Final report

Technical Assistance to the Commission on the implementation of the GHS

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Content

1 Executive summary

The **task** of the service contract "Technical assistance to the Commission on the GHS implementation" was to assess differences between the current system of classification and labelling of substances and preparations as defined in Directives 67/548/EEC and 1999/45/EC and the GHS as adopted in July 2003. Issues related to the transport sector as well as to questions of international developments on the GHS or the harmonization with REACH were not within the scope of the contract.

In order to take account of work already done, the comparison of the two systems was performed using two **methodological approaches**:

- reviewing documents of EU working groups, and of GHS committees and working groups;
- carrying out expert interviews on different topics.

The main **output** of the work is a **two-part synopsis**, in which the detailed comparison of the various elements of the two systems are documented and proposals and options for the implementation of the GHS provisions are cited. These proposals and options have been identified in the documents analyzed and in interviews conducted with experts.

The **comparison** revealed that the two classification systems are conceptually similar and cover the same structural elements. They differ in that the GHS is a single document covering classification and hazard communication (labelling and safety data sheets) of substances and preparations, whereas the EU has one Directive for the classification and labelling of substances, one for the classification and labelling of preparations, and a third one for the structure and content of safety data sheets.

The GHS test methods and classification criteria for **physical-chemical hazards of substances** are based on the 'UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria' and thus differ markedly from the current EU system for supply and use. Due to these differences, no in-depth assessment of tests and criteria was undertaken. As a result of the alterations to the tests and criteria, there will be major changes to the classification of physical-chemical hazards. However, no principal problems are envisaged, as classification in the transport sector is routinely performed; furthermore, as the TDG system encompasses additional methods, no gaps should arise from the transition to the new system. As **preparations** are classified in the same way as substances in the two systems, their classification under the GHS will be similarly affected.

For the classification of **substances** with respect to their **health hazards**, the following differences and similarities have been identified:
In contrast to the EU system, the GHS does not prescribe specific test methods but allows the use of any data which are scientifically valid. Both systems cover roughly the same endpoints. There are as yet no hazard categories in the GHS comparable to the EU R-phrases R37, R65, or those for the so-called other toxicological properties, except for R64. Unlike the EU system, the GHS foresees separate hazard classes for acute toxic effects and systemic toxicity (TOST). Regarding the subdivision of hazard classes into hazard categories, for some classes the GHS exhibits a more differentiated structure than does the EU system. Similarly, the criteria defining the thresholds for the categories differ in the two systems.

As the criteria for carcinogenicity, reproductive toxicity and target organ systemic toxicity were assessed as open to interpretation, further clarifications or additional guidance is deemed necessary.

The comparison of the classification of **preparations** for **health hazards** resulted in the following observations:
In both systems classification is structurally similar in terms of available methods: testing of mixtures, conclusions drawn from similar mixtures, calculation methods based on ingredients of the mixtures. However, in the GHS the sequence of these methods constitutes a prescribed hierarchy, which is not the case in the EU system. Contrary to the EU system, testing of mixtures for CMR-properties is permitted in the GHS. The cut-off values for the various hazard categories are, if different, lower in the GHS than they currently are in the EU system. In contrast, the concentration limits for considering ingredients in a preparation for classification in the GHS are either equal to or higher than those in the EU system.

From the comparison of the classification of **substances** for **environmental hazards** the following results were achieved:
Differences in the classification are evident in the absence of terrestrial hazard classes in the GHS and the clear division of the GHS into acute aquatic toxicity and chronic aquatic toxicity, a division which does not exist in the current EU-system. The classification criteria for aquatic toxicity only differ in minor respects.

For environmental hazards **preparations** are classified according to the same principles in both systems, yet the calculation methods are described in a simpler manner in the GHS. The 'additivity formula' is a calculation approach new to the EU system.

The current EU system and the GHS both consist of the same structural elements of **hazard communication** (label, safety data sheet). The principal **labelling** elements (symbols and text) exist in both systems and the structure and content of **safety data sheets** are generally the same. The main differences were identified in the appearance of some hazard symbols and in the introduction of a hazard pictogram, consisting of the hazard symbol and other graphic elements. The indication of danger and the specification of R-phrases of the EU system will vanish; in their stead, the structurally corresponding elements of signal word and hazard statement will be introduced by the GHS. Structure and content of safety data sheets do not differ between the two systems.

