHIP classification categories of substances and preparations that will also cause COMAH to be applied where thresholds are reached.

33. The provisions in COMAH do not take account of how the hazardous chemical is stored, for example, in one large tank or in many small containers (e.g. 1 or 5 litre). Also, for chemicals classified as “Dangerous for the Environment”, COMAH does not take into account whether such substances, assigned such classifications, are highly concentrated or dispersed at very low concentrations in a large volume of formulated product.

34. This consequence, where premises storing, for example, significant quantities of 5 or 10 litre containers of paint for domestic or professional use (e.g. DIY Warehouses), could be brought into the scope of COMAH, we believe, was unintended. The problem arises because of the simplistic way the SEVESO II Directive takes up the classification criteria, which COMAH is then obliged to implement.

35. At the time the 2nd ATP was agreed the UK Government made a declaration drawing attention to this perceived problem, and we continue to press the European Commission to amend the Seveso Directive to address this and other issues affecting its scope. The

European Commission accepts that there is an issue, and notes that the advent of new EU requirements to adopt in Europe the GHS provides an opportunity to review the linkages between classification of substances and preparations and the requirements of the Seveso II Directive (and hence COMAH).

36. Throughout 2007, HSE engaged in a dialogue with DIY retailers and various chemical related trade associations to understand whether this unintended issue with COMAH was likely to arise in practice. Discussions with the UK's three largest DIY retailers revealed that, even in a worst-case scenario, where every product they suspected may need re-classifying there would be insufficient quantities of product classified as "Dangerous for the Environment" kept at retail stores for COMAH requirements to be invoked. Of the very few products that they had identified that may need re-classification the retailers indicated that their preference would be to reformulate the products where possible. There remained a concern that central warehousing for DIY retailers and distribution of stock could be problematic, although the retailers believe that even in their larger warehouses application of COMAH could generally be avoided by careful stock management. They noted that several warehouses are already major hazard sites so it may also be possible for any affected products to be stored at those sites.

37. Whilst the DIY retail and warehousing sector has advised HSE that, through a combination of managing stock levels and, where possible, reformulation of products, they do not envisage reaching COMAH thresholds, it is possible that as business needs change, new products could enter the market, and the increasing trend towards larger store sizes could lead to higher stock levels of relevant products.

38. Currently, if a Local Authority enforced site, such as a retail or wholesale warehouse, becomes subject to the COMAH Regulations, the Competent Authority would enforce the COMAH provisions and HSE would take over from Local Authorities the enforcement responsibilities for all other relevant statutory provisions for the purposes of the Health and Safety at Work (etc) Act 1974 (HSWA). Although unlikely, it is still possible that a very small number of sites that currently are enforced by Local Authorities (e.g. certain retail premises) could become COMAH sites, if not now then in the future. The preference of HSE and Local Authorities would be to keep enforcement of COMAH at those sites with the Competent Authority, but to consider transferring back to Local Authorities on a case-by-case basis the enforcement of all other relevant statutory provisions for the purposes of the HSWA. Doing so would ensure that enforcement of the HSWA provisions would remain with the authority most familiar with that sector and the enforcement issues likely to occur.

39. In the longer term, as discussed in paragraph 35, future changes to the Directive on which COMAH is based¹ could take such sites outside the scope of COMAH and resolve potential unintended effect and enforcement issues. However, those amendments may be several years away and may not be completed in time to address enforcement allocation in the interim period. Therefore, as a precautionary measure, a minor amendment to the enforcement provisions of COMAH is proposed. Draft regulation 7 allows HSE to transfer back to Local Authorities, on a case by case basis, enforcement responsibility for the other relevant statutory provisions for the purposes of the HSWA.

¹ Directive 96/82/EC on the control of major-accident hazards involving dangerous substances, as amended by Directive 2003/105/EC.

40. In addition, and notwithstanding the above, the COMAH Competent Authority (CA) proposes a proportionate approach to enforcing COMAH at any premises that may be brought into scope as a result of applying the changes to generic concentration limits of substances Dangerous for the Environment. Such an approach is consistent with the Better Regulation principles outlined in the Government's 'Regulators Compliance Code'. In deciding what is proportionate the CA will take into account the hazards and risks posed by the establishment. A measured approach will be taken to the assessment of the safety report and inspection of the establishment should a major accident hazard not be considered to exist.

41. A second change to Annex III of the DPD concerns Schedule 3, Part III of CHIP. The change adjusts the classification and labelling requirements for preparations containing ozone-depleting substances, to align with corresponding changes already made to the DSD through Directive 2001/59/EC. Table 5 of Annex III of the DPD has been amended to require preparations containing ozone depleting substances ($\geq 0.1\%$) to be classified with the symbol N (Dangerous for the environment) in addition to the risk phrase R59 (Dangerous for the ozone layer). Previously some preparations dangerous for the ozone layer were classified with just R59. Therefore these changes delete the existing Table 5 at Schedule 3, Part III of CHIP and replace it with a new Table 5. In addition, as a result of the new table, Schedule 3, Part II, Paragraph 19(2) of CHIP is no longer relevant and so is deleted.

Amendment to Annex V of the DPD

42. Annex V of the DPD outlines the special provisions concerning the labelling of certain preparations. The wording of the specified warning phrases has been criticised in the past due to the lack of consistency. As a result, the 2nd ATP modifies the wording to make it more accurate. Whilst the changes are largely editorial, for clarity, the whole of Annex V has been replaced.

43. The phrase "the label on the packaging" is now used consistently in each of the specified label warning phrases. Previously several different forms of words were used (e.g. the package label; labels on packages; and the packaging).

44. There is also one change to a warning phrase in Annex V. Under paragraph 8 of Annex V, the phrase "Warning" is changed to "Caution". However, this is already correct in CHIP so in this respect no further changes are needed.

45. The changes that will result because of the 2nd ATP will also address a typographical error currently in paragraph 5 of Schedule 5, Part II (B) of CHIP. Paragraph 5 sets out the requirement for preparations that contain active chlorine that are sold to the general public to carry the phrase:

"Warning! Do not use with other products. May release dangerous gases (chlorine)".

46. This omits the word "together" after the word "... use..." Changes to the CHIP regulations to take account of the new Annex V to the DPD will correct this error.

47. These changes are reflected in the proposed CHIP amending regulations by replacing the existing text in Schedule 5, part II of CHIP with the corresponding text as given in the 2nd ATP.

Updates to the British, European and International standard specifications relating to child resistant closures and packaging.

48. Regulation 11 and Schedule 6 of CHIP 3 refer to British, European and International Standards relating to child resistant closures, packaging and tactile warnings of danger. These standards have either been updated or renamed since the CHIP3 regulations were written and stakeholders have requested that HSE use this opportunity to update the references.

49. HSE has given consideration to including such an amendment. Unfortunately, the origin of these measures (Article 22 and Annex IX of the Dangerous Substances Directive) does not make available to Member States the facility to update to the latest standards. Therefore HSE are not proposing to update the references on this occasion.

50. However, to a large extent, manufacturers are already complying with the latest standards. In addition, the forthcoming European Classification, Labelling and Packaging Regulation [based on the Globally Harmonised System (GHS)], currently under active negotiation at the European level, provides the opportunity needed. The proposed provisions relating to 'Child Resistant Closures' (*copies are available at http://ec.europa.eu/enterprise/reach/ghs_en.htm*) are included in Article 37, and section 3 of Annex II. The European regulation is likely to be adopted in 2008 and to be in force mid-2009

Correcting minor errors in previous amendments to CHIP concerning the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004.

51. As the HSE are amending CHIP to implement the 2nd ATP, there is an opportunity to correct certain errors that have arisen via amendments to CHIP concerning the Carriage of Dangerous Goods and use of Transportable Pressure Equipment Regulations 2004, and in particular, the labelling of single receptacles and receptacles in outer packagings where the national and international rules also apply. Draft Regulation 3 in the proposed amending regulations corrects a cross-reference in regulation 9(2) of CHIP. Draft Regulation 6 revokes amendments to the principle regulations that were made in error, as they duplicate amendments already made in an earlier Statutory Instrument.

TRANSITIONAL PERIODS

52. In line with other ATPs, no transitional periods have been provided for in the 2nd ATP (Directive 2006/8/EC), therefore, no similar provisions can be made in these proposed CHIP amending regulations. However, owing to the earlier perceived problems between the 2nd ATP and the COMAH regulations (see paragraph 31- 36) the UK will be a year-and-a-half late in implementing the ATP, so this may actually go some way to relieving the difficulties that may have faced some businesses in preparing for change. We will be advising the enforcement bodies about the potential difficulties that some businesses may have in timing changes and on appropriate action to be taken.

