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Technical support for the preparation of Annexes for
the draft EU legislation implementing the Globally Harmonised
System for Classification and Labelling of Chemicals (GHS)

FINAL PROJECT REPORT

20 December 2005

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ENVIRONMENTAL LAW & POLICY

This Draft Report has been prepared by Milieu Ltd, under contract to the European Commission's DG JRC, IHCP (Contract n. CCR.IHCP.C431044.XO), drawing on the expertise of Milieu Associates, Jim Hart, Iona Pratt and Bob Warner, together with Milieu's Principal, Gretta Goldenman.

The views expressed herein are those of the consultants alone and do not represent the official views of the Commission.

**Technical support for the preparation of the Annexes for the draft EU legislation implementing
the Globally Harmonised System for Classification and Labelling of Chemicals (GHS)**
A project for DG JRC carried out by Milieu Ltd

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Abbreviations used in project report

ATE	Acute Toxicity Estimate
ATP	Adaptation to Technical Progress
BCF	Bioconcentration Factor.
CBI	Confidential Business Information
CEN	European Committee for Standardisation
CMR	Carcinogenicity, Mutagenicity and Reproductive Toxicity (refers to current EU classifications)
CS/HCCS	Coordinating Group for the Harmonisation of Chemical Classification Systems
DG	Directorate General
E	Symbol indicating classified as “Explosive”
EC	European Community
ECB	European Chemicals Bureau
ECOSOC	UN Economic and Social Committee
EEA	European Economic Area
EEC	European Economic Community
EU	European Union
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IARC	International Agency for Research on Cancer
IOMC	Interorganisational Programme for the Sound Management of Chemicals
ILO	International Labour Organisation
ISO	International Standards Organisation
log K_{ow}	logarithm of the octanol-water partition coefficient
OECD	Organisation for Economic Co-operation and Development
OJ	Official Journal of the European Union
pm	Pro memoria (indicating a section that will be completed at a later date)
PPE	Personal Protective Equipment
PS	GHS Precautionary Statement
(Q)SAR	(Quantitative) Structure Activity Relationship
REACH	Draft Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

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R-phrase	EU term corresponding to GHS Hazard Statement
SAR	Structure Activity Relationship
SDS	Safety Data Sheet
SPR	Structure Property Activity Relationship
STOST	Specific Target Organ Systemic Toxicity
S-phrase	EU term corresponding to GHS Precautionary Statement
TC	EU Technical Committee
TGD	Technical Guidance Document
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNCETDG/GHS	UN Committee on the Transport of Dangerous Goods and on the Globally Harmonised System of Classification
UNSCETDG	UN Sub-Committee of Experts on the Transport of Dangerous Goods
UNSCEGHS	UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals.
UNECE	UN Economic Commission for Europe
UN RTDG	UN Recommendations on the Transport of Dangerous Goods Model Regulations
WG	Commission Working Group
WSSD	World Summit for Sustainable Development

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Executive Summary

Introduction

This report explains the methodology and the guiding principles used to prepare technical Annexes for a draft EU Regulation on classification and labelling that will implement the Globally Harmonised System for Classification and Labelling of Chemicals (GHS)¹. These draft technical annexes are intended as texts to replace the corresponding sections in the existing EU regulatory framework, currently covered by separate legislative instruments on the classification and labelling of dangerous substances (Directive 67/547/EEEC) and dangerous preparations (Directive 1999/45/EC).

The work involved the following main tasks:

- drafting of a proposal for the technical Annexes to the new EU regulations on classification and labelling, implementing the GHS criteria for supply and use;
- integration of the criteria for substances and mixtures and of classification and labelling provisions, as is done in the GHS;
- development of proposals for the incorporation of precautionary statements and criteria for their application; and
- development of proposals for how substances currently classified according to the existing EU criteria for supply and use can be “translated” or “migrated” to their corresponding classification according to the GHS criteria.

In proposing ways of implementing the GHS in EU legislation, the report follows closely the principles stated in the Commission Status Paper presented to the GHS coordination meeting in Helsinki June 2005. The core principles underlying the approach taken were as follows:

- The new framework will maintain (or enhance) the existing standard of protection;
- The new scheme will be as close as possible to the existing EU scheme; this will also facilitate implementation by the industries concerned;
- The new scheme will implement as much as possible of the currently agreed GHS criteria into EU legislation.

The report provides a detailed commentary on issues related to points in the draft Annexes, including, where relevant, different options for addressing these issues and suggestions for where future work may be needed. Appended to the report are the draft Annexes themselves.

The principle followed in the draft Annexes for implementation of the GHS proposals has been to replace the current EU classification criteria wherever possible with the criteria of the corresponding hazard class and hazard category from the GHS. Provisions in the current EU legislation not (as yet) covered by GHS have been retained in the draft Annexes, and can continue to be retained as long as they are considered necessary or until they are incorporated into the harmonised system.

A basic function of both the Dangerous Substances Directive and the Dangerous Preparations Directive is to provide a basis for distinguishing “*dangerous*” from “*non-dangerous*” chemicals on the basis of agreed criteria. Over 20 other EU legislative acts currently reference

¹ This report and the draft Annexes were prepared in the context of a contract awarded to Milieu Ltd by the Joint Research Centre of the European Commission (Contract N° CCR.IHCP.C431044.XO).

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these classification criteria, either directly or indirectly, and in this context a reference to a classified substance means that it is classified as “*dangerous*”. Other chemicals may have no hazards above the threshold of concern, and these chemicals are “*not classified*” as dangerous. However, in the current EU legislation there is provision for some hazards that are not classified as “*dangerous*”, but nevertheless are of some concern, to be included as “*additional labelling provisions*”.

The GHS system includes a definition of *hazard class* (the nature of the physical, health or environmental hazard) and *hazard category* (the division of hazard class according to severity), but not a definition for the process of classification or for the concept of “*dangerous*”. Thus classification under the GHS system is a more neutral process of determining a hazard class, and not one of determining which chemicals should be classified as “*dangerous*”.

The approach adopted for the preparation of the draft Annexes combines the GHS and the current EU systems. An administrative distinction is made between those hazard classes which are “*classified as dangerous*” (the subject of draft Annex I) and those which should be included within the new regulatory framework but which would be “*classified but not as dangerous*”. The latter are included in draft Annex II on special labelling provisions. This has made it possible to maintain the current level of protection and to maintain the current concept of “*dangerous*” whilst incorporating virtually all the new elements from the GHS system.

During the final consultation on this report, our view was asked on the relevance of maintaining this concept in the draft legislation. We have described a three-stage process involving hazard identification, hazard classification, and a third stage in which a distinction is made between those hazards which are considered as “*dangerous*” and those that are “*classified, but not as dangerous*”, but which still should be included within this regulatory framework. We regard this distinction as important as it reflects concepts currently deeply embedded in the EU regulatory framework for chemical controls.

However, we also recognise that an alternative approach is possible. The distinction between “*hazardous*” as reflected by the GHS building blocks and “*dangerous*” as currently understood in the EU system could be ignored. Classification could be confined to a two-stage process whereby all GHS classes and categories, those included in the current EU system and the new GHS elements, are treated equally in the hazard classification step. This would imply that the relevant Parts of Annex II in this document are transferred to Annex I. The Annexes to this report have been drafted so that it is possible to make such changes editorially as required.

Discussion of Options for the Technical Annexes

The structure of the draft Annexes appended to this report are as follows:

- Annex I – Classification and Labelling Requirements for Dangerous Substances and Mixtures
- Annex II – Special Provisions for Labelling and Packaging
- Annex III – Hazard Statements
- Annex IV – Precautionary Statements
- Annex V – Pictograms
- Annex VI – Harmonised List of Dangerous Substances

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Draft Annex I sets forth the GHS criteria for classification according to physical, health and environmental properties. It also includes additional EU classifications not (yet) covered by the GHS, as well as criteria for allocation of Precautionary Statements. Where issues are raised in replacing the current EU classification criteria with the GHS criteria, the discussion sets out options to consider, and in most cases states which is the preferred option.

Draft Annex II provides the GHS hazard classes and categories for physical, and health hazards that are currently not “*classified as dangerous*” according to existing EU legislation. It also retains some of the current EU “additional R-phrases” for certain physical and health hazards, as well as special labelling and packaging provisions. Confidentiality for the chemical identity of a substance is also treated in this section.

Draft Annex VI suggests a process for “translating” substances currently classified according to the current EU criteria to a draft Annex VI of the new Regulation, which will consist of a list of dangerous substances with formally harmonised classification and labelling information. It proposes that this new Annex VI includes Tables of equivalence that will enable simple and transparent conversion for all substances and preparations currently classified according to the EU criteria without the need for reassessment of the hazard classification *ab initio*. The Annex would also retain the current information in Annex I of Directive 67/548 in a legally secure text.

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Introduction

Project commissioning and scope

This project has been carried out following the acceptance of Milieu's bid to carry out work described by the Commission in the Restricted Call for Tender issued by the Joint Research Centre of the European Commission for technical support for the preparation of Annexes for the draft EU legislation implementing the Globally Harmonised System for Classification and Labelling of Chemicals (GHS), (Contract N° CCR.IHCP.C431044.XO).

The overall aim of the project was to develop and finalise existing draft technical annexes containing the criteria for classification and labelling provisions for the Draft Regulation on classification and labelling. The revised technical annexes, following discussion and amendment of the content by the European Commission and Member States, will replace the corresponding sections in the existing classification and labelling regulatory framework, currently covered by separate legislative instruments on the classification and labelling of dangerous substances and dangerous preparations.

The work involved the following main tasks:

- drafting of a proposal for the technical Annexes to the new EU regulations on classification and labelling, implementing the GHS criteria for supply and use;
- integration of the criteria for substances and mixtures and of classification and labelling provisions, as is done in the GHS,
- development of proposals for the incorporation of precautionary statements and criteria for their application
- development of proposals for how substances currently classified according to the existing EU criteria for supply and use can be “translated” or “migrated” to their corresponding classification according to the GHS criteria.

Report structure and scope

This report explains the methodology and the guiding principles used in drafting the technical Annexes to the draft Regulation. The report provides a detailed commentary on issues related to points in the draft Annexes, including, where relevant, different options for addressing these issues and suggestions for where future work may be needed.

The report also includes the drafts of the technical Annexes to the planned EU Regulation on classification and labelling, implementing the GHS criteria for classification and labelling provisions for supply and use.

The starting point for drafting the technical Annexes was the draft technical Annexes X and Y prepared by Dr Iona Pratt in 2002 whilst seconded to the European Chemicals Bureau (ECB) as a visiting scientist. These needed revising and updating to reflect more recent UN ECOSOC agreements on several issues. The majority of these recent agreements related to Part 3 of GHS - classification for health properties - as detailed in the tender document, Technical Annex A:

- Changes in terminology in chapter 3.6 (reproductive toxicity)

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- Criteria for classification for aspiration hazards
- Criteria for respiratory irritation
- Criteria for narcotic effects
- Criteria for classifying mixtures containing substances which may cause effects on lactation
- Changes in the chapter on acute toxicity (chapter 3.1)

A further issue highlighted in the Technical Annex A of the tender document was that of the formula for calculating the Acute Toxicity Estimate for a mixture, for which problems have been identified in the application e.g. to gases.

The draft Annexes X and Y had adopted the approach of separating the criteria for classification (Annex X) from provisions for labelling (Annex Y), following discussions in the White Paper Technical Working Group on Classification and Labelling which met in 2001 – 2002 to develop advice for the Commission on development of a future Community classification and labelling system for substances and preparations. However, the Call for Tender indicated that “As a first option, labelling provisions should preferably also be introduced into the same Annex on the basis of the adopted GHS text in line with the format used in the GHS document if no relevant arguments against this idea can be found”. This approach has therefore been adopted in the revised technical Annexes, in addition to integration of the criteria for substances and mixtures, as is done in the GHS.

Documents

The documentary sources used for this work are listed in the references. In addition to the formal call for Tender, the principal published documents were:

- the UN GHS Text (as amended in June 2005) [1]
- Directives 67/548/EEC [2] and 1999/45/EC [3] as amended, together with their Annexes
- the draft REACH proposal, as published in the Official Journal [4]

Unpublished documents of particular relevance were:

- Draft Annexes incorporating GHS criteria prepared by Dr Iona Pratt in 2002 for the ECB
- Reports of the Commission White Paper Technical Working Groups on Classification and Labelling (ECBI/03/02) [5] and other relevant material submitted by the ECB
- Commission Status Paper [6] presented to the GHS coordination meeting in Helsinki June 2005 and other reports made to this meeting.
- Final report: Technical Assistance to the Commission on the implementation of the GHS. Ökopol Institute for Environmental Strategies, July, 2004 [7]

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Methodology and guiding principles

This project was carried out as a desk-based exercise, drawing on the expertise of Milieu's Associates, Jim Hart, Iona Pratt and Bob Warner, and Principal, Gretta Goldenman. Throughout the work liaison was maintained with the formal Commission project liaison officer, Gunilla Ericsson.

In addition, experts with special experience of certain areas of classification and labelling (in particular with regard to physical-chemical and environmental hazards) were consulted concerning factual matters related to the criteria.

In approaching the tasks required by the Contract, we recognised that the issues involved cannot be considered in isolation. In particular the underlying principles enshrined in the GHS and the existing (and proposed REACH) regulatory framework for both supply and transport in the EU are crucial influences on the content of the proposed Annexes. We have therefore prefaced our proposals with a discussion of these principles and set out some of the constraints and opportunities which result.

In proposing ways of implementing the GHS in EU legislation we have tried to follow closely the principles stated in the Commission Status Paper presented to the GHS coordination meeting in Helsinki June 2005 [6], together with other reports on this issue.

The core principles underlying our approach to this work were as follows:

- The new framework will maintain (or enhance) the existing standard of protection,
- The new scheme will be as close as possible to the existing EU scheme.

The body of this report is therefore a consideration of the issues affecting the options for the Annexes and, where relevant, arguments for our suggestions as to how the GHS requirements can be implemented in EU legislation. In some cases, where different approaches are possible, we have also included arguments to consider different options where appropriate.

Scope of the future legislation

Since all chemical substances and mixtures in commerce are made in a workplace (including consumer substances and mixtures), transported and handled during shipment and transport by workers, and used by workers and/or consumers, there are no complete exemptions from the scope of the system for any particular type of substance or mixture. For example, pharmaceuticals are covered by workplace and transport requirements in the manufacturing, storage, and transport stages of the life cycle.

Currently, separate criteria for classification of hazardous chemicals apply in the two main regulated sectors: Supply and Use, and Transport. Implementation of GHS will lead to a common basis for classification and labelling for use in both sectors. In theory, therefore, the future EU legislation could encompass the requirements both for Supply and Use and for Transport. We have taken care to ensure that our proposals will facilitate this and have made specific suggestions to eliminate differences and confusion. Our proposals provide the criteria for allocating substances and mixtures to all of the current GHS hazard classes and hazard

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categories with one exception, “corrosive to metals²”, and thus provide the basis for a classification system that can be used by both Supply and Use and Transport.

Whilst working in collaboration with DG TREN, the Commission Status report [6] on the Implementation of GHS makes it clear, however, that the present Regulation will implement the GHS criteria for supply and use only as a collaboration between DG ENTR, DG ENV and DG JRC. The status report also makes clear that DG TREN, the Commission service responsible for implementing the GHS provisions on Transport of Dangerous Goods, are intending to up-date their Directives [8] [9] in 2007 and 2009. Since implementation of the GHS provisions in EU Transport Directives will require the implementation of GHS in the UN Model Regulations, the implementation in this first step will occur separately in the two sectors. When GHS has been implemented in both sectors, there will be further opportunities to consider an integration of the provisions of the two sectors.

Essential terminology

Although not expressly stated in the recitals³ of either Directive 67/548/EEC [2] or Directive 1999/45/EC [3], a basic function of these Directives is to provide a basis for distinguishing “*dangerous*” from “*non-dangerous*” chemicals on the basis of agreed criteria. As a result, these criteria form the basis for setting the scope of much downstream EU legislation. Over 20 EU legislative instruments refer to the classification criteria in these two Directives either directly or indirectly, and in this context, reference to a classified substance means that it is classified “*as dangerous*”.

The GHS system includes formal definitions of a number of the terms used in the system. The GHS definitions include a definition of *hazard class* (the nature of the physical, health or environmental hazard) and *hazard category* (the division of hazard class according to severity). They do not however include a definition for the process of classification or for the concept of “*dangerous*”⁴, leaving it to individual jurisdictions to set an appropriate level of protection.

The question of the terminology is not merely an academic issue. The implications of changing the current specific use of the word “classified” as meaning a chemical classified “*as dangerous*” under the current EU legislation to a more neutral reference to a hazard class is the background for much of the subsequent discussion in this report.

The practice of hazard classification and labelling has led to the development of a raft of expressions to describe steps in the process. Several of the texts (e.g. the UN GHS Document [1]) contain definitions but these may not be fully consistent with current usage. There is the potential for some confusion and we believe it is important to explain how we will use terms in this report.

All chemicals possess intrinsic properties. These can be identified and sometimes quantified. In both current EU legislation and in the GHS, the term *hazard* is used to describe those

² This hazard class is not a concern for human health or the environment, but reflects concerns for the integrity of transport packaging.

³ The recitals are the “whereas” clauses prefacing EU legislation giving the reasons and background for the legislation proposed.

⁴ The GHS labelling system does distinguish between the signal words “Danger” for certain categories of hazard and “Warning”, for other, lower, categories of hazard.

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properties which signal the potential to harm. In order to provide information to manage chemicals there are schemes which characterise the hazards in a systematic way – these are *classification* schemes.

The current EU classification scheme is concerned with identifying the existence of the hazard and qualifying it according to the degree of the hazard, using set *criteria*. The activity of identifying and characterising the hazards is described as *hazard classification* or simply *classification*. Some hazards are of a kind or magnitude which warrants special concern, and are regarded as “*dangerous*”. Thus a particular chemical may be “*classified as dangerous*” because a hazard exceeds an agreed threshold. Both the UN Transport classification system (UN RTDG) and the EU supply and use classification systems use the term “*dangerous*” to indicate chemicals which are of particular concern. Information on hazard is usually transmitted by a label on a package. For chemicals “*classified as dangerous*” the label is prescribed by law, although there is some discretion in the way the elements are applied.

Other chemicals may have no hazards above the threshold of concern, and these chemicals are “*not classified as dangerous*”. In the jargon of the EU Classification and Labelling Working Groups, these compounds are “Not classified”.

In addition, some chemicals may have other hazards which are not “*classified as dangerous*” that are nevertheless of concern under certain circumstances⁵. As a result, in current EU legislation there are requirements to label certain chemicals to draw attention to special concerns.

In this report, we have attempted to resolve this dilemma by making it clear which hazard classes (and, where relevant, categories) are considered as “*classified as dangerous*” and to distinguish these clearly from the hazard classes (and, where relevant, categories) that are “*classified but not as dangerous*”, but where legally binding provisions are required.

The approach that has been adopted combines the GHS and the current EU approaches, in a way that we consider is consistent with both approaches.

The first stage of the process is hazard identification. This step identifies the intrinsic properties that can give rise to a hazard, either on the basis of test data or on the basis of other information.

The second stage of the process is hazard classification. This step compares the hazards that have been identified with a set of agreed criteria. Wherever possible, we have used the criteria agreed by the GHS. In other cases, i.e., for hazards not covered by the GHS, the criteria from the current EU system have been used. The result of this process is the allocation of a chemical to a particular hazard class or, for some hazard classes, a hazard category within that hazard class⁶.

⁵ In the current EU legislation these are not identified as “hazards” or described as “classified” but are merely described as additional properties.

⁶ It should be noted that the GHS terminology of hazard class and categories can equally apply to the current EU criteria, including the so-called additional properties. R31 (“Contact with acids liberates toxic gas”) and R32 (“Contact with acids liberates very toxic gas”) can be regarded as hazard statements assigned to two different categories of a single hazard class. In the current EU legislation, this hazard class is not however regarded as “*dangerous*”.

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As a final step, an administrative distinction has been made between those hazard classes which are “*classified as dangerous*” and those which are “*classified, but not as dangerous*”. For hazards evaluated using the current EU criteria this distinction is already clear from the current Annex VI to Directive 67/548/EEC. For hazards evaluated using the GHS criteria, we have tried to equate the GHS hazard classes and categories with the hazards already in Annex VI that the GHS criteria replace, and to reproduce as closely as possible the current distinction between what is considered as “*dangerous*” and what is not⁷.

We have included the hazard classes and categories that are “*classified as dangerous*” in the draft Annex I, and the hazard classes and categories that are “*classified, but not as dangerous*” in the draft Annex II. Hence, both Annex I and Annex II contain hazard classes and categories from both the GHS criteria and the criteria for hazards in the current EU legislation that are not (yet) part of the GHS.

Although the process of hazard identification and hazard classification is identical in both Annex I and Annex II, we have not included any reference to “classification” in the title of Annex II. In order to maintain consistency with the current practice in both Directive 67/548/EEC [2] and 1999/45/EC [3]⁸, we have used the wording “Special labelling provisions” for the title of Annex II⁹. Omission of the word “classification” in the Title of the Annex in this draft is deliberate in order to avoid any possible confusion with the concept of “*classified as dangerous*”.

By using this approach we feel that it has been possible to maintain the current level of protection in general, whilst at the same time incorporating virtually all the new elements from the GHS system as well as retaining elements of the current EU system not covered by the GHS at present.

During the final consultation on this report, our view was asked on the relevance of maintaining the concept of “*classification as dangerous*” in the draft legislation. We have visualised a three stage process in which the final step is the development of the distinction between those hazards which are considered as “*dangerous*” and those which should be included within this regulatory framework but which would be “*classified but not as dangerous*” within the meaning of the current EU system. We regard this distinction as important as it reflects concepts deeply embedded in the current EU regulatory framework for chemical controls. For this reason it forms the firm basis of our recommendation.

It has been suggested to us, however, that an alternative approach is possible. The distinction between “hazardous” as reflected by the GHS building blocks and “dangerous” as currently understood in the EU system could be ignored and classification confined to a two-stage process. This would imply that the relevant Parts of Annex II in this document are transferred to Annex I. We have drafted the Annexes in a way that will make it possible to adjust the

⁷ Hazard classes in the GHS not covered by the current EU legislation present particular difficulties in this respect. This is discussed in more detail under the specific headings in the report below.

⁸ Sections 2.2.6 and 3.2.8 relating to additional R-phrases in Annex VI to Directive 67/548/EEC do not refer to substances as “classified”, but state that these R-phrases “may be assigned”. Annex V to Directive 1999/45/EC is titled “Special Provisions concerning the Labelling of Certain Preparations”.

⁹ We have included other packaging and labelling requirements not directly related to the assignment of hazard classes and categories in Annex II. These additional packaging and labelling provisions could be included in a quite separate Annex if required, but they are retained here to maintain consistency with current legislation.

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level of protection afforded by the concept of “dangerous” by moving editorially hazard classes and categories between the two different Annexes.

These options are discussed further in the General Introduction to Annex II, later in this report.

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Background

The current EU regulatory framework

The current EU system for chemical classification and labelling of dangerous substances [2] and dangerous preparations [3] is sophisticated and provides a high level of protection to citizens, workers and the environment. The system has evolved gradually over nearly 40 years and in doing so has obtained a high degree of acceptance by stakeholders and industry, including those outside the EU. It is effective and proportionate, delivering both protection and the tools for a single market in chemicals. The scheme is an integral part of the overall EU regulatory framework for chemicals, providing an agreed basis on which to identify hazards that are addressed in risk management legislation (“downstream” legislation such as the Marketing and Use Directives [10] or the Major Accident Hazards Directive [11]). Major investments in the EU scheme have been made by legislators and business and great care has been taken to ensure smooth adoption by successive candidate and new Member States.

In global terms the EU scheme is admired as effective and proportionate: it delivers its mission of protection and market facilitation in a transparent and effective manner. It has been used as the basis for a number of non-EU approaches to classification and labelling for supply.

On the other hand there are differences in principle and practice between the EU scheme and those used by many of our major trading partners, particularly the United States. In addition the scheme differs substantially from the widely accepted UN scheme relating to the transport of dangerous goods – which has been adopted for EU application.

The EU scheme delivers a very high standard of information both in terms of the chemicals themselves and any hazards through the different elements listed above. We do not have information to weigh the value of the different elements. It is not possible to argue that any one of these elements does not contribute to protection and can be abandoned.

The working assumption must therefore be that each element of the existing EU scheme is part of the protection package and that the new system should be “as close as possible to the existing EU scheme”. With the introduction of GHS each element must be checked to see if it is covered by GHS and, if not, it should be retained. Nothing should be removed from the current scheme unless it can be unequivocally shown that it does not contribute to protection. Indeed, in the existing EU scheme to do so would be contrary to the principles of GHS.

The globally harmonised scheme for classification and labelling

Following the agreement at the 1992 UNCED¹⁰ meeting in Rio de Janeiro to develop a globalised scheme for classification and labelling, OECD and United Nations fora¹¹ elaborated harmonised criteria for the classification of substances and mixtures for physical,

¹⁰ United Nations Conference on Environment and Development.

¹¹ UN organisations involved in this process include ECOSOC (Economic and Social Committee), UNCETDG/GHS (UN Committee on the Transport of Dangerous Goods and on the Globally Harmonised System of Classification), UNSCETDG (UN Sub-Committee of Experts on the Transport of Dangerous Goods) and the UNSCEGHS (UN Sub-Committee of Experts on the Globally Harmonised System of Classification and Labelling of Chemicals). Other organisations run either wholly or in part by the UN include the IOMC (Interorganisational Programme for the Sound Management of Chemicals), the Coordinating Group for the Harmonisation of Chemical Classification Systems (CS/HCCS) and the International Labour Organisation (ILO).