The conclusions of the assessment refer to **further steps** necessary for the implementation of the GHS in the EU. These can be grouped into:

- decisions to adopt the GHS provisions as they are and/or on which options to choose where country discretions / the building block approach foresee this;
- decisions on how to proceed with those items which i) exist in the EU but are not covered by the GHS, ii) were identified as being regulated differently under the GHS than in the current system, iii) were identified as needing further guidance.

As this service contract did not take note of the recent developments at international level, changes to the GHS during this biennium need to be accounted for additionally in the future EU legislation.

In the expert interviews several issues emerged which are relevant for the implementation

process but were not pursued further during this study. These are in respect of, for example, the harmonization with the existing transport legislation, the inclusion in the REACH regulation, or the consequences of the GHS implementation for industry (especially re-classification).

2 Progress of work

In January, the project team planned internally the work for the study contract, performed literature research and brought themselves up to date on the current discussion on the GHS implementation. A detailed project implementation plan was developed, based on the tender bid.

2.1 Inception meeting

The project team and the Commission representatives met on February 10th 2004[1]. At the inception meeting, the Commission representatives explained the state of play regarding the implementation of the GHS in the EU and gave some background information regarding the current time planning. The contractor introduced both their understanding of the overall scope of the study and the project implementation plan. As a result of the discussion, the scope was agreed and the time schedule of the implementation steps was reorganised.

The contractor proposed a structure for the comparison of the classification and labelling systems according to the GHS and the current European system. The synopsis consists of two parts (cf. chapter 3):

Part 1) List of keywords from the GHS and the EU system with references to sources in the legal texts and also in the second part of the synopsis;

Part 2) Standardized assessment of differences between the systems and management consequences for the Commission resulting from these differences.

The proposal was regarded as an acceptable basis on which the contractor could begin the assessment work. It was agreed that it would be beneficial to hold an early interim meeting at which the Commission representatives would have the chance to still exercise influence on the results of the synopsis. Hence it was agreed that a partially incomplete synopsis would be acceptable at the interim meeting.

2.2 Analysis of documents

The Commission's representatives provided documents to the contractor as a basis for comparing the two systems. Additional documents were obtained from Royal Haskoning, the contractor of the parallel project on the impact assessment of the GHS implementation. The documents analysed are compiled in Annex 1 to this report.

Of the documents provided by the Commission's representatives, the two annexes[2] to the planned legislation implementing the GHS (drafted in spring 2002) proved to be the most relevant. The text of the two Annexes integrates the recommendations and proposals developed by the experts of the White Paper working group "Classification and Labelling". The recommendations and options for the GHS implementation together with reasons for the proposed modes of implementation as summarised by the group in December 2001 are

[1] See the minutes of the inception meeting as Annex 1 to this report.

[2] Internally called "Annex X" and "Annex Y"

compiled in a further document[3]. The other documents of the working group which were compiled before December 2001 contain more detailed background information as well as "written discussions" among the experts of the respective sub-groups.

2.3 Expert interviews

To obtain additional information, the contractors carried out telephone interviews with twelve experts who have been involved in work at Member State, EU or UN level on the development of the GHS and its implementation in the European system. The interviewees were asked their opinion as experts and were not interviewed as Member State representatives. The interviews lasted between 45 minutes and 1.5 hours and were documented in short memos[4].

The interviews were used to:

a) confirm that the information in the analysis of documents had been understood correctly;
b) assess whether there were further issues which had not yet been addressed;
c) assess the relevance of the issues in the overall discussion and get a better understanding of the reasons for the differences between the two systems.

The results were partially included in the synopsis (as comments, or recommendations for guidance).

2.4 Interim meeting

On April 7th 2004 an interim meeting was held in Brussels[5]. The Commission representatives and the contractor discussed the structure and content of both the synopsis and the interim report and collected suggestions for their improvement. Written comments were provided later and included in the final documents. The expert meeting originally planned for further information collection on the comparison of the two systems was cancelled as no new information was expected to arise from it. It was agreed that, instead, *Synopsis Section II* was to be sent to the experts for comment.