53. This repeats the successful approach adopted for CHIP 3 (which was a far more challenging task) and, to a lesser extent, CHIP 3.1. Firms who anticipate problems should liaise with their local HSE office or Local Authority in order to develop agreed solutions. Experience from these and other previous CHIP amendments suggests that chemical suppliers usually prepare for necessary changes during the period between the Directive being formally published on the European Commission's Official Journal (in this case January 2006) and the entry into force date of the corresponding changes to CHIP. Typically this period in the past has been 18 months, however, this time it will be 33 months.

IMPLEMENTATION DATE

54. As written, the 2nd ATP had an implementation date of 1 March 2007. This date was legally binding on all Member States. However, the UK Government has not met this implementation date because of an extended period of research and consultation required to assess the implications of a perceived problem with the way the 2nd ATP interacted with the COMAH Regulations (see paragraphs 31 –37). The Health and Safety Executive is mindful of the UK Government's policy to implement, wherever possible, legislation on one of two "common commencement dates" per year (6 April or 1 October). This is designed to better assist business and industry in preparing for compliance with new regulatory requirements. This policy is to be applied to both domestic and European based legislation wherever possible. Therefore, HSE has proposed an implementation date of 1 October 2008 for the 2nd ATP.

55. Late implementation of a Directive can, potentially, result in the European Commission instigating what are termed "infraction proceedings" against the offending Member State. The delayed implementation approach adopted by the UK to date has already raised the prospect of infraction proceedings from the European Commission, so implementation needs to proceed without further delay.

56. It is not thought that the delay has had a detrimental effect on UK business and industry. Chemical suppliers can comply with the 2nd ATP before the CHIP amending regulations enter into force. Where businesses anticipate any problems with the proposed implementation date of 1 October 2008, they should liaise with their local enforcing authority – either HSE or their local authority.

COSTS AND BENEFITS

57. A preliminary Impact Assessment has been carried out, including a competition assessment and a small firms' impact test. The lower estimate of costs has been calculated at £849,000 and an upper estimate of costs calculated at £3,978,000. The main benefits of the proposed changes are expected to be continued improvement to the Single Market by requiring all suppliers of dangerous chemicals to provide the same standard of information to their customers, and possible reductions in damage to the environment and human health. Unfortunately it has not been possible to quantify such benefits. On the basis of proportionality HSE's Chief Economist has recommended that a full impact assessment is not produced.

58. This is a first attempt to assess the costs and benefits of CHIP 3.2 and we would welcome your views, and in particular, additional hard data or evidence which will enable us to develop more accurate estimates.

Simple competition assessment

59. A Competition Filter Test has been completed and the results suggested that a detailed competition analysis was not required. The DPD is a single market directive designed to create a level playing field for the chemical supply market.

Consultation with small firms – the small firms impact test

60. As recently as 2003 a previous Small Firms Impact test indicated two main areas where costs were anticipated:

- printing of new warning labels and the revision; and/or
- production of new safety data sheets.

61. The length of time available to implement the changes, and local facilities available to small firms will play a part in the calculating the extent of the costs and where those costs will be most keenly felt.

62. There are some direct costs associated with re-labelling, although these are relatively small. Respondents have previously linked the costs of re-labelling to the length of time that is available to make the change after the Directive has been published. A period of up to a year is generally seen as sufficient to use existing stocks and to avoid unnecessary wastage.

63. Amending the wording on safety data sheets is an area that suggests a wide range of costs. Respondents indicated those who have access to an automated system do not anticipate much in the way of cost. However, those respondents who do not have an automated system have cited significant costs, including temporary loss of employee expertise in order for this work to be carried out, and it is seen as a major undertaking.

64. We, therefore, assume that there will not be a significant impact on small firms as a result of the 2nd ATP given the period of implementation available, the fact that it will be 33 months since the 2nd ATP was published, and the limited scope of the labelling and any associated safety data sheet changes.

Impact Assessment

65. The negotiations in Europe for the 2nd ATP were conducted in partnership with industry and business stakeholders and our negotiating positions were developed after consultation under HSE's standing arrangements with CBI and TUC representatives. Business and relevant industries have had the opportunity, for several years, to express their views on the proposed changes and to help develop an assessment of the costs and benefits they will bring. We know there is a broad acceptance of the changes and costs. Although some stakeholders raised the potential for a large expansion of COMAH sites (paragraphs 31 to 37) further exploration has indicated that these concerns are unlikely to arise in practice.

FUTURE DEVELOPMENTS - APPROVED SUPPLY LIST (ASL)

66. HSE is exploring future options for the Approved Supply List (ASL) publication. Currently the HSE publish the Annex I of the Dangerous Substances Directive and subsequent ATPs through the Approved Supply List. Annex I of the DSD and the ASL list all the harmonised classifications and labelling requirements agreed by Member States. The ASL is currently only available in paper form. This has the disadvantage that it cannot be interrogated electronically and costs purchasers approximately £35 for one copy.

67. In practice, few organisations need access to information on all of the substances listed in the ASL, with most organisations only being interested in a very small number of chemicals each. Anecdotal evidence suggests that many ASL users would prefer electronic access to the data. In addition, the current practice of producing paper versions requires HSE to update and republishing a consolidated British version of Annex 1 of the DSD with almost every amendment of CHIP and runs the risk of typographical errors being introduced in some of the thousands of entries listed.

68. With the classification and labelling of chemicals likely to become subject to a direct acting European Regulation at the end of 2008 and with advances in technology, access to the internet and availability of online databases, we are now considering whether it is appropriate to continue publishing paper versions of the ASL. We could, for example, refer to an official EU electronic database instead, such as the one hosted by the European Chemicals Bureau, ESIS (see: <http://ecb.jrc.it/esis/index.php?PGM=cla>)

69. Therefore, in addition to your views on the proposed changes to CHIP outlined in this Consultative Document, HSE would like your views on whether there is still a need to continue to publish a paper version of the ASL.

70. In the interim before we take the decision to move towards online databases, the proposed CHIP amending regulations include a revised definition of “the Approved Supply List”. The new definition adds “*as revised or re-issued from time to time*”. This is to enable any possible errors in ASL (Eighth Edition) entries to be corrected quickly without having to publish and re-issue a whole new publication. HSE has recently been made aware of three errors in the current ASL (Eighth Edition) where the entries do not match the original Annex 1 entry or as updated by subsequent ATPs. The entries that we know are incorrect are for:

- chlorotoluron CAS 015545-48-9;
- 2-chloracetamide CAS 79-02-2; and
- ethophosphos CAS 013194-48-4

71. HSE would like to take this opportunity to ask whether you are aware of any other typographical errors or incorrectly transposed entries in the current ASL (Eighth Edition), so that we can prepare an erratum.

INVITATION TO COMMENT

72. Much of what is planned for new CHIP 3.2 regulations stems from an EC Directive. The UK Government is required to implement this in full without any change to the substantive requirements; therefore it is not possible to amend the technical contents of the 2nd ATP, regardless of comments we may receive. The UK’s negotiating position was

developed after consultation under HSE's standing arrangements with employer and employee representatives. The proposals laid out in the 2nd ATP have been discussed with business and relevant industries for a considerable period of time and we believe there is a broad acceptance of them. However, there are still aspects on which we would welcome comments.

For convenience, a response form is included at Appendix I. An electronic version is available at: <http://www.hse.gov.uk/consult/condocs/cd217.htm>

You may find it helpful to use this form for your reply. We are happy to receive written comments in any form convenient to you. We will acknowledge receipt of all comments sent to us and will give them careful consideration, however, it should be remembered that we cannot alter the technical content of the 2nd ATP amendments themselves.

73. The HSE would also like to know what you think of this consultation, both in terms of content and layout. Your views will help us to improve future consultations.

74. Please send your comments to Paul Howarth by 4 July 2008 at the address below.

Paul Howarth
International Chemicals Unit
Health and Safety Executive
9th Floor South Wing
Rose Court
2 Southwark Bridge
London. SE1 9HS

Tel: 020 7717 6937 Fax: 020 7717 6417

E-mail: paul.howarth@hse.gsi.gov.uk

APPENDIX I – RESPONSE FORM

Consultation on the proposed Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2008.