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health and environmental hazards, and an ILO working group developed a harmonised scheme for Hazard Communication, including labels and safety data sheets (SDS). These various elements, together with important contextual information such as statements of purpose and scope, comprised the initial GHS text. This was approved at the 2003 UN ECOSOC meeting.

The work focused on developing an internationally harmonised system for the supply and use of dangerous substances and mixtures, since a globally harmonised system for transport, the UN RTDG [12], was already in existence at the time of the 1992 UNCED meeting. However a primary objective was to develop an internationally harmonised system that would ensure as far as possible that the new system for supply and use was compatible with the existing UN RTDG. Thus the GHS integrates classification, labelling and hazard information transfer systems for (a) transport and (b) supply although the two systems will draw on different elements of the system as appropriate for their individual needs (the “building block” approach – see discussion below).

The EU Member States and the Commission played a major part in the development of the GHS, by participating in the various OECD, UN and ILO working groups. The GHS system of classification, labelling and hazard communication (hazard information transfer) has many similarities to the current EU system. EU Member States fully endorsed the initial GHS text in 2003 and have similarly endorsed the first round of changes which have recently been published.

Subsequent high-level commitments (e.g. the World Summit for Sustainable Development (WSSD) in Johannesburg in 2002), confirmed in the Commission’s explanatory memorandum to its 2003 proposal to revise Directive 67/548/EEC to introduce the GHS in the EU were made in the interests of the global environment and the sound management of chemicals.

Introduction of the GHS to the EU

Following the above commitments the Commission has commenced work on a draft instrument. An update on progress is outlined in a Commission Status Paper [6] which was presented to the Commission WG meeting in Helsinki on 14 June 2005. The paper makes a number of important statements of principle, in particular that incorporation should be:

“as close as possible to the existing EU scheme”

and that the GHS measure should aim to come into effect at the same time as REACH. It also highlights the potential impact of GHS on “downstream” legislation such as Major Accident Hazard legislation [11].

Chapter 1.1 of the GHS text lays out a number of important principles. In part these derive from the nature of the GHS. The GHS is a scheme where conventional terms such as implementation, adoption and introduction are used interchangeably without specifically defining their precise meaning. These terms are easily confused, especially to those more familiar with the context of the Treaty and the strict obligation on MS to implement Directives. Despite the firm commitments made by UN members, the GHS is a non-binding scheme; its success relies on voluntary introduction by jurisdictions in forms and to the extent appropriate to the needs of the region or country. Agreement in the UN does not impose a binding obligation to take up the GHS. The GHS provides a framework that allows jurisdictions to *incorporate* GHS in their regulatory regimes rather than overturning them. This is consistent with the fact that GHS is a *harmonised* scheme, not a Model Regulation (e.g. the UN RTDG [12]). It brings together existing approaches and seeks to be inclusive

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rather than applying a prescriptive approach. There is no process of UN scrutiny with respect to adoption, and each jurisdiction is free to progress as local needs demand.

GHS scope mandate (GHS 1.1.2)

This section of the GHS makes it clear that harmonised classification principles and hazard communication elements are proposed for all substances and mixtures of substances but it is not necessary to apply the harmonised system at all stages of the life cycle of a chemical or to certain substances and mixtures. It does provide for some products (such as medicines) to be excluded from GHS *labelling* at the point of “intentional intake”. For example, at the point of intentional human intake or ingestion, or intentional application to animals, substances or mixtures (products) such as human or veterinary pharmaceuticals are not subject to hazard labelling. Similarly, products such as foods that may have trace amounts of food additives or pesticides in them are not intended to be labelled under GHS to indicate the presence or hazard of such chemicals. This is compatible with current EU legislation [2] [3]

However, the scope of the GHS makes it clear that any such chemicals should be included in GHS for worker protection and transport if there is potential exposure. As a result of this requirement we cannot identify any chemicals which would be completely excluded from GHS. The working assumption must therefore be that GHS is relevant to all chemicals. It complements the various approval and authorisation regimes, and is not limited to chemicals outside those schemes.

The no reduction in protection principle (GHS 1.1.1.6 (a))

This states that:

“the level of protection offered to workers, consumers and the environment should not be reduced as a result of harmonising the classification and labelling systems.”

There are several important aspects to this principle. Firstly, acceptance that the varieties of existing schemes in different jurisdictions provide differing levels of protection and it is not the intention of the GHS to **prohibit** these differences. Secondly, and related, is the recognition that in some circumstances harmonisation **could** reduce protection and this must be prevented. Thirdly, it also recognises that it is up to the individual jurisdictions to set the level of protection they consider necessary; implementation of GHS may present an opportunity to adjust the level but any adjustment is not **a requirement** of GHS.

We believe that strict adherence to this principle is supported by all and that it is fully consistent with the “high level of protection” statements in the “whereas” clauses to the Directives on classification and labelling. We would argue that a test of successful GHS inclusion is whether or not the no reduction in protection principle is maintained.

A simple replacement of the current scheme by the GHS would result in the loss of protection in some areas, and this must be avoided. An example of the potential to lower the level of protection through GHS introduction is where a specific end point under the current EU scheme has no GHS equivalent, and would thus no longer be included if the current system is merely replaced by the GHS criteria alone. A further example is where the existing scheme contains a labelling requirement or aspect not related to an end point, but which is essential to the successful operation of the total regime. For example the obligation in the EU to provide a name and address within the EU or EEA on a label is an essential enforcement aid, but the GHS does not require this. The maintenance of these requirements is not contrary to GHS principles; indeed it is fully consistent with the no reduction in protection principle.

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The GHS building block approach (GHS 1.1.3.1.5)

This principle is complementary to the no reduction of protection principle. It states:

“countries are free to determine which of the building blocks will be applied in different parts of their systems...the elements of the GHS may thus be seen as a collection of building blocks from which to form a regulatory approach...”

It is evident that there is a high degree of optionality and freedom for the individual jurisdictions in terms of what has to be taken up with GHS introduction. This is consistent with the no reduction in protection principle. It is for the individual jurisdictions to select from the GHS those parts which are appropriate, and in doing this they will contribute incrementally to global harmonisation. Equally they are at liberty to retain elements of national systems which are necessary in order to maintain local standards of protection.

It is also clear from consideration of the status of the GHS that the introduction of GHS to the EU involves a different approach than that involved in the introduction of EU law on classification and labelling in EU Member States. With a few minor exceptions the latter is obligatory. Member States must adopt it in its entirety and may not retain earlier schemes. On the other hand the GHS has no legal imperative until it is made into law by jurisdictions. It is not a model regulation, and the individual jurisdictions may and should maintain traditionally higher levels of protection.

This means that for practical purposes the introduction of the GHS must be:

Conservative – erring on the side of protection, and

Incremental – replacing specific elements of the existing scheme whilst retaining others, and

Conditional – on the need to show that the element of change does not lower the level of protection.

Finally it is necessary to be clear that the GHS is a rolling programme of evolution following the classical UN biennial cycle. At this stage no end is foreseen; change and evolution will be necessary as knowledge of the effect of chemicals on people and the environment develops. Hence maintaining current levels of protection by retaining requirements that are currently outside the GHS system is not necessarily inconsistent with increasing concordance between the systems.

Choice of GHS building blocks (GHS 1.1.3.1.5.3)

The harmonized elements of the GHS may be seen as a collection of building blocks from which to form a regulatory approach.

There appears to be a common consensus that both hazard classes and hazard categories could be considered as building blocks within the GHS. Each sector would have the choice to select the hazard classes, and within them, the hazard categories which are applicable to it. In the case of the transport sector, for example, within the hazard class of acute toxicity only categories 1, 2 and 3 are regulated, and some GHS hazard classes are not subject to transport regulations (for example, toxic to reproduction hazard or carcinogenicity). Once the hazard class and category have been chosen, the cut-off values for those hazard classes and/or categories should be applied in accordance with the GHS. The same applies for the hazard communication elements assigned to those hazard classes and/or categories [13].

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In proposing ways of implementing the GHS in EU legislation we have tried to follow closely the principle stated in the Commission Status Paper [6] and to do so “as close as possible to the existing EU scheme”.

The active role played by the EU Member States and the Commission in the development of the GHS has considerably simplified this task by ensuring that many of the GHS criteria are similar to the current EU criteria, and hence can replace the current criteria for a particular hazard class with little or no change in the level of protection afforded. This has additional advantages in that this will simplify the work involved for Industry in adapting to the new criteria.

The principle followed in the suggestions in the draft Annexes for implementation of the GHS proposals has been to replace the current criteria wherever possible with the criteria of the corresponding hazard class and category from the GHS.

As there are provisions in the current EU legislation that are not (as yet) covered by GHS, we have retained these in the draft Annexes. These provisions can be retained as long as they are considered necessary or until they are incorporated into the harmonised system.

We have also considered the inclusion of building blocks not previously included in the EU system. These blocks mainly relate to physical hazards. We have included proposals for where these blocks might be placed in the draft Annexes. Certain building blocks have not been recommended for inclusion in the new system¹².

The report includes arguments to provide guidance to the Commission and the Member States when making a final choice with respect to the building blocks.

The advent of REACH

Several aspects of REACH [4] interlink with the implementation of GHS.

Many of the current classification criteria are closely linked to the interpretation of test data acquired by the use of the test methods in Annex V to Directive 67/548/EEC. These test methods have been used for many years for the notification dossiers prepared for new substances and more recently for the mandatory testing of High Volume Existing chemicals under the Existing Substances Regulation [14]. The test data required for different production volumes is described in Annexes VII and VIII to Directive 67/548/EEC and testing strategies to be used in the investigation of these substances is described in the Technical Guidance Document (TGD) [15]. Directives 67/548/EEC and 1994/94/EC also include a requirement for a SDS [16]. All these elements of current legislation are incorporated in the draft proposal for REACH currently under discussion in the Council and the Parliament.

Secondly the Commission’s proposal for REACH also makes specific proposals concerning the scope and nature of the harmonised list of dangerous substances (Annex I to Directive 67/548/EEC). These include the introduction of an “Industry List” to replace the present system of so-called provisional classification. The provisions for a classification and labelling inventory ensure that classifications (and consequent labelling) of all dangerous substances manufactured in, or imported into, the EU are available to all to ensure the smooth running of the REACH system. Industry will be required to include all its classifications on the inventory.

¹² Examples of building blocks not recommended for inclusion include “Corrosive to metals” and Acute Categories 2 and 3 from “Hazards to the Aquatic Environment”.

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Any divergences between classifications of the same substance should be removed over time either through co-operation between notifiers and registrants or by EU harmonisation.

The scope of the present contract is to address issues related to the implementation of GHS and not to deal with the implications of changes proposed and under discussion in REACH. However, in view of the close links between the two legislative instruments, it has been necessary to address a number of the issues related to the changes proposed under REACH.

Other relevant EU legislation

It should also be noted that the scope of the proposed GHS Regulation covers chemicals outside the scope of REACH, notably plant protection products [17] and biocides [18]. Like the draft REACH Regulation, these Directives also contain requirements for testing and include guidance on how testing should be carried out. Both these Directives draw on Directives 67/548/EEC and 1999/45/EC for their guiding principles on classification and labelling. The harmonised classifications agreed following the formal evaluation of plant protection products are included in Annex I to Directive 67/548/EEC, and a similar procedure is being introduced for biocides. The requirement to supply SDS for plant protection products is based on provisions in Directive 1999/45/EC¹³.

The GHS criteria also cover a number of types of articles, which are not included in the scope of Directives 67/548/EEC or 1999/45/EC. These include aerosols, regulated by Directive 75/324/EEC [19], explosive articles, regulated by Directive 93/15/EEC [20], and pyrotechnic articles (not specifically regulated in EU legislation¹⁴).

As with REACH, aspects of this EU legislation interlink with the implementation of GHS. These issues are outside the scope of the present contract. However, a number of the issues related to these other EU Directives have been addressed where relevant in the report.

¹³ The requirements to supply SDS for plant protection products under Directive 91/414/EEC is based on Article 1.4 in Directive 1999/45/EC. The provisions came into force on 30 July 2004 (Art. 22.2(b)). The requirement to supply SDS for biocidal products is contained in Article 21 of Directive 98/8/EEC.

¹⁴ A recital in Directive 93/15/EEC states that an additional Directive is planned in this field.

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Discussion of Options for the Technical Annexes.

Working Assumptions

The Commission have indicated that it is their intention to replace the existing classification and labelling Directives for substances and preparations with a new Regulation [6]. As in the current legislation, it is anticipated that the Regulation will include a number of Technical Annexes, containing the criteria for classification and labelling of both substances and preparations for supply and use, together with other relevant information.

The Commission have provisionally identified [21] the Annexes to the Regulation and their titles as:

- Annex I – Classification and Labelling for physical, health and environmental hazards of substances and mixtures
- Annex II – Rules for the labelling of specific substances and mixtures
- Annex III – List of Hazard Statements
- Annex IV – List of Precautionary Statements
- Annex V – Pictograms
- Annex VI – List of Dangerous Substances

We have used this draft of the structure of the Annexes to the Regulation as the starting point of our work, using the numbering system in the Commission draft. The draft Annexes are presented as Annexes to this report. We have however proposed alternative Headings for some of these Annexes. The Annexes have been drafted¹⁵ to include relevant material from

- the revised GHS text [1]]
- the relevant provisions of Directive 67/548/EEC [2], and
- the relevant provisions of Directive 1999/45/EC [3].

For the reasons given in the section above, the proposals for the attached draft Annexes are based on the following working assumptions:

- The new framework will maintain (or enhance) the existing standard of protection,
- The new scheme will be as close as possible to the existing EU scheme; this will also facilitate implementation by the industries concerned;
- The new scheme will implement as much as possible of the currently agreed GHS criteria into EU legislation.

We have sought to maintain the present level of protection as closely as possible by a careful selection of the building blocks from the GHS (hazard classes and hazard categories) system

¹⁵ The Annexes follow the approach originally adopted by Dr. Pratt in her drafts for the ECB in 2002.

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that correspond to the current classification as “*dangerous*”, as well as retaining the EU classification for “Dangerous to the ozone layer” that is not covered by the GHS system at the present time.

Building blocks from the GHS system that do not form part of the current classification system as “*dangerous*”, but which nevertheless are relevant to hazard communication at the workplace or for consumers, have also been included in Annex II together with other Special Labelling and Packaging provisions.

Clearly this division can and should be discussed. However, we do not consider that this is a discussion that relates directly to *the technical aspects of implementation of GHS* in EU legislation. This discussion is outside the scope of the present contract.

The following sections present the reasons for deviations from certain of the classification and labelling provisions of the GHS and the changes proposed, where implementation of GHS has presented specific problems.

Where there are different options for implementing the GHS (or other issues raised in the report), these options are shown in the text of this report. The arguments for and against the different options are discussed in the report below.

In almost all cases, the draft Annexes present a preferred option. In order to simplify a subsequent revision of these changes, where relevant, the text corresponding to the recommended Option is shown in ordinary text, and the option that we consider less appropriate is shown (with the text struck through). In other cases, we have not felt able to present a preferred solution: in these cases the text includes a choice of option in ordinary text.

General comments on the use of the GHS Criteria

Where the GHS text covers general principles of classification and labelling (i.e. the issues covered in Part 1 of Annex I), we have in general given emphasis to existing EU principles rather than following the GHS text closely in all cases. Examples are given in the more detailed discussion of Annex I Part 1 below.

Much of the detailed text of Annex I and parts of Annex II has been drawn directly from the UN GHS document. In doing so, we have noted a number of difficulties presented by a faithful reproduction of the GHS text without alteration. It is inevitable that a document of this provenance will contain inconsistencies and errors in terms of spelling and grammar and that some parts may not be completely clear. This is compounded by the fact that the text was not drafted as a strict legal text although in fact its transfer to the Annexes of the new Regulation will have the effect of giving it legal status.

Whilst such problems occur throughout the GHS text, there are particular concerns in certain of the chapters giving classification criteria for specific hazard classes. We would highlight the GHS text on Skin corrosion / irritation as a section which contains a number of editorial inconsistencies which may cause confusion. Another example is the criteria for flammable aerosols, where the criteria refer to a series of decision logics, but where the text explicitly excludes these decision logics from the harmonised criteria. In addition, the role of “unstable explosives” is unclear in the GHS criteria (see discussion on explosives below).

Where there have been simple errors or inconsistencies (for example the variable spelling of oxidiser or the use of the terms physicochemical and physical) we have adjusted the text. In the case of “unstable explosives”, we believe that this category can be included in the GHS

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criteria, whilst at the same time suggesting an option of including the EU classification for this effect in Part 5 of the Annex. However in other cases, we recognise that there are parts of the texts related to the specific classification criteria that may cause difficulties in interpretation, but do not consider that these are issues which should be resolved unilaterally. Especially where the issue is technical, we have not altered the text but have taken the view that it is for the competent UN body to make judgements about any changes.

There are additional difficulties with some of the Decision logics used in the GHS text. The GHS text includes Figures showing (a) the decision logic used in applying the classification procedure; (b) for certain hazard classes, e.g. skin corrosion/irritation, progressive testing strategies which should be used in applying the criteria. The role of the latter Figures is complex. They contain information that is important in applying the criteria, and as such, they play a role as part of the guidance necessary for application of the criteria. However, these Figures can also be construed as Testing Strategies, implicitly imposing data requirements that are not within the scope of a draft Regulation on classification and labelling. In the case of the decision logics falling under (a) above, the GHS notes that the decision logic does not form part of the harmonised system, and consequently they have been deleted in the present text. The Testing Strategy decision logics (b) have been retained in the draft text. The extent, however, to which these Figures form part of testing requirements, and should rather form part of the REACH legislation may require further clarification. This is also discussed in the section on sources of data in the detailed comments to Annex I Part 1.

For some physical hazards, the GHS criteria include specific reference to a substance “as packaged”. In addition to the hazard class “Gases under Pressure”, there are references to “as packaged” for some Types of organic peroxides and for self-reactive substances. This differentiation of hazards on the basis of packaging complicates the application of these criteria to a workplace situation.

In many cases, the GHS criteria contain Notes that indicate possible choices open to different jurisdictions in implementing the criteria. These Notes have been modified, either by including the possible options as a positive requirement in this draft Annex, or, where the option is not taken, to delete the Note.

The GHS criteria also include Notes addressing the problem of substances that are known to present problems in fitting the classification criteria, and where specific classifications for these substances are stipulated¹⁶. Similar examples are also well known in discussions in Commission Working Groups on Classification and Labelling, and in applying the current Annex VI criteria¹⁷. A more coherent alternative to the inclusion of these Notes would be to include the relevant substances in the List of Dangerous Substances (Annex I in the current Directive) with the stipulated GHS classification.

General comments on the scope of the draft Regulation.

As noted earlier in the section on *Essential terminology*, the scope of the two current EU classification and labelling instruments differs.

¹⁶ As an example, the criteria for classification of flammable gases includes a Note to say that “Ammonia and methyl bromide shall be classified in category 2”.

¹⁷ An important function of the Commission TC C&L is to find appropriate *ad hoc* solutions to data that are problematic in relation to a strict interpretation of the criteria.

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In the case of substances covered by Directive 67/548/EEC, the scope of the classification, packaging and labelling provisions is restricted to “substances dangerous to man or the environment” (Art. 1.1(d)). There is no restriction on the scope of substances subject to notification (Art. 1.1(d)), for the obvious reason that only as a result of the notification procedure can hazards be identified that might lead to classification as dangerous¹⁸. Annex VI to Directive 67/548/EEC includes “additional” R-phrases that can be assigned “to substances already classified by virtue of ... [the sections describing classification as dangerous]”. As these additional R-phrases do not in themselves make a substance “dangerous”, the legal requirement for their use only applies when they are added as R-phrases to dangerous substances¹⁹.

The scope of Directive 1999/45/EC [3] is wider, and includes specific provisions for certain preparations that are not formally “classified as dangerous” (Art. 1.1). Directive 1999/45/EC distinguishes between (i) dangerous preparations, (ii) preparations that are not themselves dangerous, but contain at least one dangerous substance, and (iii) preparations irrespective of their classification. Many of these specific provisions concern consumer products. This reflects the fact that most consumer products are mixtures rather than pure substances, and it is consumer exposure (and in particular, the potential for children to be exposed) that is the reason for the additional concern.

As it is intended that the new Regulation on classification and labelling for supply and use will combine the provisions of both these Directives, it will be necessary to define its scope carefully. As the range of packaging and labelling provisions, including those taken from Directive 1999/45/EC, covers chemicals that are not classified as “dangerous” as well as those that are, it would seem reasonable that the scope of a new Regulation has the same scope as the current Directive 1999/45/EC and covers all substances and preparations, irrespective of whether or not they are classified as “dangerous”.

If this proposal is accepted, an important consequence of this change is that the future Regulation will provide classification and labelling provisions for both dangerous and non-dangerous substances and preparations. It will also bring the “additional” non-dangerous criteria in Directive 67/548/EEC into a formal regulatory context. As an example, under the current legislation, there are no mandatory labelling requirements for labelling a substance which meets the criteria for R66 (“Repeated exposure may cause skin dryness or cracking”) unless the substance also meets the criteria for “classification as dangerous”. Extension of the scope would make this a mandatory requirement, even in cases where the substance or mixture was not classified as “dangerous”.

However, as discussed below, we consider that the scope of the current Annex I (now Annex VI in the draft Annexes), the “List of dangerous substances”, should be retained, limiting addition of substances to this harmonised list to those that fulfil the criteria for “classification as dangerous”. It should be noted that if the proposal for an Industry List included in the draft REACH Regulation is adopted, there would be no reason why a harmonised classification of non-dangerous substances should not be included in this list.

¹⁸ The chapter on notified substances also include a labelling requirement (“Caution – substance not yet fully tested”) that is applied to substances that do not necessarily fulfil the criteria for classification as “dangerous” (Art. 8.1.5).

¹⁹ These R-phrases can of course be used on their own for non-dangerous substances, but this use falls outside the scope of the Directive. This also means that a substance that is only labelled with these R-phrases on their own cannot be included in Annex I, since Annex I is a list of *dangerous* substances.

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Annex I: Classification and labelling requirements for dangerous substances and mixtures

The structure of Annex I reflects the structure of the GHS system, but maintains a difference between criteria that are derived from the GHS harmonised system, and classification criteria that are retained from the current EU system.

The draft Annex contains 6 Parts. Part 1 is a General Introduction, containing general considerations from both the GHS criteria and from the current Annex VI to Directive 67/548/EEC. Parts 2, 3 and 4 include the GHS hazard classes for physical-chemical, human health and environmental hazards respectively, and Part 5 includes the classification criteria that are retained from the current EU system. Part 6 contains our suggestions for guidance for the application of Precautionary Statements.

In the draft, provisions for both classification and labelling are included together. Whilst there was a clear recommendation (1.1) from the Commission's White Paper Working Group [5] that classification and labelling should be addressed separately, as stated earlier the Technical Annex in the Call for tender indicated that "As a first option, labelling provisions should preferably also be introduced into the same Annex on the basis of the adopted GHS text in line with the format used in the GHS document if no relevant arguments against this idea can be found".

One reason for preferring this option is that up-dating of the document will be easier if the format is as close as possible to the GHS document which is a living document, and continuously revised. Another argument is that this will increase comprehensibility. Finally, it is consistent with the general approach we have taken to implement GHS as closely as possible to the current EU system, and here classification and labelling criteria for each endpoint (hazard class) are combined.

Annex I, Part 1 General Introduction

The issues raised in the following sections are discussed in the order they occur in Annex I, Part 1.

Definitions

Section 1.1.2 of the draft Annex includes a list of definitions. This reflects the current practice in Annex VI to Directive 67/548/EEC. We recognise that many of these definitions will need to be included in the main body of the Regulation, but consider that repetition here is desirable as this will mean that this Annex can be consulted independently of the main Regulation. We have not addressed the question as to whether the definitions of the different hazard classes should be in the Annex rather than in the main body of the Regulation because of the need to update to Technical Progress through a Committee procedure. However, they are currently provided in a Definitions Section within each Chapter in Parts 2, 3, 4 and 5, rather than in the general Definitions in Section 1.1.2.

We note that there are some differences between the definitions in the draft REACH proposal and the GHS definitions. For instance in REACH, the definition for substances refers to substances "obtained by any *manufacturing* process, including any additive necessary to preserve its stability and any impurity deriving from the process used", whereas the GHS definition refers to substances obtained by any "*production* process, including any additive necessary to preserve the stability of the product, and any impurity deriving from the *production* process used" (Italics have been added to show the differences). The GHS

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definition of mixtures includes the additional phrase “in which they do not react”. The GHS definitions are included in this section.

Articles

The definitions include the definition of “Articles” from REACH. Three types of articles are included in the GHS criteria which are not included in the current Directives on Classification and Labelling, namely explosive articles, pyrotechnic articles and aerosol dispensers (aerosols). Inclusion of these articles in the new Regulation therefore represents a widening of the scope of the legislation compared to the current provisions.

The interaction between the classification and labelling provisions and other EU legislation is complex (see following text boxes). In the case of aerosols, labelling requirements are set in both the Aerosol and the Classification and Labelling Directives, and there are cross-references between the different instruments.

Aerosols.

The GHS criteria define aerosols in a separate Chapter on flammable aerosols (Chapter 2.3) as non-refillable receptacles made of metal, glass or plastics. The definition of aerosol dispensers in the Aerosol Directive (Directive 75/324/EEC [19]) is very similar although not identical.

The GHS includes specific flammability criteria for aerosols and includes criteria for aerosols in many of the chapters relating to hazard classes for human health effects. Directive 75/324/EEC does not classify the aerosol as such (as this is defined as a dispenser), but refers to the classification of the component substances under Directive 67/548/EEC.