2.5 Revision of Synopsis

Synopsis Section II was revised according to the comments received from the Commission representatives at the interim meeting. Additionally, the Synopsis was sent to several of the interviewed experts for comment. Most of them were ready to have a look at specific sections pertaining to their expertise, and to send their comments. Their comments were included in the Synopsis as well[6]. In connection with this, the description of the structure of the synopsis and guidance on how to read it (Chapter 3) was made more specific.

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[3] ECB1/03/02

[4] See the list of interviewed experts as well as the interview memos as Annexes to the this report on CD ROM

[5] The minutes of the interim meeting are included as Annex 6

[6] These comments are referenced in the Synopsis with brackets and the number of the respective expert, e.g. '[5]'.

In addition, the part *Synopsis Section II* on the hazard communication elements of the GHS and the EU system was provided. The table on hazard communication was established as a separate document.

As a final step in the work procedure, internal identifiers were assigned to each item of the GHS and the current EU system. The identifiers were included in a separate column within both *Synopsis Section I* and *Synopsis Section II*. All references between the two documents and within each of the documents were complemented by the internal identifiers.

2.6 Additional documents

As agreed during the interim meeting, four additional summary documents were prepared:

- a summary table of items for which guidance is regarded as necessary according to documents reviewed and expert comments. The table also informs whether guidance is under way at the level of the SCE GHS and, if so, when it is to be completed;
- a summary table of different types of cut-off values in the GHS and the EU;
- an overview table of which classification methods for preparations may be used for which hazard classes in each of the systems.

2.7 Checking consistency with the 'Differences Study' by Royal Haskoning as part of the impact assessment study

The results of the respective comparisons of the two classification systems were exchanged between the consultants. As the aims of the assessments are different, so were the level of detail and the focus of what was assessed, hence the inconsistencies.

In general, the results of the two studies are very much in line with each other. The ‘Differences study’ by Royal Haskoning was analysed by the project team and only a few inconsistencies were identified and then communicated to Royal Haskoning.

The main items noted from the perspective of this project team were:

- different opinions on coverage of hazard classes and R-phrases (flammables, TOST single and repeated exposure);
- different opinions on the classification of preparations[7] for acute toxicity (ATE);
- different opinions on a few other items, e.g. that the GHS allows preparations to be classified based on test results for CMR properties, whereas the EU system does not.

[7] The contractor believes that figure 4.3.2 only reflects one of three possible methods to classify a preparation for acute toxicity

2.8 Compilation

All materials of the study are to be compiled on a CD ROM. It contains four folders:

- Annexes à the folder contains all Annexes to the report such as the list of documents used, the additional summary papers and the interview memos.
- Interview memos à the folder contains summaries of the interviews with experts on differences between the current EU system for classification and labelling and the GHS;
- Main text report à the folder contains the electronic version of this report;
- Used documents à the folder contains all documents used in the analysis. Its contents can be looked up in the list of documents used, which gives a short description of the papers and their names;

3 Synopsis

The objective of this synopsis of the two classification and labelling systems is to provide an overview of elements in agreement and elements which differ between the two systems. This should then enable the Commission to decide for which items work is still necessary for the implementation. If possible, the type of work will be indicated. In addition, recommendations and options which have already been identified by experts in the working groups of the ECB will be summarised here, as will any additional information which might be relevant for the implementation of the GHS.

3.1 Introduction

The synopsis provided by the contractors consists of two separate tables: *Synopsis Section I* and *Synopsis Section II*.

Synopsis Section I serves as a reference table facilitating the identification of the various terms and items in the original documents (GHS, Directives 67/548/EEC, 1999/45/EC and 91/155/EEC, *Synopsis Section II*). At the same time this section can be regarded as a “thesaurus” showing differences in the terminology used in each of the two systems.

In *Synopsis Section II* the results of the analysis of documents are presented, together with the experts’ opinions expressed in the interviews on differences between the two classification and labelling systems; their recommendations for the implementation of the GHS, and unresolved issues identified by the experts.

3.2 Synopsis – Section I

Synopsis Section I, in which a comparison of terminology of the two systems is provided and which serves as an instrument facilitating the identification of terms and items in either system, is organised in a hierarchical way and consists of the parts “Structural elements” and “Elements”, the latter being sub-divided into elements regarding classification, labelling, and SDS.