2. We would like you to tell us what you think about the proposals set out in this consultative document. The questions we are particularly keen to hear your views on appear below in this reply form which you may wish to photocopy or tear out and use. Please add extra sheets if you wish.

An electronic version of this response form is available at:

<http://www.hse.gov.uk/consult/condocs/cd217.htm>

4. You do not have to answer all the questions. Some may be more relevant to your organisation than others. But please answer as many as you can.

5. Hard data, supporting evidence and realistic practical examples would be very useful if you are commenting on issues related to the impact/effect of the proposed changes or the costs and benefits.

6. *If you reply to this consultative document in a personal capacity, rather than as a post-holder of an organisation, the information you provide may constitute ‘personal data’ in the terms of the Data Protection Act 1998. For the purposes of this Act, HSE is the “data controller” and will process the data for health, safety and environmental purposes. HSE may disclose these data to any person or organisation for the purposes for which it was collected, or where the Act allows disclosure. You have the right to ask for a copy of the data and to ask for inaccurate data to be corrected. Please note that all replies may be made public unless you specifically state you wish yours to be made confidential.*

7. Please tick one box from the options below and then explain your answer in the space provided.

RESPONDENTS’ DETAILS

Title: **First Name:** **Surname:**

Organisation Name:

Address: **Line 1:**
 Line 2:
 Line 3:
 Town:
 County:
 Postcode:

Telephone:

E-mail:

Q1 a. Do you currently classify, label and package chemical products (in other words, are you a chemical manufacturer, importer, supplier, distributor or retailer) or do you use chemicals in a professional capacity? (please tick all that apply)

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

Q 1 b. Type of organisation: (*Industry, NGO, Trade Association, etc*)

Q 1 c. Size of organisation:

- Large**
- Medium**
- Small**
- Micro**

Explanation:

- Large* = over 250 Full Time Equivalent (FTE) employees
- Medium* = 50 – 249 FTE employees
- Small* = 10 – 49 FTE employees
- Micro* = 0 – 9 FTE employees

Q 1 d. Which of the following best describes your sector type? (please tick all that apply)

- | | |
|---|--|
| <input type="checkbox"/> Agriculture | <input type="checkbox"/> NGO |
| <input type="checkbox"/> Biocides | <input type="checkbox"/> Pesticides |
| <input type="checkbox"/> Chemicals | <input type="checkbox"/> Plastics |
| <input type="checkbox"/> Cleaning | <input type="checkbox"/> Police |
| <input type="checkbox"/> Construction | <input type="checkbox"/> Printing |
| <input type="checkbox"/> Engineering | <input type="checkbox"/> Quarries |
| <input type="checkbox"/> Explosives | <input type="checkbox"/> Professional user |
| <input type="checkbox"/> Fire & rescue services | <input type="checkbox"/> Railways |
| <input type="checkbox"/> Gas | <input type="checkbox"/> Recycling |
| <input type="checkbox"/> Haulage/transport | <input type="checkbox"/> Refractories |
| <input type="checkbox"/> Laundries/dry cleaning | <input type="checkbox"/> Retail / wholesale |
| <input type="checkbox"/> Local government | <input type="checkbox"/> Rubber |
| <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Surface engineering |
| <input type="checkbox"/> Member of the public | <input type="checkbox"/> Textiles |
| <input type="checkbox"/> Mining | <input type="checkbox"/> Trade Association |
| <input type="checkbox"/> National Government | <input type="checkbox"/> Trade Union |
| | <input type="checkbox"/> Waste management |
|
 | |
| <input type="checkbox"/> Other, please specify: | |

Q 1 e. – Confidentiality clause

I wish my response to remain confidential

PROPOSED REGULATION

Q 2. 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?

Agree Partly Agree Don't Agree Don't know

Comments:

Q 3. 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 the changes to the generic concentrations limits for preparations that are toxic to the aquatic environment (N, R50 or R50-53)?

Yes No Not Applicable Don't know

If there are problems, what are they:

Q 4. If you are a person who works with chemicals (as an employee or self employed person) does the proposal present any specific problems to you?

Yes No Not Applicable Don't know

If there are problems, what are they:

Q 5. What evidence or data can you provide to improve or develop the appraisal of costs in our Impact Assessment – (use supplementary sheets if necessary)?

Q 6. Please describe, and if possible quantify, any benefits of the proposal.

Q 7. Do you think this Consultative Document and the Impact Assessment presents sufficient information for you to be able to understand and comment on the proposals?

Yes No Don't know

Comment:

Q 8. What are your thoughts / comments on the future of the HSE's Approved Supply List (page 13, paragraphs 66 – 69) ?

Q 9. 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? (page 13, paragraphs 70 - 71) ?

GENERAL

Q 10: In your view how well does this consultation document explain the issue and proposed changes to the CHIP Regulations? (Please tick one box).

- Very Well
- Well
- Not Well
- Very Poorly

Comment:

Q 11: Is there anything you particularly liked or disliked about this consultation?

Please return to:

Paul Howarth
International Chemicals Unit
Health and Safety Executive
9th Floor South Wing
Rose Court
2 Southwark Bridge
London. SE1 9HS

Tel: 020 7717 6937

Fax: 020 7717 6417

E-mail: paul.howarth@hse.gsi.gov.uk

To reach him no later than 4 July 2008.

Please note: All views will be placed in HSE Information Centres unless you specifically state that this response, or a part of it, should be treated as confidential. All responses will be acknowledged.

APPENDIX II – BACKGROUND TO CLASSIFICATION AND LABELLING DIRECTIVES

a. *The Dangerous Substances Directive (67/548/EEC)*

1. The Dangerous Substances Directive was adopted by Member States in 1967. The purpose of the Directive was to standardise national provisions on chemicals to ease trade within the European Community and ensure the protection of public and worker health. The Directive introduced common provisions on:

- **classification** of dangerous substances, since placing a substance into one or several defined classes of danger characterises the type and severity of the adverse effects that the substance can cause;
- **packaging** of dangerous substances, since adequate packaging protects from the known danger(s) of a substance;
- **labelling** of dangerous substances, since the label on the packaging informs about the nature of the danger(s) of the substance inside and about the safety measures to apply during handling and use.

2. The combined standardised provisions were designed to ensure the establishment of a common market in the field of dangerous chemical substances and a high level of protection of human health and the environment.

3. The technical content of the Directive is contained in a number of Annexes which are revised from time to time. The Directive has been amended many times (9 amendments and 29 ATPs). The latest ATP, the 29th, was implemented through the Chemicals (Hazard Information and Packaging for Supply)(Amendment) Regulations 2005, brought in on 31 October 2005. Two further ATPs are expected.

4. The 30th ATP was agreed by Member States on 16 February 2007 with a timescale for implementation as 1 June 2009 – deliberately longer than is usual. The same implementation date will be used for the 31st ATP which is likely to be agreed in the next few months. The longer implementation date reflects the intention that the proposed EC Regulation to adopt GHS in the EU will be agreed before this date. The regulation will take the existing Annex 1 of the Dangerous Substances Directive, together with all the adaptations to technical progress (including the 30th and 31st ATPs), and insert them into a new Annex that will act directly at an EU level together with the existing entries for the EU system. The practical consequence is that the UK and other Member States will not need to implement the 30th and 31st ATPs into national legislation.

b. *The Dangerous Preparations Directive (88/379/EEC)*

5. The Council Directive on Dangerous Preparations extends the hazard classification, packaging and labelling requirements for chemical substances to preparations (i.e. mixtures or solutions composed of two or more substances). Directive 88/379/EEC was replaced by a new Dangerous Preparations Directive (1999/45/EC) in which the technical content has been moved to a number of Annexes, which can be revised by Adaptations to Technical Progress.

6. The latest of these is Directive 2006/8/EC, the 2nd ATP, which Great Britain must implement via these amending regulations.

c. The Safety Data Sheets Directive ((91/155/EEC) as amended by 93/112/EEC)

7. The European Commission Directive on Safety Data Sheets defines the EC system for the provision of specific information relating to dangerous preparations (and substances). This Commission Directive can be amended by further Commission Directives in the same way as Adaptations to Technical Progress.

8. It is worth noting that a further amendment to CHIP will be needed to take account of both the REACH and GHS Regulations at an EU level. This will be subject to a further consultative exercise. The REACH Regulations, which came into force in June 2007, make some adjustments to safety data sheet provisions in other Directives.