The GHS criteria for flammable aerosols (chapter 2.3) include specific labelling provisions, including separate hazard statements for aerosols (H108, H109, see Annex III). Directive 75/324/EEC includes certain labelling requirements in addition to those provided for in Directive 1999/45/EC. Directive 1999/45/EC in its turn refers to these specific labelling requirements in its Annex V, B. 7.

In the case of explosives, the need to provide a legal basis to require the provision of SDS is expressly recognised in the recitals of Directive 1999/45/EC, whilst the Directive exempts intentional explosives and pyrotechnics from its packaging and labelling provisions. A clear intention to provide specific legislation for pyrotechnic articles is stated in the recitals of the Explosives Directives, although there is at present no specific EU legislation covering these articles.

Explosive and pyrotechnic articles.

The scope of the GHS chapter on explosives (Chapter 2.1) includes explosive and pyrotechnic articles as well as explosive and pyrotechnic substances and mixtures.

Annex VI to Directive 67/548/EEC refers only to explosive substances and preparations (mixtures) and not to explosive and pyrotechnic articles. Directive 1999/45/EC in a recital refers specifically to “explosives marketed to produce an explosive or pyrotechnic effect” and the need “to classify them and assign to them a safety data sheet in accordance with the provisions of this Directive and also to label them in accordance with the international rules used for the transport of dangerous goods”. It defines explosive substances and preparations as “solid, liquid, pasty or gelatinous

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substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined". Article 12 (1) exempts "explosives placed on the market with a view to obtaining an explosive or pyrotechnic effect" from the packaging and labelling requirements of the Directive.

Explosive articles are controlled separately in Directive 93/15/EEC [20]. The Directive defines explosives as "materials and articles considered to be such in the UN RTDG and falling within Class 1 of those recommendations". The Directive makes no reference to the classification or labelling criteria in either Directive 67/548/EEC or 1994/45/EC. The Directive is a "New Approach" Directive [22] and defines the essential requirements, which must be met by explosives conformity tests.

The GHS provisions for the above articles are included in the draft Annex, together with the additional provisions from Directives 67/548/EEC and 1999/45/EC. Consideration of the optimal division of provisions between the different elements of EU legislation will be needed before a final text of the Annex can be agreed. This discussion falls outside the scope of the present contract.

Data sources

Section 1.3.2.7 of the draft includes a modified text from section 1.6.1 of Annex VI to Directive 67/548/EEC, in which references to data sources are closely linked to the notification provisions of Directive 67/548/EEC, and the data requirements in the Plant Protection Product Directive 91/414/EEC or the Biocides Directive 98/8/EC are not specifically reflected. As the provisions in REACH will replace the notification procedure, some of the present text of this section will no longer be relevant, and will need to be replaced by references to the data collection requirements under REACH²⁰. No attempt has been made to assess whether the data requirements in REACH are sufficient in order to classify a substance according to the GHS criteria.

References to specific test methods

With few exceptions, reference to test methods in the current Annex VI to Directive 67/548/EEC is to the test methods of Annex V to Directive 67/548/EEC. In most cases, these refer to test methods agreed and accepted by the OECD Test Methods programme. Annex V to Directive 67/548/EEC has been incorporated in the draft REACH Regulation as Annexes III, IV and V. Both the Plant Protection Products and the Biocides Directives also make specific reference to the test methods required to obtain the relevant data.

In contrast, the criteria of the UN RTGD, as reflected in the GHS, refer to the current revised edition of the United Nations *Manual of Tests and Criteria, Recommendations on the Transport of Dangerous Goods* [23]. In addition, for some hazard classes, the GHS criteria include extensive lists of appropriate test methods, some of which may be OECD testing methods.

The draft Annexes include sections carried over from the GHS, containing references to specific testing methods as well as general references to the UN *Manual of Tests and Criteria*, as it is recognised that the GHS criteria are designed to reflect the results of the tests cited in

²⁰ Since there are also data requirements under both the Plant Protection Products and Biocides Directives, the Commission may wish to consider specific references to these Directives here.

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these criteria. We have normally retained these references, but consider that any attempt to compare the testing methods specified with the test methods specified in other EU legislation is outside the scope of this contract.

Use of Structure-activity relationships and expert judgement

The section on data sources retains the statement in the current version of Annex VI that “the results of validated structure-activity relationships and expert judgement may also be taken into account where appropriate”. This general acceptance of validated structure-activity relationships and expert judgment (particularly as applied to read-across and the assessment of categories) is an important tool in evaluating hazards in the current EU system, and the importance of this approach to reduce the use of experimental animals and reduce the cost of testing under REACH is reflected in Annex IX of REACH (see text box).

<p style="text-align: center;">ANNEX IX</p> <p style="text-align: center;">GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES V TO VIII</p> <p>1.3. Structure-activity relationship (SAR)</p> <p>Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:</p> <ul style="list-style-type: none">- results are derived from a (Q)SAR model whose scientific validity has been established,- results are adequate for the purpose of classification and labelling and risk assessment, and- adequate and reliable documentation of the applied method is provided. <p>The Agency in collaboration with the Commission, Member States and interested parties shall develop and provide guidance in assessing which (Q)SARs will meet these conditions and provide examples.</p> <p>1.5. Grouping of substances and read-across approach</p> <p>Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or "category" of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for a reference substance within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint.</p> <p>The similarities may be based on:</p> <ol style="list-style-type: none">(1) a common functional group,(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals, or(3) a constant pattern in the changing of the potency of the properties across the category. <p>[4]</p>
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It should be noted the use of “expert judgement” in the GHS criteria (also included in the draft Annex) has a slightly different meaning than the term “expert judgement” as used in the section of Annex VI included here. In the context of GHS, the term “expert judgement” reflects the need for an appropriate level of expertise in interpreting what are sometimes complex data sets (“expert judgement is required to interpret the data on substances for classification purposes”). When used in connection with “validated structure-activity relationships” in the current Annex VI, the term “expert judgement” reflects both an expertise

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in interpreting the available data, but in addition, the use of this expertise to evaluate a hazard in the absence of specific data on the substance.

The extent to which the more specific requirements of many of the GHS criteria are compatible with the aims of Annex IX of REACH with respect to the use of structure-activity relationships and expert judgement is outside the scope of this report.

However, as part of the preparatory work for REACH, the RIP 3.3 report [24] has explored this issue in some detail in its Appendix 9 [25]. The box below shows the conclusions on this point from the RIP 3.3 report [24]

We agree with the conclusions of the RIP 3.3 report [24] shown in the text box below, namely that it is important to retain this approach to ensure that it can continue to be used for the purposes of classification.

4.4.1.1 Possibilities based on current experience concerning use of non-test information for hazard classification and labelling.

Use of read across and (Q)SARs and especially grouping have been employed for harmonised EU classification in the past by reference to the general provision of the “Labelling Guide” to the use of structure-activity relationships and expert judgement. Guidance has also been provided on how to use non-test information for self-classification. Under REACH it has to be assured that use of non-test information is adequate for the purpose of classification and labelling according to the GHS classification criteria. If not adequate for that purpose, non-test information will be useless and testing cannot be replaced with such information. It is however not obvious that such use may take place for all classification endpoints according to the current GHS criteria. For some endpoints explicit reference to use of non-test information (or some types of non-test information) does not exist in GHS. Concerning other classification endpoints such information can explicitly only be used to support available test data or to change or modify a classification of a particular substance. Nevertheless it is crucial that the GHS criteria for various endpoints are interpreted and/or implemented into EU legislation allowing for use of valid non-test information for classification purposes under REACH. Otherwise use of non-test information as alternative to testing will not be possible and the testing requirements of REACH cannot be derogated by use of non-test information, when otherwise scientifically justified. In addition it may then also not be possible to use valid non-test information as a supplementary information source for considering classification for endpoints where test data are lacking.

It is therefore recommended that the GHS should be amended to allow for a more systematic use of non-testing approaches. [24]

Substances containing impurities, additives or individual constituents

The draft Annex I retains the requirements in Annex VI section 1.7.3.1 on suppliers of these substances or mixtures containing such substances to provide the necessary data to enable a correct classification of any resulting mixture. This section was introduced to address the problem of classification of mixtures containing substances classified because of the presence of an impurity close to the concentration limit that led to classification. Information on the actual concentration of the impurity enables the formulator of the mixture to apply the correct classification, based on the actual concentration of the impurity. In the absence of such a provision, classification of the mixture (particularly in cases of multiple intermediate mixtures) could lead to classification of a mixture at concentrations substantially lower than the concentration limit of the impurity responsible for the classification.

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We consider it is important that the provisions of this section are retained in order to ensure the correct classification of mixtures, particularly when one or more intermediate mixtures are prepared.

Setting specific concentration limits

The draft Annex I contains references to specific concentration limits and their use. In the current system, specific concentration limits are not set by producers or importers, but only through Annex I to Directive 67/548/EEC. The wording of the requirements for choice of appropriate concentration limits, either for consideration in a mixture or in the calculation of an effect, reflects this. The draft REACH Regulation would suggest that specific concentration limits may also be set by producers and suppliers independently of the harmonised list of dangerous substances (see text box citing Article 110 of the draft REACH Regulation). If this is the case, then the sections related to specific and individual concentration limits will require rewording to allow for this possibility.

**Article 110
Obligation to notify the Agency**

1. Any importer or manufacturer, or group of importers or manufacturers, who place on the market a substance within the scope of Article 109, shall notify to the Agency the following information in order for it to be included in the inventory in accordance with Article 111, unless submitted as part of the registration:
- (a) the identity of the manufacturer or importer responsible for placing the substance(s) on the market;
 - (b) the identity of the substance(s) as specified in part 2 of Annex IV;
 - (c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;
 - (d) the resulting hazard label for the substance(s), resulting from application of Articles 23, 24 and 25 of Directive 67/548/EEC;
 - (e) specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

[4]

If setting specific concentration limits is to remain exclusively within the scope of the Harmonised List (currently Annex I to Directive 67/548/EEC), as at present, or if specific concentration limits set by industry are to be open to challenge, as recommended by the White Paper Working Group, then this will have implications for the scope required of the Annex.

Testing of mixtures for health hazards, in particular testing for the endpoints carcinogenicity, mutagenicity and reproductive toxicity

Directive 1999/45/EC provides the possibility of evaluating the health effects of mixtures by either evaluating the results of a test on the mixture or by the use of the conventional method (Art. 6.1).

In general, the assessment should be carried out using either existing data or the conventional method and new testing is discouraged, with reference to Directive 86/609/EEC [26], in order

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to reduce the use of experimental animals to a minimum (Art 6.2, first paragraph, and recital 8)²¹.

An even more restrictive approach is taken for the three endpoints: carcinogenicity, mutagenicity and reproductive toxicity (Art. 6.2, third paragraph). This entirely excludes the use of test data and the possibility of further testing for these endpoints.

In contrast, the GHS criteria for these endpoints allow the use of data on mixtures for classification for these endpoints. The White Paper Working Group [5] recommended that the current provisions which militate against testing for these endpoints are retained because of the limitations in the test methods and the need to take animal welfare into account. The text in paragraph 1.3.6.2.2 (iv) of Part 1 of Annex I has been included as an attempt to find a compromise solution to this difficulty. In addition, specific text has been introduced in Chapters 3.5, 3.6 and 3.7, dealing with the endpoints of carcinogenicity, mutagenicity and reproductive toxicity, addressing the situation where mixtures containing such substances have been tested outside the European Community.

Bridging rules

In the GHS text, the bridging principles for mixtures having potential health and environmental effects are reiterated in each chapter of GHS Parts 3 and 4. The wording is broadly similar from chapter to chapter but minor wording changes have been introduced to reflect the particular endpoint under consideration. An issue arises as to whether, in incorporating these bridging rules into the draft Annex, they should be repeated in each chapter of Part 3 and in Part 4, as in GHS. The specific option in relation to this is presented in the discussion of health hazards below, but the approach has been taken to present a single set of bridging rules in Part 1 of the Annex and to provide any variations to these in the individual chapters of Part 3 and Part 4.

Animal welfare

Relevant sections on animal welfare and the need to limit the use of experimental animals from both the GHS (e.g. GHS Section 1.3.2.4.6) and Annex VI have been included in the draft Annex. However, since the draft Annex I deals primarily with classification and labelling, and issues of data requirements are now in other legislation, this section might be more appropriate in the legislation directly concerned with data acquisition and we have set the text out as strike-through.

Substances or mixtures posing special problems

The GHS section 1.3.2.4.5 has been included as section 1.3.7.4 in the draft Annex I. This section states that "a substance or mixture need not be classified when it can be shown by conclusive experimental data from internationally acceptable test methods that the substance or mixture is not biologically available" with particular reference to polymers and metals.

The draft Annex also includes the current labelling requirements from Annex VI (section 1.4.7) where these substances and mixtures containing these substances are classified, but where there are labelling exemptions where these "do not present a hazard to human health by

²¹ According to Article 7(2) of Council Directive 86/609/EEC, an experiment entailing the use of experimental animals shall not be performed if another scientifically satisfactory method to obtain the result sought is reasonably and practicably available.

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inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market". The conclusions of the White Paper Working Group [5] were that these substances should be classified and that the existing labelling derogations should apply.

We have shown the relevant part of section 1.3.4.7.1 in strike-through text, in accordance with the recommendations of the White Paper Working Group.

Specific considerations for classification of substances and mixtures as mutagenic, carcinogenic or toxic for reproduction

The existing text of the introduction to Chapter 4 of Annex VI in the current Directive 67/548 is included as section 1.3.8 in the draft Annex for the sake of completeness. These provisions were introduced to ensure that any new information concerning these effects should result in an evaluation of the data with a view to a possible adaptation of the list of dangerous substances to technical progress. It is possible that this section is redundant in view of the proposals in REACH.

Training users in the interpretation of hazard information

The GHS section on training users in the interpretation of hazard information has not been included as we consider that this is irrelevant in the context of this Annex outside the scope of classification and labelling requirements.

Safety data sheets

The components of the GHS harmonised hazard communication system are labels and SDS, and the system requires the use of these components to convey information about each of the hazard classes and categories. The draft Annex I includes the description of the hazard communication system from the GHS, but the draft Annexes do not include any requirements for SDS.

Under the current Directives 67/548/EEC and 1999/45/EC SDS are required for substances and preparations. The detailed requirements for the content of a SDS are specified in a separate Directive [16].

It was noted earlier that the recitals to Directive 1999/45/EC specifically noted the need for a safety data sheet for "explosives marketed to produce an explosive or pyrotechnic effect", whilst at the same excluding these products from labelling requirements. The requirement to supply SDS for plant protection products covered by Directive 91/414/EEC is based on Article 1.4 of Directive 1999/45/EC.

The special labelling requirements related to SDS for non-dangerous preparations containing at least one dangerous substance included in Annex V of Directive 1999/45/EC have been included in the draft Annex I, Part 1, in the section on Workplace labelling.

The draft REACH Regulation includes requirements for SDS for the chemicals covered by the scope of the Regulation. An important reason for this is to ensure a close link between the conclusions of the Chemical Safety Reports and the risk reduction measures communicated to the user by the SDS. A possible link between the safety advice in the SDS and the S-phrases / Precautionary Statements is discussed under proposals for Part 6 of this draft Annex.

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Given the importance of SDS as part of the harmonised hazard communication system of the GHS, we recommend consideration of whether the draft Regulation should include specific provisions on SDS in addition to the labelling provisions.

Classification and labelling for transport

Whilst the GHS text makes several references to the UN classification and labelling requirements for transport, these references have not been included in the draft Annex, as these are covered by separate EU legislation. Section 1.4.6.3.3 includes a statement that when transport and supply and use criteria apply at the same time, the transport label elements have precedence and need not be repeated for supply and use.

Elements in the label

The provisions listed here retain unchanged the elements required under current legislation. Whilst future discussions may conclude that some of these elements may be deleted in a future Regulation, these elements are retained here for the reasons of ensuring that current levels of protection are retained.

The GHS system distinguishes between “harmonised” elements and “supplementary or non-standardised information”. Whilst many of the current EU mandatory labelling elements are included as part of the “harmonised” elements, others are not. Elements not part of the GHS provisions include the EC Number, the requirement for a substance included in the List of Harmonised Substances (Annex VI) to include the word “EC Label” and the requirement to include the name, full address and telephone number of the person established in the Community or the European Economic Area who is responsible for placing the substance or mixture on the market.

There are many other mandatory labelling requirements also included in the current EU provisions. These include the labelling provisions for the EU classes not included in the GHS system as well as the special labelling provisions in Annex V to Directive 1999/45/EC. They include requirements for substances and mixtures offered or sold to the general public (including tactile warnings) and at the workplace. Other supplementary labelling requirements are shown in Annex II.

We have retained the provisions of the GHS system with respect to a “harmonised label”. We consider however, that the division between the content of the “harmonised label” and “supplementary information” adequately provides for the placing of other mandatory information on the label. The GHS notes that “Competent Authorities may require additional information”, and we have shown these requirements (of the current EU legislation) as mandatory information that must be provided.

We have retained a section on the “supplementary information” that is entirely at the discretion of the supplier.

Updating information on labels

The draft Annex includes provisions concerning updating of the label.

This section may need to be reviewed with regard to its placing, whether in the Annex or in the body of the Regulation, or whether it is a requirement that is more appropriate in the sectorial legislation related to data generation and review (REACH [4], Directive 91/414/EEC [17] and Directive 98/8/EC [18]).

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Confidential business information (CBI)

Consideration needs to be given to the scope of Confidential Business Information (CBI) in the draft Regulation. At present, this applies only to mixtures and not to substances. In addition, the confidentiality extends only to a provision to replace a specific chemical name (which is considered as confidential) by a generic name covered by Annex VI to Directive 1999/45/EC. If these provisions are to be retained, the Annex VI from Directive 1999/45/EC will need to be included in the draft Regulation. A separate part of Annex II is proposed where the text of this Annex from Directive 1999/45/EC can be included.

Multiple hazards and precedence of labelling information

The GHS provides guidance in the case of multiple hazards and the precedence given to different elements of hazard information. There is guidance in the GHS to reduce the number of pictograms shown on the label. The GHS requires that all hazard statements should be allocated on the label.

The current legislation provides more guidance on the issue of precedence of hazard information. This has been considered important in order to ensure that the label draws particular attention to those hazards that are of most concern.

For substances or mixtures classified in relatively few hazard classes, precedence of hazard information is not a problem, as inclusion of all the information on the label does not lead to a loss of clarity or impact in recognising the important properties of concern. However for some substances that are classified in a number of different hazard classes/categories²², inclusion of all the possible relevant labelling elements can make it difficult to recognise the hazards of principal concern, and so rules for setting precedence of hazard information in these cases have been considered necessary.

The current EU system includes rules of precedence for symbols that under normal circumstances mean that no more than one symbol for each type of hazard (physical, human health, environment) will appear on the label²³. The GHS system in general will result in more pictograms, not least due to the addition of a new pictogram for health hazards.

The GHS contains a rule²⁴ for precedence of symbols that follows the rules of the UN RTDG [12]. These do not however translate readily into the GHS system (or the current EU system) as the UN RTDG uses a pictogram associated with subsidiary hazard categories. The GHS criteria provide for the possibility of requiring all pictograms for physical hazards to be used. We have included this option in the text in section 1.4.6.3, although we recognise that this will mean that more than one pictogram for physical hazards will be required for certain substances and preparations.

²² As an example, ammonium dichromate (Index number 024-003-00-1) is classified for 11 different hazards under the current legislation.

²³ In certain specific cases, both the skull and cross bones and the corrosive symbol can occur on the same label if there are particular concerns for corrosivity.

²⁴ “For substances and mixtures covered by the *UN Recommendations on the Transport of Dangerous Goods, Model Regulations*, the precedence of symbols for physical hazards should follow the rules of the UN Model Regulations. In workplace situations, the competent authority may require all symbols for physical hazards to be used.”

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For both R- and S-phrases, the current EU system includes combined phrases that eliminate redundant repetition. For acute toxicity by more than one route of administration, the phrase “Toxic by ...” is not repeated for each route, but combined as “Toxic by inhalation and if swallowed”. Combined phrases of this kind are not included in the GHS Hazard Statements shown in the draft Annex III. The absence of combined hazard statements will in itself lead to additional information being included on the label.

For hazard statements, additional reductions in the number statements are possible in the EU system, but not in the GHS. The rules for preparations state that “as a general rule a maximum of six R-phrases shall suffice ...”. There are also rules that certain R-phrases are not used when other specific phrases are present²⁵. Since there are reasons not to include hazard statements that duplicate others or are redundant (e.g. the EU rules for not including the statement for narcotic effects where there are other hazard statements relating to more serious inhalational toxicity) we have included a statement to this effect in paragraph 1.4.6.5 – “*Unless there is evident duplication or redundancy all hazard statements resulting from the classification shall appear on the label.*”

Similar restrictions on the numbers of S-phrases are also applied in the current EU system. The most obvious example of a conscious attempt to limit the number of S-phrases in order to ensure clarity and impact is to limit the S-phrases for health and physical-chemical hazards to S53 and S45 for all Category 1 and 2 carcinogens, mutagens and reproductive toxins²⁶. We have also retained the combined S-phrases in draft Annex IV.

In accordance with the recommendation from the White Paper Working Group [5], the additional guidance from Annex VI on reduction of hazard statements in cases where there are multiple hazards has not been included in the draft Annex.

However, in the work plan for the 2005-2006 biennium [27], it has been agreed to “Discuss the need, and if appropriate develop a proposal, for a hierarchy of labelling elements for chemicals presenting multiple hazards.” We consider this an issue that should receive further consideration in the GHS.

Special labelling arrangements

The Special Labelling Arrangements in sections 8 and 9 of Annex VI to Directive 67/548/EEC have been retained in this part of the draft Annex I. We consider that these provisions, which in fact are largely derogations from the normal labelling requirements, need to be included in this draft of the revised legislation. This section also includes the labelling exemptions for explosives and pyrotechnics, as well as the small quantity labelling exemptions.

Workplace and consumer labelling

We have included two sections specifically addressing issues related to workplace and consumer Labelling.

²⁵ R64 is not included if the substance or preparations is labelled with R20, R23, R26, R68/20, R39/23 or R39/26. R40 (the classification for Category 3 mutagens until the revision in the 28th ATP was not included in the label of substances classified as Category 1 or 2 carcinogens).

²⁶ S60 and S61 can be applied where appropriate for environmental concerns, since these are addressed to a different audience (management) than S53 and S45 (workers directly involved in handling the material).

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These sections in part include additional information concerning workplace labelling from the GHS. We have not considered to what extent this is compatible with other EU legislation on workplace labelling, but they have been included here as they are provisions in the GHS that need to be addressed.

Inclusion of these two sections provides a convenient way of codifying some of the other requirements (mainly from Directive 1999/45/EC) for special provisions for products sold to the general public. The scope of the hazards in the current legislation that require tactile warnings has been transcribed to cover the same range of health hazards as are required by GHS for including the name of a substance to be included in the product identification of a preparation.

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Annex I, Part 2 Classification for Physical Properties according to the GHS Criteria

It was the recommendation of the White Paper Working Group [5] in 2002 that all the elements of the GHS physical-chemical criteria should be adopted for all use settings with a small number of exceptions. The main exception was that the class “Corrosive for metals” should be used for the transport sector only. Category 4 of the hazard class “flammable liquids” was relevant for storage due to the potentially large volumes involved. The working group generally felt that the GHS would provide for a better level of protection than the current EU system covering supply and use.

The criteria in the draft Annexes follow these recommendations in general, although the principle that these proposals should reflect the current level of protection in the current legislation has led to a division of some of these classes and/or categories between Annex I (where substances and mixtures are classified as “*dangerous*”) and the Special Labelling provisions included in Annex II.

In cases where we have a preference for a division between the two Annexes, the text in the Annex where we suggest the relevant classes/categories is included is shown as direct text, and in the Annex where we do not recommend it should be included it is shown as strike-through text.

The reasoning behind these recommendations is set out in more detail below for the different hazard classes. In addition, specific issues for certain hazard classes are also discussed below.

Unstable explosives

An unstable explosive is defined as an explosive which is thermally unstable and/or too sensitive for normal handling, transport and use. It is recognised that special precautions are necessary for handling substances, mixtures and articles of this class. The status of this category of explosive in the GHS system is somewhat ambiguous. Whilst the written criteria appear to exclude this category²⁷, “unstable explosives” are included in the criteria for explosives shown in Table 2.1.1 and in the label elements for explosives shown in Table 2.1.2. A hazard statement for this effect is also included in the GHS harmonised list.

In a comparison of EU risk phrases and GHS Hazard Statements [28], it is noted that the EU classification E; R3²⁸ is used for substances that are not permitted for transport because they are too sensitive. Therefore the highest level of warning is appropriate for handling in the workplace, and although strictly speaking these are not fully within the GHS criteria, the GHS Hazard Statement for Division 1.1 has some relevance. .

There are 11 entries covering 19 individual substances currently included in Annex I to Directive 67/548/EEC which are classified as E; R3²⁹ [29]. Whilst many of these substances

²⁷ “Substances, mixtures and articles of this class, which are not classified as an unstable explosive, are assigned to ...”

²⁸ R3: Extreme risk of explosion by shock, friction, fire or other sources of ignition.

²⁹ 080-005-00-2: mercuric fulminate; 080-006-00-8: mercuric oxycyanide; 082-003-00-7: lead azide; 603-033-00-4: diethylene glycol dinitrate; 603-034-00-X: glycerol trinitrate; 603-035-00-5: pentaerythritol tetranitrate; 603-036-00-0: mannitol hexanitrate; 603-037-00-6: cellulose nitrate (containing > 12.6% nitrogen); 609-010-00-5: salts of picric acid (a group entry containing 9 separate compounds in EINECS); 609-019-00-4: lead styphnate; 609-053-00-X: hydrazine trinitromethane. Whilst cellulose nitrate (containing > 12.6% nitrogen) is permitted for transport as Class 1.1.D, most of the remaining substances are not permitted for transport without some kind of

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are included by name in the UN RTDG [12], all except one of these entries refer to the substances in either a wetted or a desensitised state. It would appear that whilst not permitted for transport in an unstable form, such substances can appear in the workplace, and classification and labelling would be appropriate for handling in the workplace. This is reflected in the fact that labelling provisions for this type of explosive are included in the GHS criteria.

Option 1:

In order to remove the ambiguity for this category, the GHS criteria have been amended to specifically include unstable explosives in the written criteria. The two GHS tables containing the classification and labelling criteria (Table 2.1.1 and 2.1.2.) are included without modification. The relevant GHS Hazard Statement (H100: Unstable Explosive) is included in Annex 3.

Option 2:

The current EU classification E; R3 is included in Part 5, Additional EU classifications.

Given that this category is contained in the GHS criteria (however ambiguously), Option 1 has been selected for the draft Annex.

Consideration should be given to clarifying this issue in future revisions of the GHS.

Flammable gases

The current EU criteria for flammability distinguish between physical state (solid, liquid, gas) using a different approach than in the GHS criteria. In the current EU system, gases can only be “extremely flammable” (R12).

For flammable gases, the GHS criteria distinguish between “extremely flammable gases” (Category 1) and “flammable gases” (Category 2).

The differences in the criteria do not make it possible to decide immediately whether inclusion of Category 2 for this class represents an extension of the concept of classification as “*dangerous*”³⁰. Both classes have been included in this Annex.

Inclusion of an extra hazard category in the GHS classification may pose complications to the “migration” of the current R12 classification to the new system.

stabilisation. Mercuric fulminate, lead azide, pentaerythritol tetranitrate, mannitol hexanitrate, ammonium picrate and lead styphnate are permitted for transport as wetted explosives. Mercuric oxycyanide and lead azide are permitted for transport when desensitised. Nitroglycerin is permitted as an alcoholic solution containing up to 10% nitroglycerin. Hydrazine trinitromethane is not included as an individual entry in the UN RTDG [12].

³⁰ A note to the criteria indicates that ammonia and methyl bromide should be classified in category 2. Anhydrous ammonia (a gas) is classified as R10 in Annex I to Directive 67/548/EEC; methyl bromide is not classified for flammability. The classification for ammonia would appear to reflect a similar concern to that shown by the note, as the correct classification for a gas would be F+; R12.

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Flammable aerosols

As mentioned earlier under the discussion of general problems with the GHS, the criteria in the GHS document are complicated by the fact that their application depends on a series of decision logics which do not form part of the harmonised criteria. This is a problem that we consider should be addressed in the context of a revision of the GHS. We regard this as an important issue, since this brings into question whether these criteria are applicable in their present form.

As discussed above in the comments to the General Introduction, consideration should also be given to the appropriate placing of these criteria, either by widening the scope of the draft Regulation to include articles, or to include these provisions in a revised Aerosols Directive.

Option 1:

Include these criteria in this Annex.

Option 2:

Include these criteria in a revision of Directive 75/324/EEC.

Option 3:

Do not include these criteria until the ambiguities in the criteria have been resolved.

The GHS provisions are provisionally included in this draft Annex (Option 1), although we consider that both the other options deserve consideration.

Gases under pressure

This hazard class is included in the UN RTDG, and includes four types of pressurised gas: Compressed gas, Liquefied gas, Refrigerated liquefied gas, and Dissolved gas. This property is not included in the current EU supply and use classification system³¹. The fact that the gas is pressurised is not normally regarded as an intrinsic property of the substance or mixture [30], and is a hazard related to the form in which it is packaged. This is made clear by the criteria which specify that the “Gases shall be classified, according to their physical state when packaged”.

The hazard communication information conveyed by the GHS elements for this hazard class provides useful information relevant for safety at the workplace and, where relevant, for consumers.

³¹ The Annex I entry (Index No. 008-002-00-3) for “Liquid Air” is classified as C; R34 (in addition to O; R8), very probably to reflect the cryogenic burns that may be caused by liquid air. This concern is expressed more directly in the Hazard Statement for this GHS group: “Contains refrigerated gas; may cause cryogenic burns or injury”.

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Option 1:

Include the criteria for this hazard class in Annex II.

Option 2:

Include the criteria in Annex I.

Option 3:

Do not include this hazard class.

We consider that this hazard class should not result in a chemical being considered as “*dangerous*” as this is not an intrinsic property of the substance or mixture. We do however consider that this hazard class provides useful information relevant for safety at the workplace and, where relevant, for consumers and should be included in Annex II rather than Annex I (Option 1).

Flammable liquids

As discussed in the previous section, the current EU criteria for flammability distinguish between physical state (solid, liquid, gas) using a different approach than in the GHS criteria. In the current EU system, liquids can be “extremely flammable” (R12), “highly flammable” (R11) or “flammable” (R10). For flammable liquids, the GHS criteria distinguish between four categories rather than three. There are slight differences in the cut-offs used for the different flash points, but in general, the three higher GHS categories correspond broadly to the three EU current classifications.

It was the recommendation of the ECB White Paper Working Group [30] that Category 4 of the hazard class “flammable liquids” was relevant for storage due to the potentially large volumes involved. The range of flash points for the GHS category 4 is above the current EU cut-off for classification of a liquid as flammable, and hence, for classification as “*dangerous*”.

Option 1:

Include Category 4 flammable liquids in Annex II.

Option 2:

Include the criteria in Annex I.

Option 3:

Do not include this hazard category

Since the range of flash points for the GHS category 4 is above the current EU cut-off for classification of a liquid as flammable, and hence, to be classified as “*dangerous*”, we do not consider that it is consistent with the general principles for our choice of building blocks to include the GHS category 4 for “Combustible liquid” in Annex I. The text for this category is shown as strike-through text in Annex I, and this category has been included in Annex II (Option 1).

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The GHS criteria include a Note concerning the classification of certain types of products, including paints and varnishes. A modified version of the text from Annex VI, section 2.2.5 on the same topic has been included in the section on “Additional Classification Considerations”.

Flammable solids

As discussed in the previous section, the current EU criteria for flammability distinguish between physical state (solid, liquid, gas) using a different approach than in the GHS criteria. In the current EU system, solids can only be “highly flammable” (R11). It should be noted that the EU Major-Accident Hazard legislation [11] includes the current EU class of “highly flammable” but includes a definition that restricts this to liquids.

For flammable solids, the GHS criteria distinguish between “flammable solids” (Category 1, with “Danger”) and “flammable solids” (Category 2, with “Warning”).

The differences in the criteria do not make it possible to decide immediately whether inclusion of Category 2 for this class represents an extension of the concept of classification as “*dangerous*”. Both classes have been included in this Annex. Inclusion of an extra hazard category in the GHS classification may pose complications to the “migration” of the current R11 classification for solids to the new system.

Self-reactive substances and mixtures.

The EU and GHS (transport) systems have different philosophies in considering precedence for explosive and Self-Reacting properties. The GHS (transport) system gives precedence to a classification as an Organic Peroxide or Self-Reactive Substance, and explosive properties are considered a secondary hazard, whereas the EU will always give precedence to explosive properties [30].

The GHS system divides Self-reactive substances and mixtures into seven different categories (“A” to “G”). The most problematic of these categories is Category “A” and the Hazard Statement for this category is “Heating may cause an explosion”. Type A Self-reactive Substances are not permitted for transport [30]. The Hazard Statement for category B is “Heating may cause a fire or explosion” and for categories C, D, E and F “Heating may cause a fire”. The hazard is not only related to the intrinsic properties of the substance, but is affected by the packaging, and the criteria specifically make reference to the substance or mixture “as packaged”.

Self-reacting substances are not included under the current EU supply and use legislation. The R-phrase R44 (“Risk of explosion if heated under confinement”) can be applied [30]. The wording for the hazard statement for Types A and B of this GHS hazard class, “Heating may cause an explosion”, is the same as the wording for R-phrase R5, which is an additional R-phrase in section 2.2.6 of Annex VI to Directive 67/548/EEC. This additional R-phrase does not however cover the same properties as the GHS hazard class. Self-reactive substances are not included in the EU Major Accidents Hazard legislation [11], although the nature of the hazard would appear to be relevant in this context.

Option 1:

Do not consider this hazard class as “dangerous” and include these criteria in Annex II.

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Option 2:

Include some categories of this hazard class as “dangerous” and include the criteria for them in Annex I. Criteria for the other, lower categories should be included in Annex II.

Option 3:

Include the criteria for the whole of this hazard class in Annex I.

Following the general principles stated above, this would suggest that this class of hazard should not be included in Annex I, but instead in Annex II. This conclusion is based on the argument that the wording of the hazard statement for the highest category of this class (i.e. the same wording as for R5) is not considered as “*dangerous*” in the current EU system, nor does the criteria for the closest relevant R-phrase, R44, lead to classification as “*dangerous*”. Finally, the hazard is not independent of the nature of the package. In order to be consistent with the general principles for our choice of building blocks, the text for this class is shown as strike-through text in Annex I, and Categories A to F³² of this hazard class are included in Annex II (Option 1).

However, we recognise that these general principles may be less relevant in this particular case, due to the differences in philosophy in the approaches used in the two systems [30]. The fact that Type A Self-reactive Substances are not permitted for transport shows clearly that this is considered to be a “*dangerous*” property in this context. We recognise that inclusion of some of the categories of this hazard class (Option 2) is equally appropriate. Types A and B could be included as dangerous, whilst lower categories could be included in Annex II.

Option 3 - that all (option 3) of the elements of this category are included in Annex I -could also be considered.

We consider that further discussion of this point is needed.

Pyrophoric liquids and solids

The GHS has hazard classes for pyrophoric liquids and solids (2.9 and 2.10). The GHS criteria for pyrophoric liquids and solids correspond closely to the current EU classification as R17 “Spontaneously flammable in air”. Pyrophoric liquids and solids are included in the draft Annex I as the criteria clearly match the current level of concern as “*dangerous*”.

Self-heating substances and mixtures

In addition to the GHS hazard classes for pyrophoric liquids and solids, the GHS criteria also have an additional lower level of hazard, self-heating substances, for which there are two categories. The EU includes a relevant test method (Annex V, A16) but the results of this test are not used for classification [30]. There are also no additional R-phrases in the section 2.2.6 of Annex VI to Directive 67/548/EEC with the same hazard statements for this class: “Self-heating; may catch fire” or “Self-heating in large quantities; may catch fire”.

³² There are no hazard communication elements associated with Category G, and therefore no labelling consequences of including this category.

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This hazard class has particular relevance for storage of substances, particularly in bulk. It has a wide scope of relevance covering many substances such as ingredients of domestic washing powders, charcoal, coal, fine particles of iron (II) oxide etc. [30].

Option 1:

Include this hazard class in Annex II.

Option 2:

Include the criteria in Annex I.

Option 3:

Do not include this hazard class.

Since this hazard class of Self-heating substances and mixtures appears not to match the level of concern as “*dangerous*”, we do not consider that it is consistent with the general principles for our choice of building blocks to include this class in Annex I. The text for this class is shown as strike-through text in Annex I. Categories 1 and 2 of this hazard class are included in Annex II (Option 1).

Substances and mixtures which in contact with water emit flammable gases

The current EU criteria for flammability distinguish between physical state (solid, liquid, gas) using a different approach than in the GHS criteria. In the current EU system, gases can only be “*extremely flammable*”. Hence, substances and mixtures which in contact with water can only emit flammable gases (R15).

For this hazard class, the GHS criteria distinguish between three different categories. All three categories stipulate a minimum rate of emission of flammable gas of 1 litre per kilogram per hour. Hence all three categories are considered as “*dangerous*” according to the current classification with R15.

Inclusion of extra hazard categories in the GHS classification will pose complications to the “migration” of the current R15 classification to the new system.

Oxidizing liquids

The GHS criteria for oxidizing liquids have three categories.

The current EU criteria do not distinguish between solids and liquids, but do reflect two different levels of hazard. R9 “Explosive when mixed with combustible material” is equivalent to the GHS Cat. 1 Hazard Statement for liquid oxidizers and R8 “Contact with combustible material may cause fire” is equivalent to the GHS Cat. 2 Hazard Statement for liquid and solid oxidizers and the GHS Cat. 1 Hazard Statement for oxidizing gases [28]. The GHS Cat. 3 Hazard Statement for liquid and solid oxidizers “WARNING: May intensify fire; oxidizer” is probably a lower level of hazard than R8 [28].

Option 1:

Include Category 3 liquid oxidizers in Annex II.

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Option 2:

Include this category in Annex I.

Option 3:

Do not include this hazard category

Following the general principles for the choice of building blocks, the text for Category 3 liquid oxidizers is shown as strike-through text in Annex I. Category 3 of this Hazard Class is included in Annex II (Option 1).

Oxidizing solids

As for oxidizing liquids (see above) the GHS criteria for oxidizing solids have three categories.

The current EU criteria do not distinguish between solids and liquids, but do reflect two different levels of hazard. R9 “Explosive when mixed with combustible material” is equivalent to the GHS Cat. 1 Hazard Statement for liquid oxidizers and R8 “Contact with combustible material may cause fire” is equivalent to the GHS Cat. 2 Hazard Statement for liquid and solid oxidizers and the GHS Cat. 1 for oxidizing gases [28]. The GHS Cat. 3 Hazard Statement for liquid and solid oxidizers (“Warning: May intensify fire; oxidizer”) is probably a lower level of hazard than R8 [28].

Option 1:

Include Category 3 solid oxidizers in Annex II.

Option 2:

Include this category in Annex I.

Option 3:

Do not include this hazard category

Following the general principles for the choice of building blocks, the text for Category 3 solid oxidizers is shown as strike-through text in the draft Annex I. Category 3 of this Hazard Class is included in the draft Annex II (Option 1).

Organic peroxides

The GHS criteria divide this hazard class into seven categories "Types A to G". It should be noted that the criteria for Types A to C for this hazard class include considerations of packaging “Any organic peroxide which, as packaged, ...”. As noted above, this definition can present problems with workplace classification. The criteria for Types D – F rely on the results of laboratory testing and do not contain a reference to packaging.

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The current EU criteria for organic peroxides use a single R-phrase, R7 (“May cause fire”). This R-phrase³³ is assigned to Organic Peroxides of Types B to F [28].

Organic peroxides Types A to F are included in Annex I as they correspond to the current classification as “*dangerous*” with R7.

Category G is not included in this Annex, as the criteria appear to be below the level of concern as “*dangerous*” represented by the current EU classification as R7. Category G is not included in Annex II as there are no hazard communication elements associated with this Category, and therefore no labelling consequences of including this category.

Corrosive to metals

This category of danger has long formed part of the UN RTDG, as corrosivity presents a hazard to the integrity of particular types of packaging. This hazard, whilst relevant as hazard information, is not regarded as being within the formal scope of a classification system intended to ensure the protection of human health and the environment.

The White Paper Working group concluded that this GHS hazard class should be applied to transport only [5]. If necessary for other use settings, it could be covered in the hazard communication by a Precautionary Statement or information in the SDS [30].

Option 1:

Do not include this hazard category for supply and use

Option 2:

Include this hazard category as supplementary labelling information in Annex II

We have retained the text for this hazard class shown as strike-through text in this Annex for the sake of completeness only. The criteria and associated hazard labelling requirements for this hazard class have been included in draft Annex II, the Special Requirements for Labelling and Packaging. However, as we do not consider that this hazard class falls within the scope of a Regulation concerned with the protection of human health and the environment, the text in both Annex I and Annex II is shown as strike-through text. The requirement to make reference to other legislation in the SDS, together with the inclusion of corrosive effect on materials shown in the pictogram, is considered to provide adequate information on this point (Option 1).

³³ The same phrase is also included as an additional R-phrase, not leading to classification as dangerous for reactive substances such as fluorine or sodium hydrosulphite. In this case the Annex I entry is R7 and not O; R7. For further discussion of R7 as an additional R-phrase, see comments to Annex II.

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Annex I, Part 3 Classification for Health Properties according to the GHS Criteria

This part of the draft Annex contains proposals for how the GHS health hazard categories/classes could be dealt with in the future EU legislation. In formulating these proposals account has been taken of (a) the recommendations of the ECB Technical Working Groups [5] set up to examine the technical issues associated with the possible adoption of the GHS within the EU and (b) the findings of the 2004 Ökopol study [7].

In drafting the Annexes, in particular Annexes I and II, we used as a basis the draft technical Annexes X and Y prepared by Dr Iona Pratt in 2002. However these Annexes needed revising and updating to reflect recent UN ECOSOC agreements on several issues. The majority of these recent agreements related to Part 3 of GHS, classification for health properties:

- Changes in terminology in chapter 3.6 (reproductive toxicity)
- Criteria for classification for aspiration hazards
- Criteria for respiratory irritation
- Criteria for narcotic effects
- Criteria for classifying mixtures containing substances which may cause effects on lactation
- Changes in the chapter on acute toxicity (chapter 3.1)

A further issue highlighted in the Technical Annex A of the tender document was that of the formula for calculating the Acute Toxicity Estimate for a mixture, for which problems have been identified in the application e.g. to gases.

These issues have all been addressed in the discussion below.

In the draft technical Annexes X and Y prepared by Dr Iona Pratt in 2002, the classification endpoints “aspiration hazard”, “respiratory system irritation” and “narcotic effects” which existed under the current EU scheme had no GHS equivalent, and were included in a Part 2 of Annex X. Since criteria for these effects have now been included in the GHS, they have been integrated into Part 3 of this Annex.

In addition, we have taken account of the following hazard categories/classes of the GHS:

- Acute toxicity Category 5
- Skin irritation Category 3
- Effects on or via lactation

We have suggested as a result of this analysis that these provisions should not be regarded as “*dangerous*”, for classification purposes. We consider, nevertheless, that they are relevant to hazard communication at the workplace or for consumers, and for this reason they have been included in Annex II, Special Labelling Provisions. Particular issues arise regarding inclusion of Skin irritation Category 3 in Annex II, which are discussed below (discussion on Part 3, chapter 3.2) and in the discussion of Annex II.

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Part 3 of GHS also presents a number of options for division of hazard categories, e.g. for carcinogens where category 1 may be divided into Category 1A and 1B. In general the text of the draft Annex reflects the option which we consider to be most appropriate for the future EU system, while both options are shown in the discussion which follows below for the different health hazard classes. In addition, specific issues for certain hazard classes, e.g. *Acute toxicity Category 1*, are also discussed below.

Finally, certain other health effects in the existing EU scheme are covered under the heading of “Other toxicological properties”, namely those effects covered by the additional R-phrases R29 “Contact with water liberates toxic gas”, R 31 “Contact with acids liberates toxic gas”, R 32 “Contact with acids liberates very toxic gas”, R33 “Danger of cumulative effects”, R64 “May cause harm to breastfed babies”, R66 “Repeated exposure may cause skin dryness or cracking” and R67 “Vapours may cause drowsiness and dizziness”.

As a result of our analysis, we have suggested that the majority of these effects should also be included in Annex II, Special Labelling Provisions. However, the updated GHS criteria for Specific Target Organ Systemic Toxicity (STOST) after a single exposure now accommodate classification for narcotic effects (R67), and for this reason we propose that this effect should be accommodated within Part 3 of Annex 1, Chapter 3.8. In contrast, we consider that the R-phrase R33 “Danger of cumulative effects”) was already largely covered by the criteria for R48 “Risk of serious damage to health” in Annex VI of Directive 67/548/EEC and is now covered by the criteria for Specific Target Organ Systemic Toxicity (STOST) after repeated exposure, and propose that this R-phrase is not retained in the future EU system.

In cases where we have a preference for a division between the two Annexes, the text in the Annex where we suggest the relevant classes/categories is included is shown as direct text and in the Annex where we do not recommend it should be included is shown as strike-through text.

The drafting approach adopted in Part 3 of this Annex was to adopt the Part 3 GHS text broadly word for word, with some editorial amendments.

The use of Bridging Principles for the classification of mixtures

When a mixture has not been tested in toxicity studies and hence there are no test data available, the approach taken in the GHS is to apply the so-called bridging principles of Dilution, Batching, Concentration, Interpolation within One Toxicity Category, and Substantially Similar Mixtures.

In the GHS text, the bridging principles for mixtures having potential health effects are reiterated in each chapter of GHS Part 3. The wording is broadly similar from chapter to chapter but minor wording changes have been introduced to reflect the particular endpoint under consideration. An issue arises as to whether these bridging principles must be repeated in each chapter of Part 3. The options are as follows.

Option 1:

Include a common set of bridging principles for mixtures which can be applied to any mixture, irrespective of the health hazard endpoint, in Part 1 of the Annex, addressing common principles for classification.

Option 2:

Include the specific bridging principles for mixtures which form part of each Chapter of Part

3 of GHS in the equivalent section of Part 3 of Annex 1

Our recommendation and approach taken in Part 3 is that a common set of bridging principles for mixtures should be included in Part 1 of the Annex, with cross reference being made to them from relevant parts of the chapters in Part 3. We consider that these principles are applicable in the majority of situations, irrespective of the health hazard endpoint, and have noted as appropriate when this is not the case.

Chapter 3.1 Acute Toxicity

(a) Cut-off criteria

The GHS criteria for classification of substances or mixtures as acutely toxic comprise five toxicity categories based on acute toxicity by the oral, dermal or inhalation route. There are differences between the numeric cut-off criteria used for the GHS categories compared with the existing EU system. For example, the cut-off for *acute toxicity oral category 1* is ≤ 5 mg/kg and that for category 2 is ≤ 50 mg/kg, while the cut-off for *Very Toxic* in the EU is ≤ 25 mg/kg. Similarly, the cut-off for GHS category 3 is ≤ 300 mg/kg while the cut-off for *Toxic* in the EU is ≤ 200 mg/kg. While GHS has a category 5 for substances or mixtures having acute oral toxicities in the range 2000 – 5000 mg/kg, no such classification exists at present in the EU. A similar lack of correspondence exists between a number of the cut-offs for individual categories for acute toxicity by the dermal or inhalation routes. These differences were recognised during the negotiations leading to GHS, and the cut-offs now in the text were compromises, accepted by those EU Member States involved. They will have to be reflected in the future EU legislation, although this will pose some problems for the migration of classifications from the current EU system to the future one.

There are 2 hazard classes for which this principle is not considered to hold, namely *acute toxicity categories 1* and 5. *Acute toxicity category 5* is covered in the next section, while a discussion of the options for *acute toxicity category 1* follows.

Acute toxicity category 1 was included as a separate category in the GHS to address the concerns for the transport of exceptionally highly toxic substances (as reflected by the current UN RTDG [12]). It is arguable whether it is needed for classification and labelling provisions for supply and use where a three-tiered approach has proved satisfactory in the past. The following options exist:

Option 1:

Combine the GHS categories 1 and 2 for each route of exposure, for the purposes of the future classification and labelling provisions for supply and use.

Option 2:

Maintain a distinction between GHS categories 1 and 2 in the future legislation for supply and use.

We consider that it is preferable to combine categories 1 and 2 as a Cat. 1/2 (nomenclature to be resolved) for each route of exposure as in Option 1. This gives a single highest hazard category with cut-off criteria of ≤ 50 mg/kg for oral exposure, ≤ 200 mg/kg for dermal exposure, ≤ 500 ppmV for gases and vapours by the inhalation route and ≤ 0.5 mg/L for dusts and mists, i.e. the cut-offs applied for GHS category 2, effectively resulting in a “no take up” of category 1. This is the option presented in Table 3.1.1 of the Annex.

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We consider this a valid option under the building block approach, but recognise that the resolution of this issue and the underlying principle involved is a policy issue beyond the scope of this report. We note however that if this is done, it enables a somewhat easier migration of the EU classifications T+; R26, T+; R27 and T+; R28 than would be possible if the separate categories 1 and 2 are maintained. The ECB White Paper Working Group [5] recommended that these two categories should not be combined, in view of the broad application of the supply and use system and also recognising the needs of the transport system. However it was also recommended that category 1 should be included for transport use only. Since the scope of Annex 1 has been limited to classification and labelling for supply and use only, it is considered justifiable not to use the GHS category 1 as a separate distinct category in the new system. The issue can be revisited in the future if closer links between the two systems are considered.

(b) Acute toxicity category 5

The acute toxicity category 5 has been included in GHS to enable the identification of chemicals which are of relatively low acute toxicity hazard but which under certain circumstances may present a danger to vulnerable populations. The question of whether to include category 5 in the future legislation was extensively discussed by the ECB White Paper Working Group [5], and two options, either to take up this category or not to take up this category, were recommended for consideration. Opinions were divided on these options, those favouring the latter considering that sufficient information for consumers (the main target group) could be provided by alternative means/special labelling. We consider that the inclusion of this category in Annex II resolves these concerns, ensuring that appropriate labelling is included without regarding this hazard category as “dangerous”. We have therefore proposed the following three options:

Option 1:

Adopt category 5 for oral toxicity only and include in Annex II.

Option 2:

Adopt category 5 for oral toxicity only and include in Annex I.

Option 3:

Do not adopt category 5.

Our recommendation, as outlined in the Overview above is that this hazard category should not be regarded as “*dangerous*” for classification purposes.

We consider that this hazard category is primarily relevant for hazard communication to consumers, and for this reason acute toxicity category 5 has been included in Annex II, Special Labelling Provisions, for acute oral toxicity only. The advantages of this approach include the extension of protection in certain cases, as well as providing some compensation for a possible loss in protection due to changes in the calculation methods for assessing mixtures, in addition to maximisation of harmonisation. The disadvantages are the need for additional assessments in a low priority area, and pressure for further testing. Not to include this category would avoid an additional evaluation burden. However, not to include category 5 will mean that the opportunity is lost to extend and conserve the relevant protection, particularly for mixtures. On balance therefore, we recommend its inclusion in Annex II.