APPENDIX III – LIST OF ORGANISATIONS & INDIVIDUALS CONSULTED

Government Departments

Cabinet Office – European Secretariat
Cabinet Office – Office of Public Service
Cabinet Office – Better Regulation Executive
Central Office of Information
Crown Estate Commissioners
Department of Agriculture and Rural Development – Northern Ireland
Department for Communities and Local Government
Department for Constitutional Affairs
Department for Education and Skills
Department for Environment, Food and Rural Affairs
 Chemicals and GM Policy Division
 Global Atmosphere Division
 Pesticides Safety Directorate
 Waste Management Division
 Water Quality Division
Department of Health
Department of Trade and Industry
Department of Trade and Industry – Small Business Service
Department for Transport
Department for Work and Pensions – Workplace Health Division
Foreign and Commonwealth Office
Health and Safety Agency for Northern Ireland
HM Prison Service
HM Revenue and Customs
HM Treasury
Home Office
Law Officers' Departments
Ministry of Defence
National Assembly for Wales
Northern Ireland Department of Enterprise, Trade and Investment
Northern Ireland Office
Scottish Executive Environment and Rural Affairs Department
Scottish Executive Health Department

Public Bodies

British Broadcasting Corporation
Civil Aviation Authority
Countryside Agency
Environment Agency
Forestry Commission
Historic Royal Palaces Agency
House of Commons Library
House of Lords Library
Joint Nature Conservation Committee
Laboratory of the Government Chemist

Law Commission
Maritime and Coastguard Agency
National Consumer Council
Office for National Statistics
Scottish Environment Protection Agency
Scottish Law Commission

European Union, Crown Dependencies and Overseas Territories

Government of Gibraltar – Ministry of Employment
Health and Safety Authority – Republic of Ireland
Health and Safety Executive, Guernsey
Department of Local Government and the Environment, Isle of Man
Department of Employment and Social Security, Jersey
UK Permanent Representation to the European Union

Local Government Organisations

Association of London Government
Convention of Scottish Local Authorities
LACORS
Local Government Association
National Association of Local Councils
Northern Ireland Local Government Association

Employers' Organisations and Small Firms' Representatives

Alliance of Independent Retailers
British Association of Entrepreneurs
British Chambers of Commerce
Building Employers Federation
Confederation of British Industry
CBI – Smaller Firms Council
Electrical Contractors Association
Engineering Employers' Federation
European Association of Craft, Small and Medium-Sized Enterprises (UEAPME)
Federation of Small Businesses
Institute of Directors
Universities and Colleges Employers' Association

Trade Unions and Employee Organisations

Amicus
Association of Teachers and Lecturers
Bakers, Food and Allied Workers Union
BALPA
BECTU
British Medical Association
Communications Workers Union
Fire Brigades Union
Fire Officers Association

General Federation of Trade Unions
GMB
NATFHE
National Association of Colliery Overmen, Deputies and Shotfirers
National Union of Domestic Appliances and General Operatives
NUMAST
Police Federation of England and Wales
Prospect
Royal College of Nursing
Scottish Police Federation
Scottish Trades Union Congress
Society of Radiographers
Trades Union Congress
Transport and General Workers Union
UCATT
UNISON
USDAW

Trade Associations and Learned Bodies

Adhesive Tape Manufacturers Association
Agricultural Engineers Association
Agricultural Industries Confederation
Association of British Mining Equipment Companies
Association of the British Pharmaceutical Industry
Association of Light Alloy Refiners Ltd
Brick Development Association
British Adhesives and Sealants Association
British Aerosol Manufacturers Association
British Agrochemicals Association
British Apparel and Textile Confederation
British Association for Chemical Specialties
British Battery Manufacturers Association
British Ceramic Confederation
British Chemical Distributors and Traders Association
British Coatings Federation
British Colour Makers Association
British Contract Furnishing Association
British Electrotechnical and Allied Manufacturers Association
British Fluid Power Association
British Footwear Association
British Furniture Manufacturers Association
British Glass
British Institute of Professional Photography
British Jewellers' Association
British Leather Confederation
British Non-Ferrous Metals Federation
British Pest Control Association
British Plastics Federation
British Printing Industries Federation
British Pump Manufacturers Association

British Pyrotechnists Association
British Rigid Urethane Foam Manufacturers Association
British Rubber Manufacturers Association
British Secondary Metals Association
British Surface Treatment Suppliers Association
British Textile Technology Group
British Veterinary Association
British Wood Preserving and Damp Proofing Association
Building Employers Confederation
Castings Development Centre
Cast Metals Federation
Chemical Industries Association
Civil Engineering Contractors Association
Composites Processing Association
Confederation of British Wool Textiles
Construction Industry Research and Information Association
Construction Products Association
Cosmetics, Toiletries and Perfumeries Association
Crop Protection Association
Dairy Industry Federation
Defence Manufacturers Association
Digital and Screen Printing Association
Energy Institute
Engineering Industries Association
European Process Safety Centre
Explosive Industry Group - CBI
Farmers Union of Wales
Fertiliser Manufacturers Association
Food and Drink Federation
Freight Transport Association
Friends of Pyrethrum
Glass and Glazing Federation
Grain and Feed Trade Association
Horticultural Trades Association
Institute of Metal Finishing
Institution of Chemical Engineers
Institution of Electrical Engineers
Intellect
Law Society of England and Wales
Law Society of Scotland
National Farmers Union
National Farmers Union of Scotland
National Federation of Demolition Contractors
National Specialist Contractors Council
Offshore Contractors Association
Paint Research Association
Painting and Decorating Association
Paper Federation of Great Britain
Plastics and Board Industries Federation
Quarry Products Association
Resin Flooring Association

Road Haulage Association
Royal Agricultural Society of England
Royal Highland and Agricultural Society of Scotland
Royal Pharmaceutical Society of Great Britain
The Royal Society
Royal Society of Chemistry
Scotch Whisky Association
Scottish Food and Drink Federation
Scottish Pharmaceutical Federation
Shipbuilders and Ship repairers Association
Society of British Aerospace Companies
Society of British Gas Industries
Society of Chemical Industry
Society of Dyers and Colourists
Solvents Industry Association
Surface Engineering Association
Tank Storage Association
Textile Services Association
Tile Association
Timber Trade Association
UK Cleaning Products Industry Association
United Kingdom Lubricants Association
Water UK
Welding Manufacturers Association

Police and Emergency Services Bodies

Association of Chief Police Officers of England, Wales and Northern Ireland
Association of Chief Police Officers in Scotland
Chief Fire Officers' Association

Health and Safety Specialists

Association of Port Health Authorities
Biotechnology and Biological Sciences Research Council
British Institute of Occupational Hygiene
British Occupational Hygiene Society
British Safety Council
Chartered Institute of Environmental Health Officers
Institute of Occupational Medicine
Institution of Occupational Safety and Health
Natural Environment Research Council
Newcastle Occupational Health
Royal Environmental Health Institute of Scotland
Royal Society for the Prevention of Accidents
Society/Faculty of Occupational Medicine

Academic Institutions

Institute of Cancer Research
University of Birmingham – Institute of Occupational and Environmental Medicine

Other Organisations

Cancer Research UK
The Consumers Association
The Environment Council

Individual Companies

Adshead Ratcliffe and Company Ltd
Agropharm Ltd
Airbus UK Ltd
Akcros Chemicals
Alcohols Ltd
Allied Glass Containers
Arkema Ltd
Atofina UK Ltd
Avon Rubber plc
B&Q
BAE Systems
BASF plc Industrial Chemicals
Bayer UK Ltd
Becker Acroma Ltd
Britannia Refined Metals Ltd
Caswell Adhesives
Chemtek Ltd
Ciba Specialty Chemicals
Clariant UK Ltd
Contract Chemicals
Dexter Paints Ltd
Domino UK Ltd
Dunlop Aircraft Tyres Ltd
Elementis Chromium
Ellis and Everard (Chemicals) plc
Energys
Fenner Dunlop
Four D Rubber Co Ltd
Hickson and Welch Ltd
Home Retail Group Plc
Honeywill and Stein Ltd
Hornett Bros and Co Ltd
Huntsman Corporation UK plc
Huntsman European Chemicals
Ineos Chlor Ltd
International Paint Ltd
Kingspan Ltd
Kingspan Insulation Ltd
Luminescence
Mallinckrodt Chemical Ltd
Morris Lubricants