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The relevant text providing the criteria and hazard communication elements is shown in Part 3 of Annex I as strike-through text and in Annex II as direct (clear) text.

(c) Acute toxicity estimates for classification of mixtures

If a mixture cannot be classified for acute toxicity using the bridging principles referred to above, then classification is based on the acute toxicity hazards of the ingredients of the mixture, where known. This involves the use of “Additivity Formulae” and takes into consideration the acute toxicity estimate (ATE) of each of the ingredient in the mixture.

The ECB White Paper Working Group [5] discussed the use of the Acute Toxicity Estimate of the mixture, ATE_{mix} in those cases when test data on the preparation/mixture itself is not available or when bridging is not possible. Concerns were raised that incorrect self-classifications could result because the ATE is complicated to apply. Furthermore, a Swedish analysis suggested that in cases where more than 90% of the ingredients in a mixture have acute toxicity data, and only one component is acutely very toxic or toxic (within the current EU system), a number of mixtures would be downgraded to category 3 and 4 respectively using the GHS principles, compared with their current equivalent classification status under Directive 1999/45, while a further number currently classified as harmful in the EU would be downgraded to category 5, using the GHS approach.

Since these discussions, a further problem has potentially been identified by the gases industry in applying the ATE approach to toxic gases. In a paper [31] submitted to the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals in December 2003 the industry stated that the formula gives anomalous results and under-predicts the acute toxicity of gaseous mixtures. They proposed that a simple cut-off approach should be used for gaseous mixtures, similar to that used for carcinogens, mutagens and reproductive toxicants. An expert working group under the auspices of the OECD has begun work on this issue. As a result of these discussions, it appears that the additivity formula gives the correct LC_{50} or ATE equivalent for gaseous mixtures and allows acute lethality of toxic gas mixtures to be ranked to compare severity of hazard. The problem thus may not therefore be as great as first envisaged.

Nevertheless, the suggestion that application of the ATE approach will lead to a decrease in the level of protection for a number of mixtures is of significant concern. Inclusion of category 5, for at least oral toxicity and possibly also for inhalational toxicity, will address to a certain extent these concerns. Nonetheless, we consider that the GHS methods for estimating the acute toxicity of mixtures need further discussion (see below).

Consideration of the above indicates two options:

Option 1:

The ATE approach and the additivity formulae are used in the future EU system for derivation of the acute toxicity classification of a mixture.

Option 2:

Do not include the ATE approach for derivation of the acute toxicity classification of a mixture.

Despite the possible weaknesses identified in the ATE approach, our recommendation is to retain the ATE approach and the additivity formulae as an option for the derivation of the classification of a mixture for acute toxicity. While the previous analyses outlined above

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indicate that there may be a problem applying the approach in the case of certain mixtures, it is part of GHS and was accepted at the time by those EU Member States involved.

As noted above under our general discussion of problems with the GHS criteria, we believe that development of a solution to this problem is not one for the EU to solve unilaterally. We recommend that further work is undertaken within the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals. Since it is important that this is resolved quickly to prevent a loss of protection, we recommend that this is an issue that is given priority in future discussions with a view to resolving this in the current biennium. As indicated, the question of the acute toxicity estimates for gaseous mixtures is currently under discussion in the OECD Working Group.

(d) Corrosive to the respiratory tract

Paragraph 3.1.2.6.5 of GHS states that “if data are available that indicates that the mechanism of toxicity was corrosivity of the substance or mixture, certain authorities may also choose to label as *corrosive to the respiratory tract*.”

Option 1:

Retain this reference and the labelling provision.

Option 2:

Do not retain this reference and the labelling provision.

We have left the provision in Part 3 (amended in paragraph 3.1.2.3.3 of Part 3) and have included the statement under the labelling provisions in Hazard Communication in Chapter 3.1 and also in Annex III, Hazard statements, but without a number.

Chapter 3.2 Skin corrosion/irritation

We have noted earlier that there are potential difficulties with the text of this Chapter. The chapter is headed Skin Corrosion / Irritation as is the Hazard Communication Table 3.2.4.1. The text suggests that the correct descriptor of hazard categories in this class should be “Skin Corrosion / Irritation Category 1” and “Skin Corrosion / Irritation Category 2”, etc. However the term “corrosive” alone is used as a description of category 1 at various places in the text, and there is a specific section on skin irritation. The text is also technically inconsistent and interchanges “skin” and “dermal”. However, we do not believe that development of a solution to this problem is one for the EU to solve unilaterally.

(a) Corrosion

The GHS contains a single category for corrosives, Category 1, but provides the option to divide it into three subcategories dependent on the length of time of exposure and observation period. Category 1A is equivalent to R 35 in the current EU system, while a hybrid 1B/1C (corrosive effects occurring between 3 minutes and 4 hours exposure and observation period up to 14 days) is equivalent to R34.

Option 1:

Corrosive category 1 is divided into three subcategories 1A, 1B, 1C.

Option 2:

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Corrosive category 1 is not divided into subcategories.

We consider that it is appropriate to adopt Option 1 in the future EU legislation and this is the option shown in Part 3. We take this view because this subdivision broadly reflects the current treatment of skin corrosives, and is in line with the recommendations of the ECB White Paper Working Group [5] for this hazard category. It should be noted that the labelling elements for the three subcategories are identical.

We have suggested a provision in paragraph 3.2.2.1.3, whereby if test data already generated for the classification of substances as corrosive with R34 under Directive 67/548/EEC or other relevant EU legislation does not enable differentiation between categories 1B and 1C and cannot be re-examined, the substance or mixture should be classified as category 1B. Whilst providing a conservative approach, we consider that this option would prevent unnecessary retesting, as well as help in translating the current EU classification to a GHS hazard category. An additional option would be to combine categories 1B and 1C from the outset. We are reluctant to include a partial fusion of categories in this way, as the problems identified above can be covered by a solution that is more consistent with the building block principle, and we have therefore not included this third option.

(b) Irritation

The GHS contains two categories for skin irritancy, irritant (category 2) and mild irritant (category 3). The criteria for category 2 are very similar to those for R 38 while category 3 falls into the category of a GHS health effect building block in the GHS system which does not form part of the EU current classification system for dangerous chemicals.

Consideration of the above indicates 3 options:

Option 1:

Mild irritant (category 3) is not included in the future EU system.

Option 2:

Mild irritant (category 3) is included in Annex II.

Option 3:

Mild irritant (category 3) is included in Annex I.

As already discussed, we have suggested as a result of our analysis that this hazard category should not be regarded as “*dangerous*”, for classification purposes. We consider, nevertheless, that this category could be relevant for hazard communication in certain circumstances e.g. for consumers or for certain types of chemicals (the category was included in GHS in part for the purpose of labelling of pesticides). The ECB White Paper Working Group [5] provisionally recommended that this category should not be included in the future EU system, but Ökopol [7] identified opposing views on the adoption of the category. We have therefore included category 3 skin irritants in Annex II, Special Labelling Provisions (Option 2). As described previously, the relevant text relating to the criteria and hazard communication elements for category 3 skin irritants is shown in Part 3 of Annex I as strike-through text and in Annex II as direct (clear) text.

We have considered whether this category could encompass the current EU additional toxicological property R66, defatting for skin (Repeated exposure may cause skin dryness or cracking), but have concluded that the criteria for assignment of R66 and classification as

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category 3 are distinct, and both have been included in Annex II. We consider that this is an issue that should be addressed in future discussions of these Annexes. Our view is that there may be some overlap between these 2 hazard categories, despite the fact that the criteria are largely distinct, and that the future system does not need two categories of mild (“soft”) skin irritation. Thus while both have been included in Annex II, our ultimate recommendation is that Mild irritant category 3 should not be included in the future EU system and it is therefore shown in strike-through text in both Annex I and Annex II (Option 1).

(c) Testing and evaluation strategies for dermal corrosion and irritation potential

As discussed earlier in this report, the GHS text for skin corrosion/irritation includes Figure 3.2.1, showing the testing and evaluation strategy which should be used in applying the criteria for these endpoints. This Figure can be construed as implicitly imposing data requirements that are not within the scope of a draft Regulation on classification and labelling. It has however been retained in the draft text pending a policy decision regarding the extent to which such Figures form an integral part of the GHS or are more appropriately included as part of REACH or as guidance material to aid in the interpretation of the criteria. It should be noted that the parallel decision logics to be used in applying the classification procedure for each GHS hazard class specifically state that these are not part of the GHS, whereas a similar statement is not associated with Figure 3.2.1.

Chapter 3.3 Serious Eye Damage/Eye Irritation

The GHS contains a single category for substances and mixtures causing serious eye damage (category 1) the criteria for which are very similar to those for R41. This category can be transposed directly in the future legislation, as proposed in Part 3. There is also one category for eye irritants (category 2); however GHS makes provision for this category to be divided into two subcategories 2A (irritant) and 2B (mild irritant). These 2 subcategories differ only in the length of time which is specified for full reversibility to be seen, 21 days in the case of 2A and 7 days in the case of 2B. The criteria for R36 specify that effects should occur within 72 hours after exposure and should persist for at least 24 hours. Categories 2A and 2B thus encompass R36. The options are as follows:

Option 1:

The hazard category 2, “irritating to eyes”, should not be divided into two subcategories 2A (irritant) and 2B (mild irritant).

Option 2:

The hazard category 2, “irritating to eyes”, should be divided into two subcategories 2A (irritant) and 2B (mild irritant).

We have implemented Option 1 in Chapter 3.3, in line with the provisional recommendation of the ECB White Paper Working Group [5] that category 2B should be included in the future EU system. The relevant text relating to the criteria and hazard communication elements for category 2B eye irritants is therefore shown in chapter 3.3 of Annex I as strike-through text. In contrast to category 3 skin irritants, which we have included in Annex II, Special Labelling Provisions as an additional category not currently covered by EU criteria which could be relevant for hazard communication in certain circumstances e.g. for consumers (albeit with a caveat), we do not consider that mild irritants (2B) should be included in Annex II. The underlying rationale is that the current R36 encompasses both category 2A and category 2B

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and is covered by the single category 2. This enables a ready migration from the existing Xi, R36 to Category 2 in the future system.

In relation to testing and evaluation strategies for serious eye damage and eye irritation, as for skin corrosion/irritation above, the GHS text includes a Figure 3.3.1, showing the testing and evaluation strategy which should be used in applying the criteria for these endpoints. The same arguments apply to inclusion of this figure as outlined for skin corrosion/irritation.

Chapter 3.4 Respiratory or Skin Sensitisation

The GHS contains a single category 1 for respiratory sensitisers. The criteria are very similar to those currently applied for R42 substances in Annex VI of Directive 67/548/EEC, and this category can be transposed directly in the future legislation, as proposed in Part 3. There is also a single category for skin sensitisers, criteria for which are similar to those for R43 substances, and again this can be transposed directly in the future legislation, as proposed in Part 3.

One issue arising in relation to Chapter 3.4 is the status of substances causing immunological contact urticaria. In the current EU system it is specified that “Some substances or preparations, which meet the criteria for R42 may in addition cause immunological contact urticaria. In these cases, information concerning contact urticaria should be included by the use of appropriate S-phrases (...) and in the Safety Data Sheet.” The GHS contains this provision but additionally recommends the consideration of their classification as contact sensitisers, irrespective of their properties as respiratory sensitisers. Both provisions have been included in Part 3, chapter 3.4.

Chapter 3.5 Germ Cell Mutagenicity

(a) Division into subcategories

The GHS criteria for germ cell mutagens provide for two categories, category 1 (Chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans) and category 2 (Chemicals which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans).

There is provision, however for category 1 to be divided into 2 subcategories, 1A (Chemicals known to induce heritable mutations in germ cells of humans) and 1B (Chemicals which should be regarded as if they induce heritable mutations in the germ cells of humans). The hazard communication elements for the two subcategories are identical. The classification criteria for the three categories, 1A, 1B and 2, are broadly similar to those for category 1, category 2 and category 3 mutagenic substances in the current EU system, while the GHS category 1 effectively encompasses the EU categories 1 and 2. However the issue is whether the future EU legislation will use the subcategories 1A and 1B or just use category 1 and category 2.

Option 1:

The future EU legislation will not differentiate category 1 germ cell mutagens into category 1A and 1B

Option 2:

The future EU legislation will differentiate category 1 germ cell mutagens into category 1A and 1B

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We have implemented Option 1 in Chapter 3.5 of Part 3, in line with the recommendation of the ECB White Paper Working Group [5] that category 1A and 1B should be combined in the future EU system. We consider that this is justified in the case of germ cell mutagens, since in practice substantive evidence of induction of heritable mutations in the germ cells of humans is not available for any chemical.

(b) Testing strategy for germ cell mutagens

The GHS text (paragraphs 3.5.2.5 - 3.5.2.9) contains examples of toxicological tests that can be used in the identification of germ cell mutagens. We have identified earlier in this report testing strategies or references to specific tests that could implicitly impose data requirements that are not within the scope of a draft Regulation on classification and labelling. However at this stage we have retained these examples within chapter 3.5, as paragraphs 3.5.2.5.4 to 3.5.2.5.8. A policy decision will be required regarding references to testing strategies or testing requirements in the Annex (see also comment (c) on skin corrosion/irritation above).

(c) Testing mixtures for mutagenicity

In contrast to the current EU system, where classification of a preparation for mutagenicity can only be based on application of the conventional (cut-off) method, the GHS allows testing of mixtures for CMR properties on a case-by-case basis, although it does state clearly that “Classification of mixtures will be [primarily] based on the available test data for the individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens”. The issue for the future legislation is whether the EU will or can maintain its current stance regarding non-testing of mixtures for these properties.

Option 1:

The future EU legislation will not allow testing of mixtures for germ cell mutagenicity.

Option 2:

The future EU legislation will allow testing of mixtures for germ cell mutagenicity on a case-by-case basis.

The approach taken in Part 3, Chapter 3.5, is classification of a mixture for germ cell mutagenicity can only be based on available test data on germ cell mutagenicity for the individual ingredients of the mixture and using cut-off values/concentration limits as established in Chapter 3.5. This is in line with the recommendation of the ECB White Paper Working Group [5]. However it has been identified that under the GHS harmonised system, the EU cannot reject test data on a complete mixture generated outside the EU. The ECB White Paper Working Group recommended that for mixtures where test data are already available which can be used for classification, an assessment will have to be done on a case-by-case basis.

For this reason, text has been included in paragraph 3.5.3.1.2 which states that “In the case of mixtures that have been manufactured and tested for germ cell mutagenicity outside the Community, the classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole.”

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Chapter 3.6 Carcinogenicity

(a) Guidance to the criteria

The GHS criteria for carcinogens provide for 2 categories, category 1 (known or presumed human carcinogens) and category 2 (suspected human carcinogens). Category 1 may be divided into 2 subcategories, 1A and 1B. The classification criteria for the three categories, 1A, 1B and 2, are broadly similar to those for category 1, category 2 and category 3 carcinogens in the current EU system.

Evaluation of the GHS criteria for classification of carcinogens has raised concerns that the criteria are somewhat vague and open to misinterpretation compared with those currently in use within the EU. It is recognised that additional guidance on interpretation of the GHS criteria is needed, particularly in cases where the data are poor or incomplete. These issues have been discussed within the OECD Task force on Harmonisation of Classification and Labelling [32]. At the July 2005 meeting of the UN Experts on GHS [13] a revised text for additional guidance was agreed, for addition to the GHS text at the next round of revisions.

Although revised guidance to the criteria has now been adopted by the UNSCEGHS, these have not been formally adopted as part of the GHS. There are still concerns that this guidance falls short of the guidance in the current EU legislation, and that application of the GHS criteria may still provide less clarity than the current guidance. We regard these concerns as fully justified. We consider that further development of additional guidance is required, and this work should lead to further, longer term, revision of the GHS.

We also recognise that considerations of carcinogenic potency have still not been addressed in the GHS document. Whilst these matters are included in the work plan for the next biennium [27], the UNSCEGHS in July 2005 noted that several delegations considered that, due to the difficulty in agreeing on the use of potency estimation, the work should be discontinued for the time being. The UNSCEGHS finally decided to ask the OECD Technical Focal Point on health hazards to come to a conclusion on this issue and to present a report at the December 2005 session.

Given the above, we have given consideration to whether the GHS criteria for classification of carcinogens should form part of the draft EU legislation to implement the GHS until such time as the GHS text is revised. The following options were considered:

Option 1:

The current GHS text for classification of carcinogens will be used as the basis in drafting Chapter 3.6 of Part 3

Option 2:

The current GHS text for classification of carcinogens will not be used as the basis in drafting Chapter 3.6 of Part 3. Instead, the current text of Annex VI of Directive 67/548/EEC will be used to provide classification criteria for carcinogens.

Notwithstanding our reservations, our approach in the current text has been that outlined in Option 1, and the text in Chapter 3.6 of Annex I follows the GHS text, with some editorial

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amendment. Consideration could also be given to including the revised guidance³⁴ [27] agreed at the UNSCEGHS before this is formally adopted by the GHS.

While the analyses referred above indicates that the GHS criteria may be difficult to apply, they were accepted at the time by those EU Member States involved in the work, and it would represent a significant departure from the harmonised system not to use them in the draft legislation. Were this option to be used, the EU would effectively be “opting out” of the GHS for this endpoint, and the current criteria for carcinogenicity would have to be included in Part 5 of Annex I.

(b) Division into subcategories

A further issue is whether the future EU legislation will use the subcategories 1A and 1B or just use category 1 and category 2. The hazard communication elements for the two subcategories are identical.

Option 1:

The future EU legislation will not differentiate category 1 carcinogens into categories 1A and 1B.

Option 2:

The future EU legislation will differentiate category 1 carcinogens into categories 1A and 1B.

The only difference in the two categories is that the source of the evidence is different, whilst the strength of the evidence can be considered to be the same in both cases. This approach is followed for three hazard classes, carcinogenicity, germ cell mutagenicity and reproductive toxicity, but not for other end points. We can see no technical case for this distinction and so we have implemented Option 1 in Chapter 3.6 of Part 3. This is in line with the recommendation of the ECB White Paper Working Group [5] that categories 1A and 1B should be combined in the future EU system. The same option has been followed for the two related endpoints, germ cell mutagenicity and reproductive toxicity.

(c) Testing of mixtures for carcinogenicity

As already discussed for germ cell mutagenicity and in contrast to the current EU system, where classification of a preparation for carcinogenicity can only be based on application of the conventional (cut-off) method, the GHS allows testing of mixtures for CMR properties on a case-by-case basis, although it does state clearly that “Classification of mixtures will be [primarily] based on the available test data for the individual ingredients of the mixture using cut-off values/concentration limits for the ingredients classified as germ cell mutagens”. The issue for the future legislation is whether the EU will or can maintain its current stance regarding non-testing of mixtures for these properties.

Option 1:

The future EU legislation will not allow testing of mixtures for carcinogenicity.

Option 2:

The future EU legislation will allow testing of mixtures for carcinogenicity on a case-by-case

³⁴ This guidance was based on the OECD document ENV/JM/HCL(2005)2REV.

basis.

The approach taken in Part 3, Chapter 3.6, is classification of a mixture for carcinogenicity can only be based on available test data on carcinogenicity for the individual ingredients of the mixture and using cut-off values/concentration limits as established in Chapter 3.6. This is in line with the recommendation of the ECB White Paper Working Group [5]. However under the GHS harmonised system, the EU cannot reject test data on a complete mixture generated outside the EU. The ECB White Paper Working Group recommended that for mixtures where test data are already available which can be used for classification, an assessment will have to be done on a case-by-case basis.

For this reason, text has been included in paragraph 3.6.3.1.2 which states that “In the case of mixtures that have been manufactured and tested for carcinogenic hazard outside the Community, the classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole.”

Chapter 3.7 Reproductive Toxicity

(a) Use of GHS criteria

The issues in relation to reproductive toxicity are similar to those outlined for carcinogenicity above. Concerns have been expressed about the interpretation of the GHS criteria for classification of substances for reproductive toxicity and whether equivalent classifications will result from application of the GHS criteria as currently would be the case when applying the EU criteria. The recent updating of the GHS text to replace the phrase “adverse effects on reproductive ability or capacity” by “adverse effects on sexual function and fertility” may help to resolve differences in terminology between the two systems, but residual concerns remain. The issues are as follows, presented as options as for the other endpoints.

Option 1:

The current GHS text for classification of substances for reproductive toxicity will be used as the basis in drafting Chapter 3.7 of Part 3.

Option 2:

The current GHS text for classification of substances for reproductive toxicity will not be used as the basis in drafting Chapter 3.6 of Part 3. Instead, the current text of Annex VI of Directive 67/548/EEC will be used to provide classification criteria for reproductive toxicity.

Notwithstanding our reservations, our approach in the current text has been that outlined in Option 1, and the text in Chapter 3.7 of Annex I follows the GHS text, with some editorial amendment.

While the analyses referred above indicates that the GHS criteria may be difficult to apply, they were accepted at the time by those EU Member States involved in the work, and it would represent a significant departure from the harmonised system not to use them in the draft legislation. Were this option to be used, the EU would effectively be “opting out” of the GHS for this endpoint, and the current criteria for reproductive toxicity would have to be included in Part 5 of Annex I.

(b) Division into subcategories

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Option 1:

The future EU legislation will not differentiate category 1 reproductive toxicants into categories 1A and 1B.

Option 2:

The future EU legislation will differentiate category 1 reproductive toxicants into categories 1A and 1B.

The only difference in the two categories is that the source of the evidence is different, whilst the strength of the evidence can be considered to be the same in both cases. This approach is followed for three hazard classes, carcinogenicity, germ cell mutagenicity and reproductive toxicity, but not for other end points. We can see no technical case for this distinction and so we have implemented Option 1 in Chapter 3.7 of Part 3. This is in line with the recommendation of the ECB White Paper Working Group [5] that categories 1A and 1B should be combined in the future EU system. The same option has been followed for the two related endpoints, germ cell mutagenicity and carcinogenicity.

(c) Testing of mixtures for reproductive toxicity

Option 1:

The future EU legislation will not allow testing of mixtures for reproductive toxicity.

Option 2:

The future EU legislation will allow testing of mixtures for reproductive toxicity on a case-by-case basis.

As for classification for germ cell mutagenicity and carcinogenicity, the approach taken in Chapter 3.7 has been to implement Option 1 in each case, with underlying justification outlined above.

(d) Choice of cut-off levels

Table 3.7.1 in the GHS gives two values for cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants that would trigger classification of the mixture. These cut-off values apply both to solids and liquids (w/w units) and gases (v/v units). A footnote to the Table explains that this is a compromise classification scheme that involves differences in hazard communication practice in existing systems, and considers that the numbers of affected mixtures will be small. The distinction between the figures given reflect that for the lower figure some jurisdictions will require information in the SDS whilst a label warning would be optional; for the higher figure, both a SDS and a label would be required.

The figures shown are 0.1% and 0.3% for category 1 reproductive toxicants (corresponding to Repr. Cat 1 and 2 under the current EU system) and 0.1% and 3% for category 2 reproductive toxicants (corresponding to Repr Cat 3).

The corresponding cut-off values in Annex II to Directive 1999/45/EC are 0.5% (and 0.2% for gaseous preparations) for Repr. Cat. 1 and 2, and 5% (and 1% for gaseous preparations) for Repr. Cat. 3.

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Option 1:

Adopt cut-off values of 0.3% for Category 1 Reproductive toxicants and 3% for Category 2 Reproductive toxicants.

Option 2:

Adopt a cut-off value of 0.1% for both Category 1 and Category 2 Reproductive toxicants.

We have indicated the higher value in the text (Option 1), showing the lower values (Option 2) as strike-through values, since this choice more accurately reflects the current situation in the EU.

(e) Effects on or via lactation

The GHS states that “Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes, such effects are treated separately”. As shown in GHS Figure 3.7.1 (b) such effects are allocated to a separate single hazard category to which no symbol or signal word is allocated for hazard communication purposes, but only the hazard statement “May cause harm to breast-fed children”. This has parallels with the current EU system, where effects on lactation are included under the heading of “other toxicological properties” and the risk phrase R64 is only allocated to substances already classified for another endpoint.

As discussed in the Overview to this section of the report, we recommend that this hazard class should not be regarded as “*dangerous*”, for classification purposes. We consider nevertheless that it is relevant to hazard communication at the workplace and for consumers, and for this reason it has been included in Annex II, Special Labelling Provisions. It is shown in Chapter 3.7 of Annex 1 as strike-through text and in Annex II as direct (clear) text.

Chapter 3.8 Specific Target Organ Systemic Toxicity – Single Exposure

The updated GHS criteria for STOST – single exposure provide for three categories, category 1 (Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following single exposure), category 2 (Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following single exposure) and category 3 (Transient target organ effects). The parallels in the current EU system are R39, “danger of very serious irreversible effects”, and R68, “possible risk of irreversible effects”, corresponding to categories 1 and 2, respectively. Category 3 encompasses effects such as narcotic effects and respiratory tract irritation (see below).

While issues do arise regarding the transparency of the GHS criteria for STOST and whether equivalent classifications will result from application of the GHS criteria as currently would be the case when applying the EU criteria, these appear to be less serious than for the C/R criteria, and the GHS text has been used as the basis of the text in chapter 3.8, with no significant issues arising. The recent updating of Chapter 3.8 of GHS may have improved the ease of application of the criteria, and the text for chapter 3.8 of the Annex includes the GHS criteria for classification of substances in categories 1, 2 or 3.

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(a) Respiratory tract irritation

The additional criteria for category 3 STOST – single exposure included in the updated GHS chapter 3.8 provide the criteria for classifying substances for respiratory tract irritation, with allocation of the symbol “exclamation mark”, the signal word “warning” and the hazard statement “May cause respiratory irritation”. This addresses the problem of a classification endpoint which existed under the current EU scheme but had no GHS equivalent, and which in the draft Annex X prepared in 2002 had been placed in Part 2 of that Annex. Such substances are classified as “Irritant” in the current EU scheme, with the risk phrase R37. The criteria are now provided in Chapter 3.8 of Annex I, Part 3.

(b) Narcotic effects

Similarly, the additional criteria for category 3 STOST – single exposure included in the updated GHS chapter 3.8 provide the criteria for classifying substances for narcotic effects, with associated hazard communication elements (the symbol “exclamation mark”, the signal word “warning” and the hazard statement “May cause drowsiness and dizziness”). In the current EU system R67 is, like R64, treated as “other toxicological properties” and is only allocated to substances already classified for another endpoint. There are two options for the inclusion of this hazard category in the future EU legislation:

Option 1:

To include category 3 STOST - narcotic effects in chapter 3.8 of Annex I, Part 3, with the symbol “exclamation mark”, the signal word “warning” and the hazard statement “May cause drowsiness and dizziness”.

Option 2:

To include category 3 STOST - narcotic effects in Annex II, Special Labelling Provisions with the hazard statement “May cause drowsiness and dizziness”.

Our approach has been that outlined in Option 1 above. While we recognise that this represents an increase in the level of protection for such substances compared with the current EU system, since under this option they will be regarded as “dangerous” substances and be assigned a pictogram and signal word in addition to a hazard statement, in practice we believe that the majority of such substances will already be classified as dangerous for other endpoints. We also consider that adoption of Option 2 would represent an incorrect application of the building block approach, and would result in a lack of international harmonisation for this endpoint.

Chapter 3.9 Specific Target Organ Systemic Toxicity – Repeated Exposure

The GHS criteria for STOST – repeat exposure provide for two categories, category 1 (Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated exposure), category 2 (Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following repeated exposure). The parallels in the current EU system are “Toxic” with the risk phrase R48, “danger of serious damage to health by prolonged exposure”, and “Harmful” with the risk phrase R48, “danger of serious damage to health by prolonged exposure”.

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Again while issues do arise regarding the transparency of the GHS criteria for STOST, repeat exposure, and whether equivalent classifications will result from application of the GHS criteria as currently would be the case when applying the EU criteria, these do not appear to be of major significance, and the GHS text has been used as the basis of the text in chapter 3.9, with no significant issues arising.

Chapter 3.10 Aspiration Hazard

The 2005 updated GHS text contains a new chapter 3.10, aspiration hazard. This inclusion addresses the problem of a classification endpoint which existed under the current EU scheme but had no GHS equivalent. Such substances had been classified as “Harmful” with the risk phrase R65 “Harmful: may cause lung damage if swallowed”.

The GHS criteria provide for classification in two categories, category 1 (Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard) and category 2 (Chemicals which cause concern owing to the presumption that they cause human aspiration toxicity hazard). This represents an additional level of protection compared with the existing EU system, which only has one hazard category. The 2 categories have different hazard communication elements.

We consider that it is appropriate to implement the new GHS criteria in the future EU system as they stand, and indeed to do otherwise would be an incorrect application of the building block approach, and would result in a lack of international harmonisation for this endpoint. The GHS criteria are provided unchanged in Chapter 3.10 of Annex I, Part 3.

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Annex I, Part 4 Classification for Environmental Properties according to the GHS Criteria

The current EU criteria in Annex VI to Directive 67/548/EC for classifying substances and preparations as dangerous for the environment are divided into two parts - Section 5.2.1, Aquatic environment and Section 5.2.2, Non - aquatic environment. The GHS criteria for environmental hazard classification (GHS Part 4) currently only cover classification as “hazardous to the aquatic environment”.

The EU criteria for the non-aquatic environment include criteria for the terrestrial environment and dangers to the ozone layer. It was the recommendation of the ECB White Paper Working Group [33] in 2002 that the risk phrases R54 “*Toxic to flora*”, R55 “*Toxic to fauna*”, R56 “*Toxic to soil organisms*”, R57 “*Toxic to bees*” and R58 “*May cause long-term adverse effects in the environment*” relating to the non-aquatic environment in Section 5.2.2 should not be included in the new legislation. Their rationale for this recommendation was that these risk phrases are unlikely to be those actually developed by a classification system going beyond the aquatic environment and are difficult to apply within the present system. They recommended that the new scheme should allow for the development of new criteria for the non-aquatic environment but any new R-phrases should be added as developed.

This approach has been adopted in Annex 1, Part 4, which includes only Chapter 4.1, “Hazardous to the Aquatic Environment”. The limited criteria for classification as dangerous for the non - aquatic environment with the risk phrases R54, R55, R56, R57 or R58 have not been included in the Annex, pending the development of new criteria for the non-aquatic environment and associated hazard communication elements, either within GHS or at EU level. As there are no relevant criteria for hazards to the ozone layer in the GHS system, these criteria for the non-aquatic environment have been included in Part 5 of the draft Annex as EU criteria not yet included in the GHS.

Annex 1, Part 4 thus contains the criteria for classification of substances and mixtures as “hazardous to the aquatic environment”, together with associated hazard communication elements. The GHS system is very similar to the current EU system but includes three acute classification categories (Acute Categories 1, 2 and 3) and four chronic classification categories (Chronic Categories 1, 2, 3 and 4). In the current EU system only substances (and preparations containing them) that are very toxic to aquatic organisms (R50, equivalent to Acute Category 1), with acute toxicities for fish (96 hr LC₅₀), daphnia (48 hr LC₅₀), or algae (72 hr IC₅₀) ≤ 1 mg/L, are classified as dangerous in the environment on the basis of acute aquatic toxicity alone. R51 substances (acute aquatic toxicity in the range >1 to ≤10 mg/L, equivalent to Acute Category 2) or R52 substances (acute aquatic toxicity in the range >10 to ≤100 mg/L, equivalent to Acute Category 3) are only classified as dangerous in the environment when they have other properties which would indicate a potential to persist in the environment (R53).

The GHS categories Chronic Categories 1, 2, 3 and 4 are directly equivalent to the EU R50-53, R51-53, R52-53 and R53. There is no category corresponding to R52 alone in GHS. There are minor differences in the properties indicating a potential to persist in the environment, e.g., log K_{ow} ≥ 3.0 goes to log K_{ow} ≥ 4 and BCF ≤ 100 goes to BCF < 500. The view of the ECB White Paper Working Group "Classification and Labelling", Sub-group 4, was these changes were not significant and in the main would be beneficial. They recommended that they should be implemented as per the GHS.

The approach adopted in Annex 1, Part 4, has therefore been to adopt the Part 4 GHS text largely word for word, with minor drafting amendments.

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(a) Inclusion of Acute toxicity categories 2 and 3.

Option 1:

Do not include Acute toxicity classes 2 and 3 in the draft Regulation

Option 2:

Include Acute toxicity classes 2 and 3 in Annex II of the draft Regulation as “*classified, but not as dangerous*”

Option 3:

Include Acute toxicity classes 2 and 3 in Annex I of the draft Regulation as “*classified as dangerous*”

The GHS Categories Acute 2 and Acute 3 are shown as strike-through text in the draft Annex I. We consider that these should not be included in the future EU system, since they were included in GHS primarily to cover situations where transport of large quantities of a substance may give rise to short-term dangers arising from accidents or major spillages. As these scenarios are primarily related to transport concerns, this is considered to lie outside the scope of the draft legislation. As a result, these two hazard categories have also not been included in the special labelling provisions in Annex II.

(b) Inclusion of the additivity principle

Option 1:

Include the criteria according to the GHS

Option 2:

Do not include the additivity principle in the criteria.

In relation to the introduction of the GHS ‘tiered approach’ concerning classification of mixtures, involving i) test data on the mixture when available, ii) bridging principles and iii) ‘summation’ approach and/or ‘additivity’ formula, the ECB White Paper Working Group [33] recommended two options, either to implement directly as per GHS or to not include the additivity formula (paragraph 4.1.3.5.5 of the draft Annex), as it is unlikely that the additivity formula will be used in the EU. The justification for the latter approach is that if data are available on components, classification will be required and the summation approach used. The approach adopted in Annex 1, Part 4, has been to include the additivity formula, and to implement the GHS criteria in its current form.

GHS also includes a multiplying factor (M-factor) in the summation method, to be applied to highly toxic components of a mixture. The ECB White Paper Working Group [33] were in favour of this approach, since it offers a positive route to self classification and may allow for accurate classification of preparations containing very toxic substances which do not have specific concentration limits. This approach has therefore been included in Annex 1, Part 4.

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(b) Status of guidance documents

The final issue in relation to Annex 1, Part 4 is the status of the guidance documents which constitute Annex 9 (guidance on hazards to the aquatic environment) and Annex 10 (guidance on transformation/dissolution of metals and metal compounds) of the GHS.

Option 1:

Include a direct reference in the legal text to Annex 9 and 10 of the GHS and implement as EU guidance documents.

Option 2:

Include Annex 9 of the GHS directly in the legal text, e.g. as an annex in the new legislation and a direct reference to Annex 10 in the Regulation.

The recommendation of the ECB White Paper Working Group "Classification and Labelling", Sub-group 4, was that there should either be a direct reference in the legal text to both Annexes implemented as EU guidance documents or a document (Annex 9) that should be given a status similar to the TGD [15] for risk assessment, with the 'dissolution protocol' as an annex to the metals chapter (Option 1), or that Annex 9 should be implemented as part of the legal framework, e.g. as an annex in the new legislation and a direct reference to Annex 10 in the Regulation (Option 2).

The approach taken in Annex 1, Part 4, has been to make reference to both documents, rather than to include Annex 9 or Annex 10 as an annex to the Annex. In addition we have made it clear in the draft Annex that the Annex 10 has not yet been validated.

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Annex I, Part 5 Additional EU Classifications

As already discussed in this Report (see “Discussion of Options for the Annexes” above), the working assumption has been made that the new scheme will be as close as possible to the existing EU scheme, and that it will maintain (or enhance) the existing standard of protection. For this reason, Part 5 of Annex I has been included to retain any EU classifications that are not (yet) covered by the GHS system.

The draft Annex X incorporating GHS criteria prepared in 2002 by Dr Iona Pratt included classification criteria for the endpoints “respiratory system irritation”, “aspiration hazard” and “dangerous for the ozone layer” in Part 2 of Annex X for the same reason. Since 2002, the endpoints “respiratory system irritation” and “aspiration hazard” have been included in the GHS, and hence have also been included in Part 3 of this Annex, in Chapter 3.8 and Chapter 3.10 respectively. Thus the only endpoint included in Part 5 of this Annex is “dangerous for the ozone layer”, discussed below³⁵.

Annex X also included in Part 2 separate sections including criteria for assignment of hazard statements to substances having additional toxicological properties. These properties were not regarded in the existing EU system as imposing a classification as dangerous in their own right but substances having such properties were assigned Risk Phrases if they were already classified as dangerous for other endpoints. These properties included “narcotic effects” and “defatting effects on skin”. Defatting effects on skin has been included in Annex II (Special Labelling and Packaging provisions), while narcotic effects has now been included in Part 3 of this Annex, in Chapter 3.8.

Dangerous for the ozone layer

Substances presenting a danger to the structure and/or the functioning of the stratospheric ozone layer are included in the EU system but not in GHS. Annex I to Council Regulation (EC) No 2037/2000 on substances that deplete the ozone layer [34] and its subsequent amendments, provides a list of such substances, while Annex VI of Directive 67/548/EEC provided the framework for their classification as “Dangerous for the environment” and labelling with the Risk Phrase R59 “Dangerous for the ozone layer”. Preparations containing such substances were classified on the basis of the conventional method in Annex III of Directive 1999/45/EC.

The same approach and criteria have been included in Part 5. The main issue arising in relation to this hazard class is the choice of symbol and pictogram to be used. This was discussed by the ECB White Paper Working Group [30] in 2002 and they recommended two options as follows:

Option 1:

The new scheme should continue to identify this hazard with the wording ‘*dangerous for the ozone layer*’. The symbol and indication of danger should be brought into line with the labelling proposals of the GHS - hence the diamond shaped white symbol with red frame and the signal word *Warning*.

³⁵ It should be noted that, if the amendments to the GHS text suggested in the chapter on explosives in Part 2 of the Annex to remove the ambiguity concerning unstable explosives are not considered to be appropriate, the EU criteria for E; R3 may need to be included in this Part of the Annex.

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Option 2:

The new scheme should continue to identify this hazard with the wording '*dangerous for the ozone layer*'. The symbol and indication of danger in the current legislation should be retained, hence the square orange symbol and the indication of danger "*Dangerous for the environment*".

We have included both options in Part 5 and in Annex V, as we consider the ultimate decision is a policy/legal one rather than a technical issue and is beyond the scope of this contract.

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Annex I, Part 6 Criteria for Allocation of Precautionary Statements

Issues

We have been asked to make proposals on how to incorporate precautionary statements and criteria for their application in the future Regulation.

Background to options development

The primary aim of all classification schemes is to provide essential information about the hazards of chemicals to enable users to take specific measures appropriate to the circumstances of use. It is generally recognised that most chemicals present risks for which general advice on the precautions to be taken should be provided and that this should be part of the package label.

Current system in the EU.

The EU scheme has evolved with “safety” or “S” phrases as supplements to the hazard information on the label. These phrases give standardised advice covering a range of situations, including response to accident, storage, precautions to avoid accident or exposure, and disposal.

The repertoire of phrases relating to appropriate medical action in response to accidental exposure has been increased in recent years, not least as a response to Austrian proposals.

Additional phrases were added covering prevention and disposal when the hazard criteria were extended to cover dangers to the environment. It proved difficult to agree on these phrases, and considerable revision was necessary before they found their present form. Part of the difficulty with these phrases was due to the recognition that the audience for this advice is less likely to be the individuals actually handling the chemical (the target audience for advice concerning Personal Protection Equipment (PPE), but rather the management responsible for the use of the chemical (the target audience for advice concerning release to the environment).

A major revision of the criteria for the application of S-phrases was carried out, prompted by the differences in the way S-phrases were applied by the Working Group concerned with the classification of new notified chemicals and the Working Group that assessed existing chemicals. The group assessing new notified chemicals had developed an approach that led to the obligatory application of certain S-phrases to certain hazards to a greater extent than that used for existing chemicals. In order to codify the difference in practice and to ensure this was properly reflected by the guidance in the Annex, the applicability of many of these S-phrases was revised. Whilst many of the criteria now included the statement that these S-phrases were “*obligatory*” for certain hazards, these statements are often qualified by focussing this obligation to certain specific conditions under which the chemical is used.

An element of “obligation” in the application of these S-phrases is necessary to ensure that proper and appropriate advice on precautionary action on the part of the user (worker or consumer) is included on the label as a necessary element of proper risk management. At the same time, differences in the circumstances under which a chemical is used makes it difficult to specify clearly and unambiguously the conditions under which this advice is in fact mandatory.

An example is given by the criteria for S46 (see text box below). Whilst apparently *obligatory* for all dangerous substances and preparations, the additional conditions limit the use of this

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phrase to certain specific chemical products. The main limitation is that this is unlikely to be relevant for substances at all, since almost all chemical products sold for consumer use are preparations rather than single substances. A second major limitation is that substances and preparations used only at the workplace are also excluded from being “obligatory”. In addition, the use is limited by a further restriction: “unless there is no reason to fear any danger from swallowing, particularly by children”.

S46 If swallowed, seek medical advice immediately and show this container or label

Applicability:

- all dangerous substances and preparations other than those which are classified as very toxic, toxic, corrosive or dangerous to the environment.

Criteria for use:

- *obligatory* for all dangerous substances and preparations mentioned above which are likely to be used by the general public unless there is no reason to fear any danger from swallowing, particularly by children.

This example clearly indicates the complication with this type of advice, namely that the appropriate allocation of the phrase requires not only information about the hazards as reflected in the intrinsic properties of the substance, but also knowledge of the use pattern expected for the particular substance or preparation. This is reflected in the guidance in Annex VI to Directive 67/548/EEC that “the final choice of S-phrases must have regard to the risk phrases indicated on the label and to the intended use of the substance or preparation”

Finally, the system clearly recognises the importance of ensuring that there is an agreed system of precedence in the provision of information, and a limit to the numbers of S-phrases on the label. This is illustrated by the practice that has been developed that recognises that for certain chemicals of high concern, advice on the label is insufficient, and much more detailed advice is required before using the chemical. This is reflected in the current practice to limit the use of S-phrases for Category 1 and 2 CMR substances to S53-45³⁶. Whilst the S45 provides medical advice in response to an accident, S53 refers to the SDS that has to be consulted before the chemical is used. This reflects a recognition that these chemicals with such severe hazards should not be used at all without proper prior information and instruction; the concise advice that the S-phrases provide is insufficient to provide adequate protection.

Role of S-phrases in Risk management

The phrases concerning prevention play an important role not only in providing advice at the workplace on the use of Personal Protective Equipment (PPE), but can also be regarded as an essential part of a risk management strategy. It is now common practice in the risk characterisation of notified substances assessed under Directive 67/548/EEC and existing

³⁶ S60 and S61 can be added as appropriate. The rationale for this is that this advice is aimed at management rather than at the individual worker handling the chemical.

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substances assessed under Regulation (EEC) No. 793/93 [34] that substances classified for certain hazards will have associated S-phrases requiring the use of appropriate PPE, and that these measures lead to a conclusion (ii) in the risk characterisation. This conclusion states that “there is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.”

The information provided by S-phrases is also provided in the SDS [16] in a more extensive form. The safety data sheet includes requirements on advice on First Aid Measures (Section 4), Fire-Fighting Measures (Section 5), Accidental Release Measures, (Section 6), Handling and Storage (Section 7) and Exposure Controls and the use of Personal Protection (Section 8). These headings are similar (but not identical) to the four groups of Precautionary Statements included in Annex 3 of the revised GHS, see below.

One of the reasons for including the SDS requirements in REACH is to provide provisions that ensure that all users of substances throughout the supply chain have the information they need to use them safely. The SDS, as set out in Annex Ia of the draft REACH Regulation, is closely linked to the Chemical Safety Reports described in Annex I of REACH [4].

GHS approach

In the negotiations on the GHS it was agreed that this system also should include safety advice, and the term “Precautionary Statements” (PS) was defined (GHS 1.2):

“a phrase (and/or pictogram) that describes recommended measures that should be taken to minimise or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product.”

In the development of the GHS priority was given to the classification system and the broad hazard communication arrangements. No resources were available to develop harmonised Precautionary Statements. A statement to this effect appeared in the first edition of the GHS [35] text section 1.4.6.2.

The revised edition of the GHS [1] contains a version of Annex 3 that has been considerably developed in comparison with the text in the first edition of the GHS [35].

The aims of the GHS Annex 3 are set out in paragraphs A 3.1.5 and A 3.1.6 quoted below:

“The goal of this annex is to promote a more consistent use of precautionary statements as shown in the attached matrix. By linking these statements to the hazard statements of the GHS, an improved understanding about appropriate precautionary behaviour is also made possible. Use of the matrix given in the annex enables the key concepts and approaches to be emphasized in training and education activities.

The guidance for assigning the phrases in the annex has been developed to provide the essential minimum phrases linking precautionary statements with relevant GHS hazard classification criteria and type of hazard. As much redundancy as possible has been removed in the wording of existing phrases in order to simplify them as much as possible.”

The guidance given in the GHS Annex 3 is given in A 3.3.1:

“This annex sets out a matrix which guides the selection of appropriate precautionary statements. It includes elements for all categories of precautionary action. All specific

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elements relating to particular hazard classes should be used. General elements not linked in particular to a certain hazard class or category should also be used.”

The specific suggestions for Precautionary Statements shown in Annex 3 are grouped under four headings: Prevention, Response, Storage and Disposal.

The work on this GHS Annex is however by no means agreed. In the second biennium work commenced on the development of a harmonised approach to Precautionary Statements. A Working Group was set up under the leadership of Germany. The group’s work concluded at the UNSCEGHS meeting in December 2004 with the following entry in the record (paragraph 40) [27]:

In the course of the discussion, it was reaffirmed that, according to the decision of the Sub-Committee, the text of Annex 3 of the GHS was to give guidance and not to standardize PS wording in a first step, and that this text would be frozen during a certain period to test its implementation and give feedback. Standardization might occur at a later stage when experience has been gained on this new Annex 3.

The UNSCEGHS agreed to amend the text of the GHS to reflect the work of the Group by revising the text of Annex 3 and amending the GHS text at 1.4.6.2 to read:

“... Although precautionary statements have not been fully harmonised in the current GHS, Annex 3 of this document provides guidance to aid in the selection of appropriate statements. Additional work to achieve greater standardization in this area may be undertaken in the future, once countries have gained experience with the system”.

Possible Options for the future EU legislation.

The current state of development of precautionary statements under the GHS presents two options for the EU, both of which are permissible with respect to the implementation of the GHS:

Option 1:

Maintain the current arrangements of S-phrases.

Option 2:

Replace the existing S-phrases and criteria with Annex 3 of the GHS.

Discussion

The current EU S-phrases scheme is well established and is familiar to suppliers and users of chemicals. It has been modified over the years to reflect the need for new advice and to clarify the criteria, which currently appear in Annex VI of Directive 67/548/EEC. There is no imperative to dismantle these arrangements in order to move to the GHS. Continuation of the current arrangements in their entirety will mean that there is least change and that GHS can be introduced “as near as possible” to the current scheme.

On the other hand, it must be recognised that the existing EU scheme for S-phrases reflects the existence of unresolved issues, as discussed above, and, as a result, has been subject to

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criticism from some Member States. Annex 3 of the GHS contains a structured and rational framework for the selection of Precautionary Statements. It was compiled on the basis of drafts submitted by Germany and it had support from EU Member States on the UNSCEGHS. A change to the framework in Annex 3 of the GHS may be advantageous and could solve some of the problems described above.

Recommendation

This is a very finely balanced argument and both of the options are sustainable. We think there needs to be a full debate at Member State and Commission level in which the strength of feeling of Member States who are concerned about the current scheme can be aired.

However, given the criterion that introduction of the GHS should be “as close as possible” to the current EU scheme, our marginal recommendation is to continue the current EU system for S-phrases and to regard these as precautionary statements within the framework of the GHS. We have therefore placed the existing EU criteria and phrases in Part 6 of Annex I with adjustments to describe the GHS classification and listed the phrases in draft Annex IV. The S-phrases and their criteria have been reordered in four sub-groups corresponding to the structure used in Annex 3 of the GHS [1]³⁷.

We do not recommend adoption of Annex 3 of the GHS at this stage because:

- it is not necessary to do so to introduce the GHS;
- it would not maintain the regulatory framework as close as possible to the existing EU scheme;
- there will certainly be costs associated with the change and the benefits cannot be easily assessed.
- as indicated in the revised GHS text of GHS 1.4.6.2, further change may occur in the future.

We accept that the current criteria for S-phrases in the EU system need rationalisation, but we do not consider that the current proposals for GHS Precautionary Statements provide a sufficient basis for their replacement at the present time. Further consideration of the issues in the context of EU legislation (including discussions on REACH) will provide an opportunity for stimulating further developments in the GHS system to ensure that these fully meet EU needs.

Among the issues to be considered are:

- the need to ensure consistency in the advice in sections 4 – 8 of the SDS and the Precautionary Statements on the label, given that the advice in the SDS for substances under REACH is linked to the Chemical Safety Report, and hence is part of ensuring that appropriate risk management measures are applied;
- the need to consider whether the divisions between the different types of Precautionary Statements (Prevention, Response, Storage, Disposal) should be modified to reflect more closely the types of advice reflected in the SDS;

³⁷ In one case (S47), criteria for application have been revised to include text from Part 2 of the GHS criteria.

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- the need to ensure that the allocation of Precautionary Statements is not only linked to particular endpoints but also takes into account the intended uses of the chemical;
- the need to ensure that the allocation of Precautionary Statements does not lead to situations where safety is compromised by the provision of excessive advice.

The first step might be to clarify the link between classifications and Precautionary Statements. As a provocation for this we have retained the GHS model hazard communication boxes in draft Annex I and Annex II with “pm” in the box for Precautionary Statements.

In the interim the appropriate statement will have to be selected from the criteria in Part 6 of Annex I as under the current EU scheme.

If the option to implement the provisions of Annex 3 of the GHS is chosen, the “pm” in the classification boxes can be replaced in the Precautionary Statement boxes in the two Annexes and the Precautionary Statements shown in the draft Annex IV replaced by the list of GHS Precautionary Statements.

Considerations of the links between the draft Regulation implementing GHS and the draft REACH Regulation are outside the scope of this report. However, we consider that the links between the Chemical Safety Reports and the SDS in the draft REACH regulation could well have implications for the allocation of the Precautionary Statements, and that this should be explored further before any changes are made to the current system.

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Annex II: Special Provisions for Labelling and Packaging.

Annex II, Part 1: General Introduction

This Annex is now a substantial independent Annex that contains the extra labelling provisions from Annex VI (sections 2.2.6 and 3.2.8) to Directive 67/548/EEC and Annex V to Directive 1999/45/EC as well as the additional GHS categories that are not regarded as “dangerous”.

The Annex also contains the procedures from Annex VI to Directive 1999/45/EC for confidentiality for the chemical identity of a substance.

Finally, it contains the Special Packaging requirements from Directive 1999/45/EC and Directive 67/548/EEC (including Annex IX) concerning the provision of child-proof fastenings.