L'Oreal Manufacturing (UK) Ltd
PDM Neptec Ltd
Perstorp Ltd
Petrochem Carless
Pirelli UK Tyres Ltd
Polyflor Ltd
Rhodia UK Ltd
Safic-Alcan UK Ltd
SGS Vernolab Ltd
Sigma Aldrich Co Ltd
Solutia UK Ltd
Spray Nine Europe Ltd
Sun Chemical Ltd
Tennants Distribution Ltd
Wickes Building Supplies Ltd
Wincanton
Witham Oil and Paint (Lowestoft) Ltd
Whyte Chemicals Group

APPENDIX IV – DRAFT STATUTORY INSTRUMENTS

DRAFT STATUTORY INSTRUMENTS

2008 No. 00

HEALTH AND SAFETY

The Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2008

<i>Made</i>	- - - -	<i>Day Month 2008</i>
<i>Laid before Parliament</i>		<i>Day Month 2008</i>
<i>Coming into force</i>		<i>1st October 2008</i>

The Secretary of State being the Minister designated⁽²⁾ for the purpose of section 2(2) of the European Communities Act 1972⁽³⁾ in relation to the regulation and control of classification, packaging and labelling of dangerous substances and preparations, in exercise of the powers conferred upon him by the said section 2(2)⁽⁴⁾ and by section 15(1), (2), (3)(a) and (c), (4)(a) and (b) of, and paragraphs 1(1)(b) and (4) and 3(2) of Schedule 3 to, the Health and Safety at Work etc. Act 1974⁽⁵⁾ (“the 1974 Act”) and of all other powers enabling him in that behalf and for the purpose of giving effect without modifications to proposals submitted to him by the Health and Safety Commission under section 11(2)(d) of the 1974 Act after the carrying out by the said Commission of consultations in accordance with section 50(3) of that Act, makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2008 and shall come into force on 1st October 2008.

(2) In these Regulations, “the principal Regulations” means the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002⁽⁶⁾.

Amendments to regulation 2 of the principal Regulations

2.—(1) In regulation 2(1) of the principal Regulations—

(a) for the definition of “the approved classification and labelling guide” substitute—

““the approved classification and labelling guide” means the guide entitled “Approved Guide to the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Fifth

-
- (2) S.I. 1976/897.
- (3) 1972 c. 68. Section 2(2) was amended by section 27(1), and paragraph 2 of Schedule 2 by section 27(2)(a), of the Legislative and Regulatory Reform Act 2006 (c.51).
- (4) As regards Scotland, see also section 57(1) of the Scotland Act 1998 (c. 46), which provides that, despite the transfer to the Scottish Ministers by virtue of that Act of functions in relation to observing and implementing obligations under Community law, any function of a Minister of the Crown in relation to any matter shall continue to be exercisable by him as regards Scotland for the purposes specified in section 2(2) of the European Communities Act 1972.
- (5) 1974 c. 37; section 1(1) (c) was modified by the Health and Safety at Work etc. Act (Application to Environmentally Hazardous Substances) Regulations 2002 S.I. 2002/282. Sections 15(1) and 50(3) were amended by the Employment Protection Act 1975 (c.71), Schedule 15, paragraphs 6 and 16 respectively.
- (6) S.I. 2002/1689, as amended by S.I. 2004/568, S.I. 2004/3386, S.I. 2005/1732, S.I. 2005/2092, S.I. 2005/2571 and 2006/2916.

Edition)” approved by the Health and Safety Commission on 16th April 2002(7) and as revised or re-issued from time to time.”;

(b) for the definition of “the approved supply list” substitute—

““the approved supply list” means the document entitled “Information Approved for the Classification and Labelling of Dangerous Substances and Dangerous Preparations (Eighth Edition)” approved by the Health and Safety Commission on 26 July 2005(8) and as revised or re-issued from time to time.”.

Amendments to regulations 8 and 9 of the principal Regulations

3.—(1) In regulation 8A(4) of the principal Regulations after the words “this regulation” add the words “and regulation 9(2)”.

(2) In regulation 9(2) of the principal Regulations—

(a) omit the words “Subject to regulations 8 and 8A”; and

(b) after sub-paragraph (b) recommence the main text of paragraph (2) by adding the words—

ixcept that where a package would be required to be labelled and marked in accordance with any of the national or international transport rules listed in regulation 8A(4) and the package consists of one or more receptacles in outer packagings, it shall be sufficient compliance with this paragraph if the package shows the labels and markings required by whichever of the national or international rules is appropriate.i.

Amendments to Schedule 3 of the principal Regulations

4.—(1) Schedule 3 to the principal Regulations shall be amended in accordance with the following paragraphs.

(2) In Part I omit paragraph 19(2).

(3) In Part II Tables II and IIA omit in both footnotes marked with a dagger the words “carcinogenic or”.

(4) For Part II Tables VI and VIA substitute the Tables contained in Schedule 1 to these Regulations, leaving the text and list headed “6.2 *Gaseous preparations*” in place between the two Tables.

(5) For Part III Tables 1 and 2 substitute the Tables contained in Schedule 2 to these Regulations.

(6) For Part III Table 5 substitute the Table contained in Schedule 3 to these Regulations.

Amendments to schedule 5 of the principal Regulations

5. For Schedule 5 part II of the principal Regulations substitute the Schedule contained in Schedule 4 to these Regulations.

Amendments to the Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2005

6. In the Chemicals (Hazard Information and Packaging for Supply) (Amendment) Regulations 2005(9) omit regulation 2(2)(b), (4), (5) and (6).

Amendments to the Control of Major Accident Hazards Regulations 1999

7. For regulation 20(6) of the Control of Major Hazards Regulations 1999(10) substitute the following paragraph—

“(6) Notwithstanding the Health and Safety (Enforcing Authority) Regulations 1998(11), the Executive shall, for the purposes of the 1974 Act, be the enforcing authority for the relevant statutory provisions at an establishment to which any of these Regulations apply, unless a transfer of responsibility is made under paragraph (7) below.

(7) ISBN 0717623696

(8) ISBN 0717661385.

(9) S.I. 2005/2571.

(10) S.I. 1999/743 as amended by S.I. 1999/2597, S.I. 2002/2469, S.I. 2005/676 and S.I. 2005/1088.

(11) S.I. 1998/494 as amended by S.I. 2008/XXXX, article 22 Schedule 3.

(7) The responsibility, for the purposes of the 1974 Act, for enforcing any of the relevant statutory provisions at any establishment to which any of these Regulations apply may be transferred from the Executive to the local authority, insofar as the main activity carried on at that establishment is the sale of goods, or the storage of goods for retail or wholesale distribution, except—

(a) at container depots where the main activity is the storage of goods in the course of transit to or from dock premises, an airport or a railway;

(b) where the main activity is the sale or storage for wholesale distribution of any substance or preparation dangerous for supply, or

(c) where the main activity is the sale or storage of water or sewage or their by-products or natural or town gas.

(8) A transfer may be made only by agreement between the Executive and the local authority.

(9) Where a transfer has been made, the local authority shall cause notice of the transfer to be given to persons affected by it.”

Signed by the authority of the Secretary of State for Work and Pensions.

William D McKenzie
Parliamentary Under-Secretary of State
Department for Work and Pensions

Date

SCHEDULE 1

Regulation 4(4)

iTable VI

<i>Classification of the substance</i>	<i>Classification of the preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration \geq 0.1% carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration \geq 1% carcinogenic R40 obligatory (<i>unless already assigned R45^(*)</i>)
Mutagenic substances of category 1 or 2 with R46	Concentration \geq 0.1% mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68 ^(**)		Concentration \geq 1% mutagenic R68 ^(**) obligatory (<i>unless already assigned R46</i>)
Substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	Concentration \geq 0.5% toxic for reproduction (fertility) R60 obligatory	
Substances “toxic for reproduction” of category 3 with R62 (fertility)		Concentration \geq 5% toxic for reproduction (fertility) R62 obligatory (<i>unless already assigned R60</i>)
Substances “toxic for reproduction” of category 1 or 2 with R61 (development)	Concentration \geq 0.5% toxic for reproduction (development) R61 obligatory	
Substances “toxic for reproduction” of category 3 with R63 (development)		Concentration \geq 5% toxic for reproduction (development) R63 obligatory (<i>unless already assigned R61</i>)

(*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.

(**) R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table II.