The content of this Annex is dependent on a distinction between hazards “*classified as dangerous*” and “*classified but not as dangerous*” as discussed earlier in this report. However, a number of options are possible in relation to this Annex:

Option 1: Accept the distinction between hazards “*classified as dangerous*” and e “*classified but not as dangerous*” and maintain the structure of Annex II as presented in this report

Option 2: Transfer the hazards identified as GHS hazards in Parts 2 and 3 of the draft Annex II to Annex I, retaining the draft Part 4, the current EU “*additional labelling requirements*” in this Annex

Option 3: Transfer the hazards identified as GHS hazards in Parts 2 and 3 of the draft Annex II as well as the draft Part 4, the current EU “*additional labelling requirements*” in this Annex to Annex I

The issues related to changes in the current EU definition of “*dangerous*” have been discussed earlier in the report. We have based our recommendations on the basis of Option 1 above. However, both options 2 and 3 are possible choices, depending on whether the current definition of “*classified as dangerous*” is maintained or not.

It should be noted that if Option 2 is chosen, further revision will almost certainly be required, as many of the hazards included in the current “*additional labelling requirements*” are under consideration for inclusion as GHS hazard categories.³⁸

Annex II, Part 2: GHS Hazard Classes and Categories for Physical Hazards included in this Annex

The following GHS hazard classes and/or categories for physical hazards have been included in this Annex:

³⁸ For further details of which specific additional labelling requirement categories are being discussed for inclusion in GHS, see the more detailed discussion below.

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- Gases under pressure
- Category 4 of flammable liquids; Combustible liquids
- Self-reactive substances and mixtures
- Self-heating substances and mixtures
- Category 3 Oxidizing liquids and solids
- Corrosive to metals

The options for including these categories in this Annex or in Annex I have been discussed above under the relevant sections in Annex I.

With the exception of “Self-reactive substances and mixtures” and “Corrosive to metals” we recommend that these classes/categories should be included here rather than in Annex I.

“Self-reactive substances and mixtures” have been included here, but we recognise that part or all of this hazard class may be more appropriately included in Annex I, in spite of the dependence of the criteria on the packaged state. It is noted that as there are no labelling requirements associated with Type G, this need not be included in this Annex.

We do not consider that “Corrosive to metals” is required in this Regulation, and this chapter is shown as strike-through text.

Annex II, Part 3: GHS Hazard Classes and Categories for Health Hazards included in this Annex

The following GHS hazard classes and/or categories for health hazards have been included in this Annex:

- Acute toxicity Category 5
- Mild skin irritation
- Effects on or via lactation.

Acute toxicity Category 5

As indicated in the Overview discussion on Part 3 of draft Annex I and in the discussion on Chapter 3.1, Acute Toxicity, we have recommended that the GHS category Acute Toxicity category 5 should not be regarded as “*dangerous*”, for classification purposes, and for this reason criteria related to the category are shown in strike-through text in that chapter. We consider, nevertheless, that the category is relevant for hazard communication to consumers, and for this reason criteria for classification of substances and mixtures as category 5 and the associated GHS signal word and hazard statement (the communication elements assigned under GHS) have been included in Annex II, Part 2.2.

However, in line with the views of the ECB White Paper Working Group [6], this category has only been included in Annex II for acute *oral* toxicity, although the GHS provides criteria for classification of substances and mixtures as category 5 for acute dermal and acute inhalational toxicity also. Inclusion of the criteria for category 5 for acute inhalational toxicity in the future Regulation may also be appropriate in the light of concerns expressed about the classification of gaseous mixtures (see discussion on Acute Toxicity Category 5 in relation to Annex I above), but we have not addressed this issue in this proposal.

We consider that classification of mixtures as acutely toxic category 5 may pose some problems, unless the mixture directly fits the criteria laid out in the draft Annex II, 3.1.2.1 (f). It appears that there may be particular issues involved in applying the additivity formulae based on the ATE estimates, outlined in 3.1.3.4 and 3.1.3.4.2.3, but further analysis of this was beyond the scope of this contract. Issues related to application of the ATE approach have been highlighted in the discussion on Part 3 of the draft Annex I above.

Mild skin irritation Category 3

We have also included category 3 skin irritants in Annex II, Special Labelling Provisions. As described previously, the relevant text relating to the criteria and hazard communication elements for category 3 skin irritants is shown in Part 3 of Annex I as strike-through text and in Annex II as direct (clear) text. However, as mentioned in the discussion on Annex I, Part 3, Chapter 3.2, we consider that there may be some overlap between category 3 skin irritancy and R66, defatting effects on skin (see discussion on Part 3 of Annex II). Thus while both have been included in Annex II, our ultimate recommendation is that Mild irritant category 3 should not be included in the future EU system and should therefore be shown in strike-through text in both Annex I and Annex II.

Effects on or via lactation

As already discussed above for Chapter 3.7 Reproductive toxicity, we have recommended that this hazard class should not be regarded as “*dangerous*”, for classification purposes, but

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consider, nevertheless, that it is relevant to hazard communication at the workplace and for consumers, and for this reason have included the relevant text relating to the criteria and hazard communication element (a single hazard statement) in Annex II. It is shown in Chapter 3.7 of Annex 1 as strike-through text and in Annex II as direct (clear) text.

The GHS criteria provide two options in the Table 3.7.1 for Cut-off values/concentration limits of ingredients of a mixture classified for effects on or via lactation that would trigger classification of the mixtures. These limits are 0.1% or 0.3%. The lower limit is accompanied by the following note:

“NOTE 1: If a Category 1 reproductive toxicant or substance classified in the additional category for effects on or via lactation is present in the mixture as an ingredient at a concentration between 0.1% and 0.3%, every regulatory authority would require information on the SDS for a product. However, a label warning would be optional. Some authorities will choose to label when the ingredient is present in the mixture between 0.1% and 0.3%, whereas others would normally not require a label in this case.”

Note 2 relating to the higher cut-off of 0.3% indicates that both an SDS and a label would generally be expected.

The statement in Note 1 does not accurately reflect the current situation in the EU. Whilst this is cut-off used in the EU for Reproductive toxicity Categories 1 and 2, the general limit in Directive 1999/45/EC for effects on lactation (R64) is 1%, unless there is a specific concentration limit in Annex I.

We have therefore deleted the lower figure of 0.1% and retained the figure of 0.3%, and note that this figure is lower than the cut-off limit included in the current EU legislation.

GHS Hazard Classes and Categories for Environmental Hazards included in this Annex

No GHS hazard classes and/or categories for the environment have been included in this Annex. Since the categories for acute toxicity categories 2 and 3 (corresponding to R51 and R52 in the current EU system) have not been included in Annex I, even though these provisions are relevant to certain forms of transport, no special labelling provisions for supply and use are considered necessary.

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Annex II, Part 4: EU “Additional R-phrases” for Physical and Health Hazards included in this Annex

Physical Hazards

Part 3 of Annex II includes the “additional” R-phrases from Annex VI that do not in themselves result in classification as “*dangerous*”. These are included as these are considered equivalent to the GHS classes included in Part 2 of the Annex, and maintenance of these labelling provisions, where relevant, is necessary to maintain the level of protection provided by the draft Regulation.

The “additional” R-phrases covering physical properties are included in Section 2.2.6 of Annex VI to Directive 67/548/EEC. Whilst the White Paper Working Group [30] made no specific recommendations concerning these phrases, ECBI/150/04 [28] suggests that these should be included as GHS Precautionary Statements and/or an appropriate Precautionary Statement and more information provided in the SDS. Since we consider that it is necessary to retain these additional R-phrases where relevant, more detailed argumentation in support of this recommendation is shown below.

R1: Explosive when dry.

Substances assigned to this Risk Phrase are diluted explosives that are not covered by the GHS, and this type of chemical may present a hazard during both handling and storage [28].

The GHS criteria refer to this type of explosive in a Note: “*Some explosive substances and mixtures are wetted with water or alcohols or diluted with other substances to suppress their explosive properties. They are treated differently from explosive substances and mixtures (as desensitised explosives) for some regulatory purposes (e.g. transport)*”³⁹.”

Desensitised explosives are currently under consideration for inclusion in GHS [36].

There are 6 entries in Annex I to Directive 67/548/EEC with this additional R-phrase [29]. These are shown in the Table below, together with the R-phases for each entry.

Annex I entry number	Name	R-phrases
053-003-00-4	iodoxybenzene	R: 1
053-004-00-X	calcium iodoxybenzoate	R: 1
603-037-00-6	cellulose nitrate, nitrocellulose, containing more than 12,6 % nitrogen	R: 1-3
612-019-00-7	dipicrylamine, ammonium salt	R: 1-26/27/28-33-51/53
612-034-00-9	2-amino-4,6-dinitrophenol, picramic acid	R: 1-20/21/22-52/53
613-003-00-2	1,2,3,4-tetranitrocarbazole	R: 1-20/21/22

³⁹ Examples of these wetted and desensitised explosives that are permitted for transport are shown as a footnote to the discussion of unstable explosives in Annex I.

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As can be seen from the above Table, the first two entries are not in fact eligible for inclusion in Directive 67/548/EEC Annex I, as these are only classified with the additional R-phrase R1 and not as “*dangerous*”. The third entry is ambiguous. “Cellulose nitrate, nitrocellulose, containing more than 12,6 % nitrogen” is normally classified as an explosive. In Annex I it is classified as E; R3 as well as with R1⁴⁰. In the UN RTDG [12], nitrocellulose containing not more than 12.6% nitrogen is classified as flammable, and with higher concentrations as a class 1.1D explosive. Picramic acid is included in the UN RTDG [12] in class 4.1 in a wetted form. The remaining two entries do not appear as specific entries in the UN RTDG [12].

Since this type of substance is currently being considered for inclusion in the GHS and in view of the Note in the current GHS criteria, it would seem reasonable to retain this R-phrase as a Hazard Statement in order to provide appropriate labelling for wetted and desensitised explosives until further GHS criteria are considered.

As some of the current Annex I to Directive 67/548/EEC entries containing this additional R-phrase appear to be incorrectly assigned [28], these entries would need to be revised to ensure that this Hazard Statement is applied correctly.

R4: Forms very sensitive explosive metallic compounds

The GHS does not directly address the concerns covered by this additional R-phrase.

There are three entries⁴¹ in Annex I to Directive 67/548/EEC which are assigned this R-phrase [29]. These three substances are also classified as E; R2.

In view of the limited use of this additional R-phrase, and the fact that the substances concerned are normally already classified as explosive, we consider that retention of this additional R-phrase is unnecessary to retain the level of protection offered by the draft Regulation. This information should more appropriately be included in the SDS.

The text for this additional R-phrase is shown as strike-through text in this Annex (and in Annex III).

R5: Heating may cause an explosion.

The additional R-phrase is applicable to organic peroxides and self-reactive substances Types A and B. It may also be applicable to some Oxidizers and other substances on a case-by-case basis [28]. The wording of this R-phrase the same as wording of the hazard statement applied to Type A Self-reactive substances, although the criteria do not cover the same properties.

There are seven entries⁴², one of which is a notified substance, in Annex I to Directive 67/548/EEC which are assigned this R-phrase [29].

⁴⁰ The additional R-phrase would appear to be redundant when the substance is already classified as E; R3

⁴¹ 609-009-00-X: 2,4,6-trinitrophenol, picric acid; 609-012-00-6: 2,4,6-trinitro-*m*-cresol; 609-018-00-9: 2,4,6-trinitroresorcinol, styphnic acid.

⁴² 008-003-00-9: hydrogen peroxide solution ... %; 015-035-00-7: O,O-dimethyl O-4-nitrophenyl phosphorothioate, parathion - methyl (ISO); 017-006-00-4: perchloric acid ... %; 601-015-00-0: acetylene, ethyne; 609-036-00-7: nitromethane; 611-127-00-1: pentasodium 4-amino-6-(5-(4-(2-ethyl-phenylamino)-6-(2-sulfatoethanesulfonyl)-1,3,5-triazin-2-ylamino)-2-sulfonatophenylazo)-5-hydroxy-3-(4-(2-

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Substances having explosive properties although not classified as explosives are currently under consideration for inclusion in GHS [36].

We consider that, as this additional R-phrase is currently used for notified substances, and since this property may be included in the GHS, it should be retained as a Hazard Statement in order to maintain the level of protection offered by the draft Regulation.

R6: Explosive with or without contact with air

This risk phrase is used for Self-reactive gases that are not covered by the GHS. The GHS has no test method, criteria or classification for Self-reactive gases [28].

Chemically unstable gases are currently under consideration for inclusion in GHS [36].

There are two entries⁴³ in Annex I to Directive 67/548/EEC which are assigned this R-phrase [29].

Since this type of substance is currently being considered for inclusion in the GHS it would seem reasonable to retain this R-phrase as a Hazard Statement in order to provide appropriate labelling for chemically unstable gases.

R7: May cause fire.

Criteria for the use of this R-phrase occurs twice in Annex VI to Directive 67/548/EEC. It occurs as O; R7, as part of a classification as an oxidizer. In this context it describes certain categories of substances classified as dangerous in Annex I to Directive 67/548/EEC. It is also included as an additional R-phrase (without the classification as oxidizer) in section 2.2.6, Other physico-chemical properties. Here the criteria for R7 refer to “reactive substances and preparations, e.g. fluorine, sodium hydrosulphite”.

The two compounds mentioned as examples are the only two substances in Annex I to Directive 67/548/EEC [29] which have been assigned R7 without the classification as oxidizing.

Fluorine (009-001-00-0) is an oxidizing substance and compressed fluorine is classified as an oxidizing substance (Subsidiary risk 5.1) in the UN RTDG [12].

Sodium hydrosulphite (sodium dithionite, 016-028-00-1) is a water reactive substance evolving toxic gases, and GHS criteria for this latter hazard are currently under development.

In view of the fact that the criteria for this additional R-phrase is duplicated by other GHS categories (existing and under development) we consider that retention of this additional R-phrase is unnecessary to retain the level of protection offered by the Regulation.

The text for this additional R-phrase is shown as strike-through text in this draft Annex II (and in Annex III).

sulfatoethanesulfonyl)phenylazo)naphthalene-2,7-disulfonate; 612-122-00-7: hydroxylamine. A proposal for a split entry for hydroxylamine, only one of which includes R5 is included in the draft 30th ATP.

⁴³ 006-089-00-2: chlorine dioxide; 601-015-00-0: acetylene, ethyne.

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R14: Reacts violently with water

This additional R-phrase is used for substances that are not covered by the GHS and they mainly evolve corrosive gases. Classification criteria for substances releasing corrosive or toxic gases in contact with water are under development, and there will be a classification system in the future⁴⁴. There are some substances, e.g. sulphuric acid, which generate heat when in contact with water, which is a hazard not covered by the GHS [28].

There are 33 entries⁴⁵ currently in Annex I to Directive 67/548/EEC which are assigned this R-phrase [29], of which four are notified substances. This phrase is therefore in widespread use in the classification of substances under the current provisions.

The phrase is specifically included in the categories covered by the EU Major Accidents Hazards legislation [11].

In view of the widespread use of this additional R-phrase, its continued relevance for notified substances and its inclusion in EU Major Accident Hazards legislation, it is considered necessary to retain this R-phrase as a Hazard Statement.

R16: Explosive when mixed with oxidizing substances

There is only one R16 substance in Annex 1 to Directive 67/548/EEC: 015-002-00-7: red phosphorous [29]. The handling of red phosphorous is extremely dangerous due to the low minimum ignition energy. This is well established and communicated to the customer by the producers [28].

Substances having explosive properties although not classified as explosives are currently under consideration for inclusion in GHS [36].

In view of the very limited use of this additional R-phrase we consider that retention of this additional R-phrase is unnecessary to retain the level of protection offered by the draft Regulation. This information should more appropriately be included in the SDS. The text for this additional R-phrase is shown as strike-through text.

R18: In use, may form flammable/explosive vapour-air mixture

This additional R-phrase is used for non-flammable liquid or solid mixtures which contain volatile flammable components. Evaporation of these flammable components may give rise to a flammable or explosive mixture of this vapour with air⁴⁶. Since the use of this phrase is restricted to mixtures, the phrase does not occur in Annex I to Directive 67/548/EEC.

⁴⁴ These criteria will also address concerns covered by the additional R-phrases R29, R31 and R32.

⁴⁵ 005-001-00-X; 005-002-00-5; 005-003-00-0; 012-003-00-4; 013-004-00-2; 013-008-00-4; 014-001-00-9; 014-002-00-4; 014-004-00-5; 015-007-00-4; 015-008-00-X; 015-009-00-5; 015-103-00-6; 016-012-00-4; 016-013-00-X; 016-014-00-5; 016-015-00-0; 016-016-00-6; 016-017-00-1; 016-019-00-2; 022-001-00-5; 030-004-00-8; 603-040-00-2; 603-041-00-8; 607-011-00-5; 607-080-00-1; 607-093-00-2; 613-009-00-5; 613-041-00-X; 615-012-00-7; 615-022-00-1; 615-023-00-7; 615-028-00-4.

⁴⁶ R30 (see below) deals with the opposite situation, where the non-flammable components of the mixture evaporate, resulting in the mixture becoming flammable.

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This additional R-phrase is used for substances that are not covered by the GHS. Additional work in the GHS on suitable criteria may be appropriate [28]. The UN RTDG [12] have an entry UN3175 which classifies solids containing flammable liquids in class 4.1, PG II. Criteria for classification are not given.

In view of the relevance of the concern for this type of effect, not least at the workplace, it would seem reasonable to retain this R-phrase as a Hazard Statement in order to provide appropriate labelling for this type of mixture.

R19: May form explosive peroxides

This additional R-phrase is used for substances that are not covered by the GHS. This is mainly an issue related to handling and storage under air or prolonged exposure to air in an open vessel [28].

There are ten entries⁴⁷ in Annex I to Directive 67/548/EEC which are assigned this R-phrase [29].

Substances having explosive properties although not classified as explosives are currently under consideration for inclusion in GHS [36].

In view of the relatively widespread use of this additional R-phrase, and its relevance for the handling and storage of this type of chemical, it would seem reasonable to retain this R-phrase as a Hazard Statement in order to provide appropriate labelling for this type of chemical.

R30: Can become highly flammable in use

This additional R-phrase is used for non-flammable liquid or solid mixtures where the lack of flammability is due to volatile, non-flammable components. Evaporation of these non-flammable components may give rise to a flammable mixture. This additional R-phrase is largely duplicated by the separate labelling provisions for “Liquid mixtures containing halogenated hydrocarbons” (together with what is in effect another additional R-phrase) in Annex V to Directive 1999/45 Part B point 10:

“For liquid mixtures 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 packaging must show the following information as appropriate:

“Can become highly flammable in use” or

“Can become flammable in use”.”

This additional R-phrase was mainly for use for special cleaners based on flammable liquids combined with fluorocarbons with low boiling points, e.g. FC 113. All of the halogenated solvents with low boiling points are probably prohibited in any case [28], since these will be

⁴⁷ These are: 601-045-00-4: 1,2,3,4-tetrahydronaphthalene; 603-022-00-4: diethyl ether, ether; 603-024-00-5: 1,4-dioxane; 603-025-00-0: tetrahydrofuran; 603-031-00-3: 1,2-dimethoxyethane, EGDME, ethylene glycol dimethyl ether; 603-045-00-X: diisopropyl ether [1], dipropyl ether [2]; 603-100-00-8: 1,2-dimethoxypropane; 603-105-00-5: furan; 603-139-00-0: bis(2-methoxyethyl) ether; 603-160-00-5: 1,2-diethoxypropane; 603-176-00-2: 1,2-bis(2-methoxyethoxy)ethane, TEGDME, triethylene glycol dimethyl ether, triglyme.

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regulated under Regulation (EC) No 2037/2000 on substances that deplete the ozone layer [34]

In view of the concern for this type of effect, not least as reflected in the provisions of Annex V to Directive 1999/45, it would seem reasonable to retain appropriate labelling for this type of mixture, at least until it is established that this effect is no longer likely to occur in practice.

The section corresponding to point 10 of Annex V Part 2 of Directive 1999/45/EC has been retained in order to retain the phrase “Can become flammable in use” from the provisions of Directive 1999/45/EC. In order not to create duplicate provisions, the criteria for this additional R-phrase are shown as strike-through text in the draft Annex II (and in Annex III).

R44: Risk of explosion if heated under confinement

This additional R-phrase is used for substances that are not covered by the GHS. They are mainly substances similar or related to, but not meeting the criteria for the GHS Self-Reactive Substances (SRS) or Organic Peroxides [28].

Substances having explosive properties although not classified as explosives are currently under consideration for inclusion in GHS [36].

There are seven entries in Annex I to Directive 67/548/EEC which are assigned this R-phrase⁴⁸ [29], comprising a total of twelve substances. It has been suggested that these entries should be reviewed to check if they meet the criteria of any of the GHS Hazard Classes [28]. Ammonium perchlorate (UN No. 0402) can be classified in class 1.1D [12] if certain conditions of particle size and packaging (Special provisions 152) are met. Ammonium perchlorate (UN No 1442) is classified as an oxidizer (Class 5.1) [12]. C,C'-azodi(formamide) (UN No. 3242) is classified as flammable (Class 4.1). DNOC (UN No. 1598) and dinoseb (UN No. 2779)⁴⁹ are classified as toxic substances (class 6.1) without any indication of subsidiary risks. Dinoterb does not appear as a specific entry in the UN RTDG [12].

It is unclear to what extent the substances covered by the criteria of this additional R-phrase meet the criteria of other GHS hazard classes, or will be included in the review recommended by Germany [36]. However, it would seem reasonable to retain this R-phrase as a Hazard Statement in order to provide appropriate labelling for this type of mixture, at least until it is established that this property is covered by other, more relevant harmonised provisions.

Chapter 4.2; Health Properties

The “additional” R-phrases covering health properties are included in Section 3.2.8 of Annex VI to Directive 67/548/EEC.

These risk phrases are as follows:

- R66 Repeated exposure may cause skin dryness or cracking

⁴⁸ These are: 017-009-00-0: ammonium perchlorate; 609-020-00-X; 4,6-dinitro-*o*-cresol, DNOC; 609-025-00-7: 6-*sec*-butyl-2,4-dinitrophenol, dinoseb; 609-026-00-2: salts and esters of dinoseb, with the exception of those specified elsewhere in this Annex; 609-030-00-4: 2-*tert*-butyl-4,6-dinitrophenol, dinoterb (ISO); 611-028-00-3: C,C'-azodi(formamide)

⁴⁹ The UN entry is for “Substituted nitrophenol pesticide, solid, toxic” and as such would presumably include the salts and esters of dinoseb (609-026-00-2).

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- R67 Vapours may cause drowsiness and dizziness
- R29 Contact with water liberates toxic gas
- R31 Contact with acids liberates toxic gas
- R32 Contact with acids liberates very toxic gas
- R33 Danger of cumulative effects

R66, R29, R31 and R32 have been retained in Part 3 of draft Annex II: Special Labelling Provisions, providing criteria for assignation of hazard statements covering additional properties not currently included in the GHS. Criteria for their application are provided in the Annex.

We consider that the inclusion is straightforward in the case of R29, R31 and R32. Classification criteria for substances releasing corrosive or toxic gases in contact with water are under development in the GHS, and this is included in the work plan for the next biennium [27]. We considered the possibility of revising the wording of these additional R-phrases to reflect GHS terminology. However, we consider that the current wording should be retained, and that any changes should await agreement in the GHS.

However, as mentioned in the discussion on the draft Annex I, Part 3, Chapter 3.2, we consider that there may be some overlap between category 3 skin irritancy and R66 (see discussion on Part 3 of the draft Annex I). Thus while both have been included in Annex II, our ultimate recommendation is that while Mild irritant category 3 should not be included in the future EU system, R66 should be retained in the future system and should be included in the draft Annex II, as we have done.

In the case of R67, narcotic effects are now covered under the updated criteria for category 3 STOST in chapter 3.8 of the GHS. We have therefore included narcotic effects in Chapter 3.8 of the draft Annex I, Part 3, with the symbol “exclamation mark”, the signal word “warning” and the hazard statement “May cause drowsiness and dizziness”. As discussed already in the discussion on Annex I, Part 3, Chapter 3.8, we recognise that this results in a change from the status in the current EU legislation as an “additional toxicological property” to a classification as dangerous, but consider that this additional level of protection is justified. It is therefore shown in strike-through text in Part 3 of the draft Annex II

Finally, in the case of R33, we propose that this risk phrase should not be retained in the future EU system and we have shown it in strike-through text in part 3 of draft Annex II. Our justification for this is the fact that the risk phrase was already largely redundant in the existing EU system, following development of the improved criteria for the assignation of R48, and within GHS cumulative effects are clearly covered by the criteria for STOST – repeat exposure.

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Annex II, Part 5: Special Labelling Provisions for Certain Specific Substances or Mixtures

This part of Annex II contains the special labelling provisions from Annex V to Directive 1999/45/EC.

The provisions of Part A of Annex V for preparations classified as dangerous within Articles 5, 6 and 7 of Directive 1999/45/EC have either been transferred elsewhere in the draft Annexes, or have been superseded by sections from the GHS.

The provisions for preparations sold to the general public have been moved either to Part 1 of Annex VI (Consumer labelling) or to the criteria for allocation of Precautionary Statements (Part 6 of the draft Annex I). The provisions for preparations used for spraying have also been moved to Part 6 of the draft Annex I.

The remaining provisions on preparations containing a substance assigned R33 or R64 are now covered by the criteria in the draft Annex I (STOST, repeated exposure) or the draft Annex II (Effects on or via lactation), respectively.

The provisions in Part B for preparations irrespective of their classification within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC have largely been retained.