Table VIA

<i>Classification of the substance (gas)</i>	<i>Classification of the gaseous preparation</i>	
	<i>Categories 1 and 2</i>	<i>Category 3</i>
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration \geq 0.1% carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration \geq 1% carcinogenic R40 obligatory (<i>unless already assigned R45^(*)</i>)
Mutagenic substances of category 1 or 2 with R46	Concentration \geq 0.1% mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68 ^(**)		Concentration \geq 1% mutagenic R68 ^(**) obligatory (<i>unless already assigned R46</i>)
Substances “toxic for reproduction” of category 1 or 2 with R60 (fertility)	Concentration \geq 0.2% toxic for reproduction (fertility) R60 obligatory	
Substances “toxic for reproduction” of category 3 with R62 (fertility)		Concentration \geq 1% toxic for reproduction (fertility) R62 obligatory (<i>unless already assigned R60</i>)
Substances “toxic for reproduction” of category 1 or 2 with R61 (development)	Concentration \geq 0.2% toxic for reproduction (development) R61 obligatory	
Substances “toxic for reproduction” of category 3 with R63 (development)		Concentration \geq 1% toxic for reproduction (development) R63 obligatory (<i>unless already assigned R61</i>)

(*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.

(**) R68 here refers to substances classified as mutagenic. Concentration limits for substances required to be labelled R68 but classified as harmful are given in Table IIA.1

SCHEDULE 2

Regulation 4(5)

Table 1a

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
N, R50-53	see Table 1b	see Table 1b	see Table 1b
N, R51-53		$C_n \geq 25\%$	$2.5\% \leq C_n < 25\%$
R52-53			$C_n \geq 25\%$

For preparations containing a substance classified with N, R50-53, the concentration limits and the resulting classification given in table 1b are applicable.

Table 1b

Acute aquatic toxicity and long-term adverse effects of substance very toxic to the aquatic environment

LC ₅₀ or EC ₅₀ value ("L(E)C ₅₀ ") of substance classified as N, R50-53 (mg/l)	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25\%$	$2.5\% \leq C_n < 25\%$	$0.25\% \leq C_n < 2.5\%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5\%$	$0.25\% \leq C_n < 2.5\%$	$0.025\% \leq C_n < 0.25\%$
$0.001 < L(E)C_{50} \leq 0.01$	$C_n \geq 0.25\%$	$0.025\% \leq C_n < 0.25\%$	$0.0025\% \leq C_n < 0.025\%$
$0.0001 < L(E)C_{50} \leq 0.001$	$C_n \geq 0.025\%$	$0.0025\% \leq C_n < 0.025\%$	$0.00025\% \leq C_n < 0.0025\%$
$0.00001 < L(E)C_{50} \leq 0.0001$	$C_n \geq 0.0025\%$	$0.00025\% \leq C_n < 0.0025\%$	$0.000025\% \leq C_n < 0.00025\%$

For preparations containing substances with a lower LC₅₀ or EC₅₀ value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).

Table 2

Acute aquatic toxicity

LC ₅₀ or EC ₅₀ value ("L(E)C ₅₀ ") of substance classified either as N, R50 or as N,R50-53 (mg/l)	Classification of the preparation N, R50
$0.1 < L(E)C_{50} \leq 1$	$C_n \geq 25\%$
$0.01 < L(E)C_{50} \leq 0.1$	$C_n \geq 2.5\%$
$0.001 < L(E)C_{50} \leq 0.01$	$C_n \geq 0.25\%$
$0.0001 < L(E)C_{50} \leq 0.001$	$C_n \geq 0.025\%$
$0.00001 < L(E)C_{50} \leq 0.0001$	$C_n \geq 0.0025\%$

For preparations containing substances with a lower LC₅₀ or EC₅₀ value than 0.00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).

SCHEDULE 3

Regulation 4(6)

Table 5

Dangerous for the ozone layer

<i>Classification of the substance</i>	<i>Classification of preparation N, R59</i>
N with R59	$C_n \geq 0.1\%$

SCHEDULE 4

Regulation 5

“PART II

PARTICULAR PROVISIONS CONCERNING CERTAIN PREPARATIONS

A

SPECIAL PROVISIONS FOR DANGEROUS PREPARATIONS

Dangerous preparations to be supplied to the general public

1.—(1) The label on the packaging of dangerous preparations intended to be supplied to the general public must in addition to the relevant safety advice bear the relevant safety phrase S1, S2, S45 or S46 in accordance with the approved classification and labelling guide.

(2) When the dangerous preparations referred to in sub-paragraph (1) are classified as very toxic, toxic or corrosive and where it is physically impossible to give the information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

Dangerous preparations intended for use by spraying

2. The label on the packaging containing dangerous preparations intended to be used for spraying shall bear the safety phrase S23 and safety phrase S38 or S51 assigned in accordance with the approved classification and labelling guide.

Dangerous preparations containing a substance affected by the risk phrase R33 (danger of cumulative effects)

3. When a dangerous preparation contains at least one substance required to show the risk phrase R33, that phrase must be shown on the label on the packaging of the dangerous preparation when the concentration of that substance is equal to or higher than 1% unless a different value is shown for that substance in the approved supply list.

Dangerous preparations containing a substance affected by the risk phrase R64 (may cause harm to breast-fed babies)

4. When a dangerous preparation contains at least one substance required to show the risk phrase R64, that phrase must be shown on the label on the packaging of the dangerous preparation when the concentration of that substance is equal to or higher than 1% unless a different value is shown for that substance in the approved supply list.

B

SPECIAL PROVISIONS APPLYING TO ANY PREPARATION

Paints and varnishes containing lead

1.—(1) The label on the packaging of paints and varnishes containing lead in quantities exceeding 0.15% (expressed as weight of lead out of the total weight of the preparation and determined in accordance with ISO Standard 6503/1984) shall bear the following inscription—

“Contains lead. Should not be used on surfaces that are liable to be chewed or sucked by children.”.

(2) In the case of packages containing less than 125 millilitres of the preparations referred to in sub-paragraph (1), the inscription on the label may be—

“Warning! Contains lead.”.

Cyanoacrylate based adhesives

2.—(1) The label on the immediate packaging of glues based on cyanoacrylates shall bear the following inscription—

“Cyanoacrylate.

Danger.

Bonds skin and eyes in seconds.

Keep out of the reach of children.”

(2) Appropriate safety advice shall accompany the package.

Preparations containing isocyanates

3. The label on the packaging of preparations containing isocyanates (whether as monomers, oligomers, prepolymers etc. or as mixtures thereof) shall bear the following inscriptions—

“Contains isocyanates.

See information supplied by the manufacturer.”.

Certain preparations containing epoxy constituents

4. The label on the packaging of preparations containing epoxy constituents with an average molecular weight ≤ 700 shall bear the following inscription—

“Contains epoxy constituents

See information supplied by the manufacturer.”.

Preparations intended to be sold to the general public that contain active chlorine

5. The label on the packaging of preparations containing more than 1% of active chlorine which are intended to be sold to the general public shall bear the following inscription—

“Warning! Do not use together with other products. May release dangerous gases (chlorine).”.

Preparations containing cadmium (alloys) intended to be used for brazing or soldering

6. The label on the packaging of preparations containing cadmium (alloys) intended to be used for brazing or soldering shall bear the following inscriptions—

“Warning! Contains cadmium.

Dangerous fumes are formed during use.

See information supplied by the manufacturer.

Comply with the safety instructions.”.

Preparations containing substances not yet tested completely

7. Where a preparation contains at least one substance which, in accordance with regulation 6(7) of the Notification of New Substances Regulations 1993(12), bears the inscription “Caution – substance not yet fully tested”, the label on the packaging of the preparation must bear the inscription “Warning – this preparation contains a substance not yet tested completely” if that substance is present in a concentration $\geq 1\%$.

Preparations not classified as sensitising but containing at least one sensitising substance

8. The label on the packaging of preparations containing at least one substance classified as sensitising and being present in a concentration $\geq 0.1\%$ or in a concentration greater than or equal to that specified under a specific note for the substance in the approved supply list must bear the inscription–

“Contains (name of sensitising substance). May produce an allergic reaction.”.

Liquid preparations containing halogenated hydrocarbons

9. For liquid preparations which show no flashpoint or a flashpoint higher than 55°C and contain a halogenated hydrocarbon and more than 5% flammable or highly flammable substances, the label on the packaging must bear the following inscription as appropriate–

“Can become highly flammable in use” or “Can become flammable in use”.