This Part of Annex II also includes the provisions of both Directive 67/548/EEC and Annex V of Directive 1999/45/EC on the requirements to label substances and mixtures that have not yet been tested completely. Whether these provisions should be retained or not is outside the scope of this report.

The only provision in this Part of Annex V to Directive 1999/45/EC that has not been retained relates to preparations containing a substance assigned R67 which are now covered by the criteria in Annex I (STOST, single exposure).

Many of the provisions require the use of statements that are neither a typical hazard statement (they do not identify a hazardous property) nor a typical precautionary statement (they do not give advice on how to avoid the hazard). Most include requirements to identify particular substances present in a mixture, e.g. "Warning! Contains lead". Whilst some of these could reasonably be replaced by either conventional hazard statements ("Can become highly flammable in use") or precautionary statements "Warning! Do not use together with other products. May release dangerous gases (chlorine)" we do not consider that a further revision of this section is needed at the present time.

The provisions in Part C for preparations not classified within the meaning of Articles 5,6 and 7 of Directive 1999/45/EC but containing at least one dangerous substance have been moved to Part 1 of the draft Annex I (Workplace labelling).

Annex II, Part 6: Confidentiality for the Chemical Identity of a Substance

The procedures for Confidentiality for the chemical identity of a substance from Annex VI to Directive 1999/45/EC can be inserted in this Part of the draft Annex II as required.

Annex II, Part 7: Special Provisions related to Packaging

This Part of draft Annex II contains the special packaging requirements from Directive 1999/45/EC and Directive 67/548/EEC (including Annex IX) concerning the provision of child-proof fastenings.

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Annex III: Hazard Statements

The draft Annex III is a list of hazard statements. The core of this is drawn from those statements set out in the GHS text.

As however our proposals for the draft Annex I and II include the maintenance of classification for hazards which are not currently part of the GHS, it will therefore be necessary to have additional hazard statements to reflect this and we have added the necessary R phrases from the current EU scheme.

A numbering system for GHS Hazard Statements is under discussion in the UN Committee of Experts. For convenience we have adopted the scheme proposed by Australia [37]. EU phrases that are retained are identified by the R-phrase number from current legislation.

In the labelling sections of the draft Annex I (and where relevant the draft Annex II) the hazard statements have been shown in full, without making a reference to the hazard number.

Annex III to Directive 67/548/EEC contains a multilingual version of the R-phrases. This multi-lingual approach was intended as a service to users who would need to prepare a label in the languages of different Member States. The current Annexes are included as monolingual Annexes.

Annex IV: Precautionary Statements

Annex IV is a list of precautionary statements. These are reproduced in a monolingual version from the text of Annex IV to Directive 67/548/EEC⁵⁰, including the combinations of phrases.

Since these phrases are unchanged from the existing EU S-phrases, no attempt has been made at this stage to change the number system used in the current legislation. We consider that if the present system is to be retained for the moment, it would be inappropriate to make further revisions (e.g. a revised numbering system) at the present time.

The S-phrases have however been shown grouped into the main types of advice as shown in Annex 3 of the GHS [1]: Prevention, Response, Storage and Disposal.

Annex V: Pictograms

The pictograms in the GHS are standardised and associated with the relevant classifications. The principle of pictograms and signal words reflects the approach used in the current EU system with pictograms and indications of danger. The GHS portfolio of available pictograms covers all of the GHS hazards as required and we can find nothing that suggests that introduction of the pictograms will reduce the standard of protection.

We therefore propose that Annex V to the draft Regulation reproduces the standard pictograms and signal words from the GHS text. A draft text for Annex V is included.

Note that the pictograms reproduced here for physical chemical hazards are the GHS pictograms. These are based on the UN RTDG pictograms although they are not the same. In particular they do not include the category number. The White Paper Working Group [5]

⁵⁰ Annex IV to Directive 67/548/EEC currently contains a multilingual version of the S-phrases

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recommended that the UN RTDG pictograms be adopted in their entirety but we believe that to do so would not conform to the GHS and may place unnecessary burdens on labellers.

We have included the current EU symbol “N” for dangers to the ozone layer, as adoption of a GHS pictogram for a non-GHS hazard may not be acceptable. However, we consider that retention of this symbol which differs only in shape and background colour is not the preferred option.

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Annex VI: Harmonised List of Dangerous Substances

Issues

We have been asked to produce:

...ideas on how substances currently classified according to the existing EU criteria could be “translated” or “transferred” to their corresponding classification according to the GHS criteria....

In this context our discussion with the Commission has indicated that the primary, but not sole, focus should be the proposal for Annex VI of the new Regulation which will include a list of dangerous substances with formally harmonised classification and labelling information. However we do not believe that this can be addressed without having regard for the enormous challenge faced by business when self classifying substances and mixtures under the GHS.

Background to options development

Introduction of the GHS will present a major challenge to the suppliers and users (both workers and the general public) of the substances and preparations currently on the EU market. For suppliers the change will involve adapting to a new set of criteria and both of these groups will need to adapt to a new style of label. Similar challenges will be faced by regulatory agencies.

Annexes I and II of this report present the system of classification under a new Regulation implementing GHS in the EU. Although it is possible for suppliers to reclassify existing products using the original data and the criteria in the Annexes it would be a major undertaking. There is the potential for considerable saving of expert resources if the task could be simplified. For many of the hazards (for example skin and respiratory sensitisation) the criteria in the two systems are so similar that it is possible to simply read across from the current EU scheme to the GHS. *Ab initio* reclassification is not necessary in these cases. But for some other classifications the EU and GHS criteria are not coherent, for example acute toxicity. In these cases defined and agreed equivalences, although not always fully scientific, could be “fit for purpose” in terms of conversion and protection. This provides the opportunity for existing EU classifications to be simply “migrated” to GHS without the need for complete reappraisal.

Current system in the EU.

Under existing EU legislation, all preparations need to be self-classified by the supplier in relation to the current EU classification and labelling criteria. For a substantial number of substances, however, the suppliers have access to an already agreed classification and label that they can use without any further assessment. Annex I to Directive 67/548/EEC is an inventory of agreed classifications for thousands of substances which have been individually assessed by EU experts. It is the most objective and widely used reference source of its kind in the world. It has been progressively expanded over the past 25 years. At each expansion stage users have been provided with more substances with harmonised classifications thus reducing costs, increasing confidence and aiding the single market.

In technical terms we believe there are two features of the current Annex I which are of special significance.

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- Firstly Annex I is *broadly based*. It has no limitations in terms of the kinds of substances in it. These include generic entries and also substances subject to specific control regimes which will be outside the scope of REACH (e.g. biocides and plant protection products)⁵¹. As a result the Annex has become a compendium of information providing a reference to regulatory agencies and business, especially SMEs.
- Secondly the Annex contains *specific legal/technical data* which is vital in terms of protection and compliance and which is not found elsewhere, for example:
 - a foreword explaining the status of the document and its structure and including important qualifying notes (for substances and preparations derived from them),
 - standardised naming information, reference numbers and alternative names,
 - formally agreed special concentration limits for use with preparations (many included as the result of a systematic approach to ensure transposition of provisions in use for three decades from the Solvents [39] and the Paints and Varnishes [40] Directives). These include special limits for skin sensitisers, carcinogens (reflecting potency considerations), and for dangers to the environment,
 - indicative information for the classification of other chemicals, either by generic entries or by use of techniques such as “read across”. This is used to classify substances which are not in the Annex,
 - a reference point for other legislation, especially downstream provisions such as the EU Major Accidents Hazards legislation [11] for which the acute toxicity and environmental information is essential.

Development of options

Any consideration of the practicalities of introducing GHS to supply and use legislation must have regard for the challenge faced by business to cope with the changeover in terms of inventory management and for the Commission in terms of commencement / transition arrangements. We have not been asked to develop ideas for these (although a number of options can be envisaged) but we have tried to develop proposals which will aid any arrangements which may be developed.

The above considerations, together with some of the principles discussed previously about the introduction of GHS (especially the no loss of protection principle and the need to be as close as possible to the existing scheme), lead to the identification of key aims for the task of transferring substances from the current scheme to GHS.

⁵¹ In this context the Annex includes a number of substances banned or restricted in the EU, and further data to update these entries is unlikely. However, inclusion of these entries in the Annex reflects the properties that have led to this action, and their retention will therefore provide a source of essential information under the PIC procedure [38].

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- where possible, simple and transparent conversion should be enabled for all substances and preparations without the need for reassessment of the hazard classification *ab initio*,
- the current information in Annex I is of continuing importance and must be retained in a legally secure text,
- the overall approach must be flexible to enable the ultimate wishes of Council (in terms of transition and the shape of REACH) to be met.

The task of moving to the GHS for substances can be delivered in two ways which represent simple options:

Option 1: Achieve transition by provision of equivalence tables to be used by suppliers who:

1. self classify substances and mixtures,
2. use the information in Annex 1 (which is retained in the new legislation).

Option 2: Achieve transition by requiring *ab initio* reclassification using the new criteria and original data by suppliers to self classify *all* substances and mixtures,

In both cases the development of a new list of harmonised classifications would require the use of the GHS criteria and current data.

We do not consider Option 2 to be viable. It is self evidently impossibly demanding for business and the Commission and would cause enormous resource conflicts with REACH. Furthermore Option 2 implies the loss of Annex 1 to Directive 67/548/EEC which, given its legal and political status, is inconceivable.

There is an important additional advantage to Option 1. If the core information in Annex 1 to Directive 67/548/EEC is retained - with the existing EU classifications - it will provide a continuing source of reference for the other EU legislation which relies on Annex 1 and the current classification system. This will mean that early revision of that legislation is not necessary and that problems, which may have arisen as a result of differences in coherence, can be avoided.

We therefore recommend the development of a solution based on Option 1 and Annex VI has been drafted accordingly. The Annex as drafted contains three parts (which are discussed further below):

- Part 1 - Tables of Equivalence to be used for the self-classification by suppliers of substances and mixtures already evaluated under the current criteria and for the conversion of the classification of substances shown in the harmonised list of dangerous substances in Annex I to Directive 67/548/EEC;
- Part 2 - A consolidated version of Annex I to Directive 67/548/EEC, including a slightly modified version of the Foreword;

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- Part 3 - A list of new harmonised classifications agreed using the criteria of the Regulation directly. There are no entries in this at present.

Discussion

We have suggested that it is essential for transparency and economy for there to be a simple and direct way of transferring classifications from the current scheme to the GHS.

We have therefore proposed a series of Tables of Equivalence in Annex VI Part 1. We have developed the equivalences using a conservative approach to ensure no loss of protection. According to the proposal, the Tables of Equivalence will be part of the Regulation and hence agreement on specific equivalences will be a policy matter for Member States and the Commission. However, the high degree of concordance between most of the current classifications and the classifications under the Regulation (not least due to the considerable input from the EU in the development of the GHS criteria) does mean that a simple transition *for both substances and mixtures* is a realistic and viable approach. Our analysis suggests that the only endpoint where a simple equivalence is not immediately possible is Explosive R2. For the relatively few substances with this classification, case by case evaluation to convert the classification to the new GHS criteria will be required.

We propose that these Tables of Equivalence are included to provide an option for suppliers of substances and mixtures to fulfil their obligations under the new Regulation without having to make an *ab initio* reclassification of their substances and mixtures which are currently correctly self classified. Should a supplier not wish to use the tables for any reason, they would then be obliged to evaluate the substance or mixture using the GHS criteria.

We also propose that a consolidated list of the harmonised classifications listed in Annex 1 of 67/548/EEC is retained in its current form in the new Regulation. Given such an opportunity it is unimaginable to expect suppliers to evaluate these substances using the GHS criteria and the original data. We therefore propose that the current harmonised classifications under Directives 67/548/EEC must be fixed in the legal record to provide a stable reference point.

We propose this list of substances as Annex VI Part 2. However it is evident that in order for the Annex to continue to serve the immediate needs of users (especially those involved with other regimes) its technical content must include *all* the information in the current Annex I, including the introduction which is set out in an updated form in the proposed Annex.

Publication of the current Annex I to Directive 67/548/EEC, with the existing data, will serve to meet the important needs set out above. For example it would continue to provide special concentration limits and act as the baseline for downstream legislation (e.g. workplace and Major Accident legislation [11]) without the risk of drawing more substances into its scope. In addition the approach would serve to provide a continuing reference in the event of any special transitional provisions.

Since the provisions of the current Annex I are legally binding, we consider that the Tables of Equivalence in Part 1 of Annex VI *must* be used to transpose the entries in Part 2 of Annex VI.

We have not addressed the question of the timing of the transition between the current labelling requirements and the requirements of the GHS as implemented by the draft Regulation (i.e. whether labels produced using the two different labelling systems are used concurrently, or whether a fixed date for a transition is agreed). We consider however that use of the Tables of Equivalence provides an adequate basis on which to transpose the current Annex I entries to the labelling elements of the Regulation, and, hence, can be used whether a

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fixed transition date is agreed or not, and that this would therefore be the simplest and most user-friendly approach.

Since the current Annex I is based on the current EU criteria, revision of the list shown in Part 2 of the draft Annex VI can only take the form of deletion of entries. Revision would be required when there is evidence that changes to the classification are required or where the Tables of Equivalence are patently unsuitable. Whilst any revision would therefore always take the form of a deletion of the entry in Part 2, a case-by-case decision can be taken as to whether the deleted entry in Part 2 should be replaced by a harmonised entry evaluated under the new criteria in Part 3 of the Annex VI, or whether a harmonised entry is no longer necessary. Under the current proposals for REACH, substances with specific hazards with important risk management consequences would be candidates for inclusion in the new harmonised list in Part 3 of Annex VI, and justification for the need for a harmonised entry would form part of the proposal. Substances evaluated under the Plant Protection Products Directive [17] or the Biocides Directive [18] would also be considered as candidates for inclusion in Part 3 of Annex VI.

We recognise that inclusion of the current Annex I in a mandatory form in the current legislation introduces an additional regulatory step in the new Regulation in that entries in this Part of the Annex will require regular revision in the form of deletion of these entries, in addition to the introduction of any new entries in Part 3. We consider however that this will not prove to be an undue regulatory burden, and that this will in any case be compensated by the advantages of the retention of this list.

Substances evaluated after the adoption of this Regulation will be classified and labelled *ab initio* using the criteria in Annexes I and II. Where such substances are to have harmonised classifications then they should be entered in Part 3 of Annex VI. We consider that the scope of Part 3 should have the same scope as the current Annex I, limiting addition of substances to this harmonised list to those that fulfil the criteria for “*classification as dangerous*”⁵².

We have not addressed the format of these entries, or attempted to draft a Foreword to Part 3 of Annex VI, although the current Foreword could provide a starting point for the text of this chapter. The development of entries in Part 3 of Annex VI will require an expert body for the purpose of making proposals to the Commission. Such a body will also act as a forum for dispute resolution, and to provide guidance for the classification of substances and mixtures that have properties that do not fit clearly into the hazard criteria of the GHS. This exists under the current arrangements for adapting the Annexes to Directive 67/548/EEC to Technical progress (the ECB based TC on Classification and Labelling) and a similar body is proposed for the Agency under REACH. A similar body exists in the UN Transport system. We see a special task for the proposed body in working with the relevant Commission Service dealing with transport legislation, able to provide a focal point for debate and coordination towards the UN forum.

Recognition has also to be given to the relationship between any list of chemicals under the “supply and use” provisions of the regulatory framework and similar lists produced for transport. Both lists provide mandatory harmonised requirements for the two sectors,

⁵² If the proposal for an Industry list included in the draft REACH Regulation is adopted, there would be no reason why an agreed classification of non-dangerous substances should not be included in this list.

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reflecting the specific needs of each sector⁵³. In addition to differences in scope of the two lists, there are differences in many of the end points in these two lists at present and simple translation of them to GHS will not remove the differences completely. A further complication is that for some chemicals, the harmonised classifications in the two systems differ, either because of differences in the data used for the evaluation or because of the application of different criteria.

Close collaboration between the two sectors is particularly important if the objective of a single list of chemicals in the EU is to be realised whether or not such a list is mandatory or voluntary. As we have indicated before simple translation is not possible and the solution would appear to lie in cooperative working between the responsible bodies within the Commission Services and Member States, as well as with the relevant International Organisations.

⁵³ The UN transport list includes many articles and preparations which fall outside the scope of EU supply and use legislation, but where appropriate transport packaging and labelling requirements are relevant.

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Suggestions for next steps

Our mandate was to analyse the various issues outlined in the tender document and to deliver the proposals which are contained in the Annexes to this report. Although we have not been asked to make any recommendations for further work we believe there are a number of issues which need to be addressed in order to ensure effective harmonisation.

We recognise that further work will be required in three areas.

Firstly, this report has identified a number of areas where further clarification of certain issues will be required from the Commission services. Examples are the possible inclusion of articles such as aerosols, and issues related to the testing requirements and specification of individual test methods.

Secondly, the report has identified a number of problems with the GHS criteria in their current, revised, form. These range from fairly trivial problems, to more serious drawbacks that have led us to recommend implementation of the GHS criteria only with some reluctance. Most of these are widely recognised and work is underway in the OECD and the UN SCEGHS in order to resolve the problems. We believe it is important to ensure that the future EU Regulation is sufficiently flexible to allow rapid adjustment of the Annexes to quickly introduce changes as soon as they are agreed at UN level. It may be necessary to reach additional (possibly informal) agreements in the UN relating to the timetabling of changes in implementing legislation and we suggest this is an issue warranting further consideration.

One of our principal concerns relates to the Acute Toxicity Estimate approach for the classification of mixtures. We regard this as a matter which should be urgently addressed in the UN forum with a view to developing a solution in the current biennium. Any outcome can then be integrated in the proposed EU Regulation before its introduction.

We have also noted some difficulties with parts of the UN GHS text in terms of terminology and editorial issues. We realise that this may be a low priority for attention given the other issues under discussion. However we do suggest that the impact of the difficulties is kept under review with a view to proposing clarification should it be necessary.

Our recommendations for implementation of the criteria which are recognised to be less than satisfactory are therefore based on the assumption that the work in the UN SCEGHS will resolve these issues. Should it not prove possible to find a satisfactory solution in this forum, the option of retaining the current EU criteria for these specific endpoints until an acceptable solution has been found still remains, and the drafts we have prepared provide for this eventuality.

Thirdly, our analysis has shown that there is a need for additional guidance material to support suppliers of substances and mixtures in fulfilling their obligations under the new Regulation. Such guidance material could include the decision logics which form part of the GHS text but are stated not to form part of the harmonised system. It is evident that additional guidance is needed on interpretation of the criteria for CMR substances, and also for STOST. Another example is the guidance on application of the environmental criteria provided by Annex 9 of GHS, options for inclusion of this have already been included earlier in this report.

While we recommend the development of suitable guidance material to underpin the future EU legislation on classification and labelling, we recognise that such guidance cannot be developed by the EU in isolation, as this could compromise the integrity of the harmonised

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system. We recommend that work should be undertaken in the UN SCEGHS to develop guidance on key parts of the harmonised system, as was the case for the GHS Annex 9.

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References

1. Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Revised Edition. ST/SG/AC.10/30/Rev.1 United Nations, New York & Geneva, 2005.
2. Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ L 196, 16.8.1967. This Directive has been amended eight times, and the Annexes to the Directive have been adapted to technical progress 29 times. A 30th Adaptation to Technical Progress is planned for October, 2005.
3. 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 substances. OJ L 200, 30.7.1999.
4. Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}. COM(2003) 644 final; 2003/0256(COD); 2003/0257(COD). Volume I. Brussels, 29.10.2003.
5. ECBI/03/02: White Paper Working Group on Classification and Labelling: Summary of Recommendations from Technical Working Group on Tasks 1 and 2.
6. CWG/08/2005: Status: Implementation of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). DG ENTR (REACH). 1 June 2005
7. Final report: Technical Assistance to the Commission on the implementation of the GHS. Ökopol Institute for Environmental Strategies, July 2004
8. Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road. OJ L 319, 12.12.1994, p. 7 – 13; OJ L 275, 28 October 1996, p. 1.
9. Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail. OJ L 235, 17.9.1996, p 25 - 30; OJ L 294, 31 October 1998, p. 1 – 775.
10. Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions relating to restrictions on the marketing and use of certain dangerous substances and preparations. OJ L 262, 27.9.1976, p. 201.
11. Directive 2003/105/EC of the European Parliament and of the Council of 16 December 2003 amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances. OJ L 345, 31.12.2003, p. 97 – 105.
12. Recommendations on the Transport of Dangerous Goods. Model Regulations. Fourteenth revised Edition. ST/SG/AC.10/1/Rev.14 United Nations, New York & Geneva, 2005.
13. Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals: Report of its 9th. Session, 11-12 (a.m.) July 2005. ST/SG/AC.10/C.4/18, 22 July 2005

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14. Council Regulation (EEC) No. 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances. OJ L84, 5. 4. 1993, p.1-75.
15. Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances. 1996. Luxembourg: Office for Official Publications of the European Communities. Part I: General Introduction and Risk Assessment for Human Health, CR-48-96-001-EN-C, ISBN 92-827-8011-2. Part II: Environmental Risk Assessment, CR-48-96-002-EN-C, ISBN 92-827-8012-0. Part III: Use of QSAR, Use Categories, Risk Assessment Format, CR-48-96-003-EN-C, ISBN 92-827-8013-9. Part IV: Emission Scenario Documents. CR-48-96-004-EN-C, ISBN 92-827-8014-7.
16. Commission Directive 2001/58/EC of 27 July 2001 amending for the second time Commission Directive 91/155/EEC defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 14 of European Parliament and Council Directive 1999/45/EC and relating to substances in implementation of Article 27 of Council Directive 67/548/EEC (Safety data sheets). O.J. L 212, 7.8.2001, p. 24 - 33.
17. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1.
18. Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 123, 24.4.1998, p. 1.
19. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers. OJ L 147, 09. 09. 1975, p. 40 – 47.
20. Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses. OJ L 121, 15.5. 1993, p. 20 - 36
21. Table of Content GHS: Draft of Table of Contents for a draft Regulation replacing Directives 67/548/EEC and Directive 1999/45/EC provided by DG ENTR (dated 050628).
22. *The New Approach in Setting Product Standards for Safety, Environmental Protection and Human Health. Directions for the Future.* Goldenman G, Hart JW, Sanz Levia L. Report prepared for the Danish Environmental Protection Agency by Milieu Ltd. Environmental News No. 66, 2002. ISBN: 87-7972-192-3, Danish EPA, Copenhagen.
23. Recommendations on the Transport of Dangerous Goods. Model Regulations. Manual of Test and Criteria. Fourth revised edition. ST/SG/AC.10/11/Rev. 4 United Nations, New York & Geneva, 2003.
24. TAPIR: 3.3– A Project for the Information Requirements of REACH. Report Submitted to European Chemical Bureau, Joint Research Centre, European Commission by a Consortium comprising: Cefic, the Danish EPA, The Environment Agency of England and Wales, ECETOC, INERIS, KemI, and TNO. Final Report – 02.8.2005. The report is available on the ECB website under <http://ecb.jrc.it/REACH/>.
25. Appendix 9 to TAPIR: Three point three – A Project for the Information Requirements of REACH. Report Submitted to European Chemical Bureau, Joint Research Centre,

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- European Commission by a Consortium comprising: Cefic, the Danish EPA, The Environment Agency of England and Wales, ECETOC, INERIS, KemI, and TNO. Final Report – 02.8.2005. The Annexes are available on the ECB website under <http://ecb.jrc.it/REACH/>.
26. Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes OJ L 358, 18.12.1986, p. 1 – 28.
 27. Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals: Report of its 8th Session, 7-9 December 2004. ST/SG/AC.10/C.4/16.
 28. ECBI/150/04: Comparison of Annex 3 Risk Phrases and GHS Hazard Statements.
 29. ECB Classification and Labelling database: <http://ecb.jrc.it/classification-labelling/>.
 30. ECBI/76/01 – Part A: White Paper working group “Classification and Labelling” Sub-group 4: Implementation of GHS – Physical Chemical Hazards
 31. UN/ST/SG/AC.10/C.4/2003/7. Classification of gas mixtures for toxic effects. Transmitted by the European Industrial Gases Association (EIGA)
 32. OECD document ENV/JM/HCL(2004)2
 33. ECBI/76/01 – rev 1: White Paper Working Group “Classification and Labelling”. Sub-group 4: Implementation of GHS - Environment.
 34. Regulation (EC) No 2037/2000 of the European Parliament and of the Council of 29 June 2000 on substances that deplete the ozone layer. OJ L 244, 29. 9. 2000, p.1 – 24.
 35. Globally Harmonised System of Classification and Labelling of Chemicals (GHS). ST/SG/AC.10/30. United Nations, New York & Geneva, 2003.
 36. UN/SCEGHS/9/INF.6. Physical Hazards. Identification of some open issues not yet properly addressed in the GHS. Transmitted by the expert from Germany.
 37. UN/SCEGHS/9/INF.8. Hazard Communication Issues. Numbering of GHS Hazard Statements. Transmitted by the expert from Australia.
 38. Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals. OJ L 63, 06.3. 2003 p. 1 – 26.
 39. Council Directive 73/173/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (solvents). OJ L 189, 11. 7. 1973, p.7. Amended by Directive 83/265/EEC, OJ L 147, 06. 6. 1983, p 11-17. Repealed by the Dangerous Preparations Directive 88/379/EEC, OJ L 187, 16.7. 1988, p. 14-30.
 40. Council Directive of 7 November 1977 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of paints, varnishes, printing inks, adhesives and similar products. OJ L 303,

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28. 11. 1977, p. 23 – 32. Amended by Directive 83/265/EEC, OJ L 147, 06. 6. 1983, p 11-17. Repealed by the Preparations Directive 88/379/EEC, OJ L 187, 16. 7. 1988, p. 14-30.

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Draft Annexes

See separate documents