Preparations containing a substance assigned the risk phrase R67

10. When a preparation contains one or more substances assigned the risk phrase R67, the label on the packaging of the preparation must bear the following inscription–

“Vapours may cause drowsiness and dizziness”,

when the total concentration of such substances present in the preparation is $\geq 15\%$ unless:

–the preparation is already classified with phrases R20, R23, R26, R68/20, R39/23 or R39/26, or

–the preparation is in a package not exceeding 125 ml.

Cement and cement preparations

11.—(1) The label on the packaging of any cement or cement preparation which would contain, when hydrated, more than 0.0002% soluble chromium (VI) of the total dry weight of the cement but for the use of reducing agents shall be marked with information on the packing date, and on the storage conditions and storage period appropriate to maintaining the activity of the reducing agent and to preventing the content of soluble chromium (VI) from exceeding 0.0002% of the total dry weight of the cement, unless it is supplied or used for controlled, closed and totally automated processes in which cement and cement-containing preparations are handled solely by machines and in which there is no possibility of contact with the skin.

(2) The label on the packaging of any cement or cement preparation containing more than 0.0002% soluble chromium (VI) of the total dry weight of the cement shall bear the inscription:

“Contains chromium (VI). May produce an allergic reaction.”

unless the preparation is already classified and labelled as a sensitiser with phrase R43.”.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. Regulations 3 and 6 of these Regulations correct certain errors in 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”) in transposing provisions of—

- (a) Council Directive 1992/32/EEC (OJ No. L154, 5.6.92, p.1) amending for the 7th time Council Directive 67/548/EEC (OJ No. L196, 16.8.67, p.1) on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (“the substances Directive”); and
- (b) Council Directive 1999/45/EC (OJ No. L200, 30.7.99, p.1) on the classification, packaging and labelling of dangerous preparations (“the preparations Directive”), concerning the labelling of single receptacles and receptacles in outer packagings where the national and international transport rules also apply. Regulation 3 corrects a cross-reference in regulation 9(2) of the principal regulations. Regulation 7 revokes amendments to the principal regulations that were made in error, as they duplicate amendments already made in an earlier instrument.

2. Regulations 4 and 5 amend the principal Regulations in accordance with the provisions of Commission Directive 2006/8/EC (OJ No. L19, 24.1.2006 p.12) amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to the preparations Directive.

3. Regulation 7 amends the Control of Major Accident Hazards Regulations 1999 (S.I. 1999/743) to provide for the Health and Safety Executive to be the enforcing authority save in the circumstance provided for.

4. A copy of the regulatory impact assessment prepared in respect of these Regulations can be obtained from the Health and Safety Executive, Economic Advisers Unit, Rose Court, 2 Southwark Bridge, London, SE1 9HS. A copy of this document has been placed in the library of each House of Parliament.

COMMISSION DIRECTIVE 2006/8/EC

of 23 January 2006

amending, for the purposes of their adaptation 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 of the Member States relating to the classification, packaging and labelling of dangerous preparations

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations ⁽¹⁾, and in particular the first paragraph of Article 20 thereof,

Whereas:

(1) Preparations composed of more than one substance being classified in Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ⁽²⁾ as carcinogenic, mutagenic and/or toxic for reproduction must currently be labelled with risk phrases (R-phrases) to indicate both category 1 or 2 and category 3 classification. However, providing both R-phrases sends a conflicting message. Preparations should therefore only be classified and labelled with the higher category.

(2) For substances very toxic to the aquatic environment (classified as N) and assigned the R-phrases R50 or R50/53, specific concentration limits (SCLs) are currently applied to substances listed in Annex I to Directive 67/548/EEC in order to avoid an underestimation of the hazard. This measure creates distortions between preparations containing substances listed in Annex I to Directive 67/548/EEC, to which SCLs are applied, and those preparations containing substances not yet included in Annex I, but classified and labelled provisionally in accordance with Article 6 of Directive 67/548/EEC and to which no SCLs are applicable. It is therefore necessary to ensure that SCLs are applied in the same way to all preparations containing substances very toxic to the aquatic environment.

(3) On 6 August 2001, the Commission adopted Directive 2001/59/EC ⁽³⁾ adapting to technical progress Directive 67/548/EEC. Directive 2001/59/EC revised the criteria in

Annex VI to Directive 67/548/EEC for the classification and labelling of ozone depleting substances. The revised Annex III now only provides for the assignment of the symbol N in addition to R-phrase R59.

(4) The terminology used to describe the packaging and the labelling requirements in Annex V to Directive 1999/45/EC has raised concerns due to the lack of consistency. It is therefore appropriate to modify the wording in Annex V to Directive 1999/45/EC to make it more accurate.

(5) Annexes II, III and V to Directive 1999/45/EC should therefore be amended accordingly.

(6) The measures provided for in this Directive are in accordance with the opinion of the Committee for the adaptation to technical progress of the Directives on the removal of technical barriers to trade in dangerous substances and preparations established under Article 20 of Directive 1999/45/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes II, III and V to Directive 1999/45/EC are amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 March 2007 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

⁽¹⁾ OJ L 200, 30.7.1999, p. 1. Directive as last amended by Council Directive 2004/66/EC (OJ L 168, 1.5.2004, p. 35).

⁽²⁾ OJ 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive 2004/73/EC (OJ L 152, 30.4.2004, p. 1).

⁽³⁾ OJ L 225, 21.8.2001, p. 1.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 23 January 2006.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX

Directive 1999/45/EC is amended as follows:

1. Annex II is amended as follows:

(a) table VI is replaced by the following table:

Table VI

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration $\geq 0,1$ % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration ≥ 1 % carcinogenic R40 obligatory (<i>unless already assigned R45 (*)</i>)
Mutagenic substances of category 1 or 2 with R46	Concentration $\geq 0,1$ % mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68		Concentration ≥ 1 % mutagenic R68 obligatory (<i>unless already assigned R46</i>)
Substances "toxic for reproduction" of category 1 or 2 with R60 (fertility)	Concentration $\geq 0,5$ % toxic for reproduction (fertility) R60 obligatory	
Substances "toxic for reproduction" of category 3 with R62 (fertility)		Concentration ≥ 5 % toxic for reproduction (fertility) R62 obligatory (<i>unless already assigned R60</i>)
Substances "toxic for reproduction" of category 1 or 2 with R61 (development)	Concentration $\geq 0,5$ % toxic for reproduction (development) R61 obligatory	
Substances "toxic for reproduction" of category 3 with R63 (development)		Concentration ≥ 5 % toxic for reproduction (development) R63 obligatory (<i>unless already assigned R61</i>)

(*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.'

(b) table VI A is replaced by the following table:

Table VI A

Classification of the substance	Classification of the preparation	
	Categories 1 and 2	Category 3
Carcinogenic substances of category 1 or 2 with R45 or R49	Concentration $\geq 0,1$ % carcinogenic R45, R49 obligatory as appropriate	
Carcinogenic substances of category 3 with R40		Concentration ≥ 1 % carcinogenic R40 obligatory (unless already assigned R45 (*))
Mutagenic substances of category 1 or 2 with R46	Concentration $\geq 0,1$ % mutagenic R46 obligatory	
Mutagenic substances of category 3 with R68		Concentration ≥ 1 % mutagenic R68 obligatory (unless already assigned R46)
Substances "toxic for reproduction" of category 1 or 2 with R60 (fertility)	Concentration $\geq 0,2$ % toxic for reproduction (fertility) R60 obligatory	
Substances "toxic for reproduction" of category 3 with R62 (fertility)		Concentration ≥ 1 % toxic for reproduction (fertility) R62 obligatory (unless already assigned R60)
Substances "toxic for reproduction" of category 1 or 2 with R61 (development)	Concentration $\geq 0,2$ % toxic for reproduction (development) R61 obligatory	
Substances "toxic for reproduction" of category 3 with R63 (development)		Concentration ≥ 1 % toxic for reproduction (development) R63 obligatory (unless already assigned R61)

(*) In cases where the preparation is assigned R49 and R40, both R phrases shall be kept, because R40 does not distinguish between the exposure routes, whereas R49 is only assigned for the inhalation route.

2. Annex III is amended as follows:

(a) in Part A, point 2 of section (b)(1) (l), is deleted;

(b) in Part B, table 1 is replaced by the following tables:

Table 1a

Acute aquatic toxicity and long-term adverse effects

Classification of the substance	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
N, R50-53	see Table 1b	see Table 1b	see Table 1b
N, R51-53		$C_n \geq 25$ %	$2,5 \% \leq C_n < 25$ %
R52-53			$C_n \geq 25$ %

Preparations containing a substance classified with N, R50-53, the concentration limits and the resulting classification given in table 1b are applicable.

Table 1b

Acute aquatic toxicity and long-term adverse effects of substances very toxic to the aquatic environment

LC ₅₀ or EC ₅₀ value ("L(E)C ₅₀ ") of substance classified as N, R50-53 (mg/l)	Classification of the preparation		
	N, R50-53	N, R51-53	R52-53
$0,1 < L(E)C_{50} \leq 1$	$C_n \geq 25 \%$	$2,5 \% \leq C_n < 25 \%$	$0,25 \% \leq C_n < 2,5 \%$
$0,01 < L(E)C_{50} \leq 0,1$	$C_n \geq 2,5 \%$	$0,25 \% \leq C_n < 2,5 \%$	$0,025 \% \leq C_n < 0,25 \%$
$0,001 < L(E)C_{50} \leq 0,01$	$C_n \geq 0,25 \%$	$0,025 \% \leq C_n < 0,25 \%$	$0,0025 \% \leq C_n < 0,025 \%$
$0,0001 < L(E)C_{50} \leq 0,001$	$C_n \geq 0,025 \%$	$0,0025 \% \leq C_n < 0,025 \%$	$0,00025 \% \leq C_n < 0,0025 \%$
$0,00001 < L(E)C_{50} \leq 0,0001$	$C_n \geq 0,0025 \%$	$0,00025 \% \leq C_n < 0,0025 \%$	$0,000025 \% \leq C_n < 0,00025 \%$

For preparations containing substances with a lower LC₅₀ or EC₅₀ value than 0,00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).'

(c) in part B, table 2 is replaced by the following table:

Table 2

Acute aquatic toxicity

LC ₅₀ or EC ₅₀ value ("L(E)C ₅₀ ") of substance classified either as N, R50 or as N, R50-53 (mg/l)	Classification of the preparation N, R50
$0,1 < L(E)C_{50} \leq 1$	$C_n \geq 25 \%$
$0,01 < L(E)C_{50} \leq 0,1$	$C_n \geq 2,5 \%$
$0,001 < L(E)C_{50} \leq 0,01$	$C_n \geq 0,25 \%$
$0,0001 < L(E)C_{50} \leq 0,001$	$C_n \geq 0,025 \%$
$0,00001 < L(E)C_{50} \leq 0,0001$	$C_n \geq 0,0025 \%$

For preparations containing substances with a lower LC₅₀ or EC₅₀ value than 0,00001 mg/l, the corresponding concentration limits are calculated accordingly (in factor 10 intervals).'

(d) in part B, table 5 of point II, is replaced by the following table:

Table 5

Dangerous for the ozone layer

Classification of the substance	Classification of the preparation N, R59
N with R59	$C_n \geq 0,1 \%$

3. Annex V is replaced by the following:

‘ANNEX V

SPECIAL PROVISIONS CONCERNING THE LABELLING OF CERTAIN PREPARATIONS

A. For preparations classified as dangerous within the meaning of Articles 5, 6 and 7

1. *Preparations sold to the general public*

1.1. The label on the packaging containing such preparations, in addition to the specific safety advice, must bear the relevant safety advice S1, S2, S45 or S46 in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

1.2. When such preparations are classified as very toxic (T+), toxic (T) or corrosive (C) and where it is physically impossible to give such information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

2. *Preparations intended for use by spraying*

The label on the packaging containing such preparations must compulsorily bear the safety advice S23 accompanied by safety advice S38 or S51 assigned to it in accordance with the criteria laid down in Annex VI to Directive 67/548/EEC.

3. *Preparations containing a substance assigned phrase R33: Danger of cumulative effects*

When a preparation contains at least one substance assigned the phrase R33, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

4. *Preparations containing a substance assigned phrase R64: May cause harm to breastfed babies*

When a preparation contains at least one substance assigned phrase R64, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the concentration of this substance present in the preparation is equal to or higher than 1 %, unless different values are set in Annex I to Directive 67/548/EEC.

B. For preparations irrespective of their classification within the meaning of Articles 5, 6 and 7

1. *Preparations containing lead*

1.1. *Paint and varnishes*

The label on the packaging of paints and varnishes containing lead in quantities exceeding 0,15 % (expressed as weight of metal) of the total weight of the preparation, as determined in accordance with ISO standard 6503/1984, must show the following particulars:

“Contains lead. Should not be used on surfaces liable to be chewed or sucked by children”.

In the case of packages the contents of which are less than 125 millilitres, the particulars may be as follows:

“Warning! Contains lead”.

2. *Preparations containing cyanoacrylates*

2.1. *Adhesives*

The label on the immediate packaging of adhesives based on cyanoacrylate must bear the following inscriptions:

“Cyanoacrylate

Danger

Bonds skin and eyes in seconds

Keep out of the reach of children”.

Appropriate advice on safety must accompany the package.

3. *Preparations containing isocyanates*

The label on the packaging of preparations containing isocyanates (as monomers, oligomers, prepolymers, etc., or as mixtures thereof) must bear the following inscriptions:

“Contains isocyanates.

See information supplied by the manufacturer”.

4. *Preparations containing epoxy constituents with an average molecular weight ≤ 700*

The label on the packaging of preparations containing epoxy constituents with an average molecular weight ≤ 700 must bear the following inscriptions:

“Contains epoxy constituents.

See information supplied by the manufacturer”.

5. *Preparations sold to the general public which contain active chlorine*

The label on the packaging of preparations containing more than 1 % of active chlorine must bear the following particular inscriptions:

“Warning! Do not use together with other products. May release dangerous gases (chlorine)”.

6. *Preparations containing cadmium (alloys) and intended to be used for brazing or soldering*

The label on the packaging of the above mentioned preparations must bear the following inscription printed in clearly legible and indelible characters:

“Warning! Contains cadmium.

Dangerous fumes are formed during use.

See information supplied by the manufacturer.

Comply with the safety instructions”.

7. *Preparations available as aerosols*

Without prejudice to the provisions of this Directive, preparations available as aerosols are also subject to the labelling provisions in accordance with points 2.2 and 2.3 of the Annex to Directive 75/324/EEC as last amended by Directive 94/1/EC.

8. *Preparations containing substances not yet tested completely*

Where a preparation contains at least one substance which, in accordance with Article 13.3 of Directive 67/548/EEC, bears the inscription "Caution — substance not yet tested completely", the label on the packaging of the preparation must bear the inscription "Warning — this preparation contains a substance not yet tested completely" if this substance is present in a concentration $\geq 1\%$.

9. *Preparations not classified as sensitising but containing at least one sensitising substance*

The label on the packaging of preparations containing at least one substance classified as sensitising and being present in a concentration equal to or greater than 0,1 % or in a concentration equal to or greater than that specified under a specific note for the substance in Annex I to Directive 67/548/EEC must bear the inscription:

"Contains (name of sensitising substance). May produce an allergic reaction".

10. *Liquid preparations containing halogenated hydrocarbons*

For liquid preparations which show no flashpoint or a flashpoint higher than 55 °C and contain a halogenated hydrocarbon and more than 5 % flammable or highly flammable substances, the label on the packaging must bear the following inscription as appropriate:

"Can become highly flammable in use" or "Can become flammable in use".

11. *Preparations containing a substance assigned phrase R67: vapours may cause drowsiness and dizziness*

When a preparation contains one or more substances assigned the phrase R67, the label on the packaging of the preparation must carry the wording of this phrase as set out in Annex III to Directive 67/548/EEC, when the total concentration of these substances present in the preparation is equal to or higher than 15 %, unless:

— the preparation is already classified with phrases R20, R23, R26, R68/20, R39/23 or R39/26,

— or the preparation is in a package not exceeding 125 ml.

12. *Cements and cement preparations*

The label on the packaging of cements and cement preparations containing more than 0,0002 % soluble chromium (VI) of the total dry weight of the cement must bear the inscription:

"Contains chromium (VI). May produce an allergic reaction"

unless the preparation is already classified and labelled as a sensitiser with phrase R43.

C. For preparations not classified within the meaning of Articles 5, 6 and 7 but containing at least one dangerous substance

1. *Preparations not intended for the general public*

The label on the packaging of preparations referred to in Article 14.2.1(b) must bear the following inscription:

"Safety data sheet available for professional user on request".

Proposals for new amending Regulations about the Classification, Packaging and Labelling of Chemicals: CHIP 3.2

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