The first part (pp. 1 – 4) lists the main structural elements of the two systems:

1. methodological elements -- the building block approach as well as the list of dangerous substances fall under this headline;
2. classification elements – structural elements which constitute the system for classification (category of danger/hazard class, classification rules for mixtures) and the general methods and tools (decision logic, guidance…) for classification are to be found here;
3. labelling elements – elements of the labelling regime of each system are listed here, e.g. "hazard symbol" or "signal word", and
4. elements of the safety data sheet – items addressing content and structure of the SDS are listed here.

The items listed under the headline 'elements' relate to the methodology of classification and labelling on a more detailed level. Here, the items are grouped as follows:

1. elements relevant to various hazard classes, e.g. 'cut-off values' or 'expert judgement';
2. categories of danger (EU terminology) / hazard classes and categories (GHS terminology) – separately for physico-chemical, health, and environmental hazards. In general the items pertaining to the EU system are listed first (e.g. for physical-chemical hazards from p. 5 to p. 6) and then the items according to the GHS are given (e.g. for physical-chemical hazards from p. 6 to p. 7);
3. items relevant to the classification of mixtures.

The hierarchical structure of Synopsis Section I is shown in figure 1.

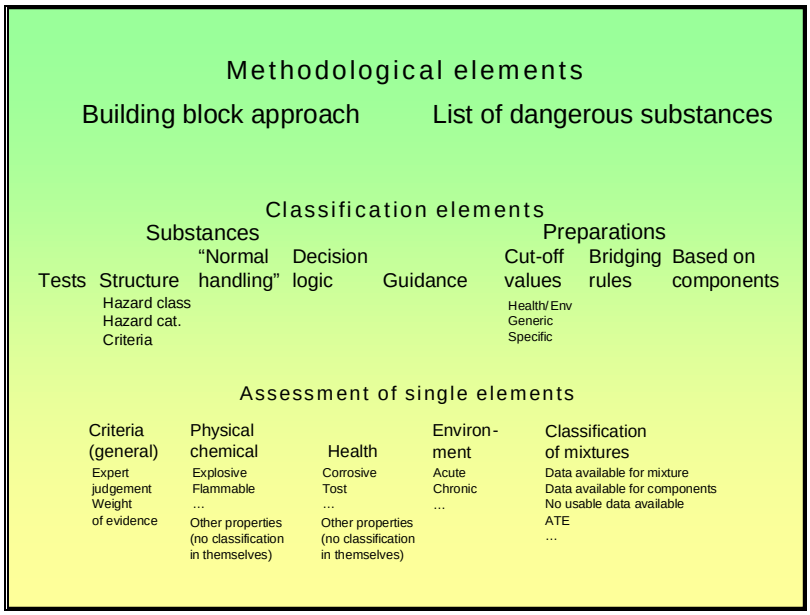

Figure 1: Structure of *Synopsis Section I*

In the first column of *Synopsis Section I*, the terms and items considered as of particular relevance to the classification systems are listed. If similar items exist in the two systems, but are named differently[8], both terms appear in separate lines in the respective part.

[8] For example: the division of different hazardous properties is called 'category of danger' in the current EU system and 'hazard class' in the GHS. Both items are listed in the column 'item'

In the second and third column it is indicated where the item is to be found in current EU legislation (Directives 67/548/EEC, 1999/45/EC, and 91/155/EEC) and in the GHS, respectively. If an item can be found only in one system, the field for the other system[9] is left empty.
If an item exists in both systems but with different terminology, reference is given to EU legislation under the term used in the EU system and to the GHS as termed in the GHS. The link between the terms is shown by referencing to the name of the item in the other system. The table below shows the logic of the synopsis for this case:

Item	Ref. EU legislation	Ref. GHS	Ref. Synopsis II
Item (name EU)	Ref. to EU legislation	[cf. name in the GHS]	
Item (name GHS)	[cf. name in EU]	Ref. to the GHS	

The last column contains an internal identifier to make references within section I of the synopsis, and also to interlink *Synopsis Section I* with *Synopsis Section II.*

The principal structure of the internal identifier numbering is given in the table below. To each item in the synopsis (cf. Annex 2), a single internal identifier is allocated. Thus, for instance, each R-phrase or hazard category (category, division, or type) corresponds to a specific internal identifier.

To enhance the transparency of the numbering scheme in the elements section, for main items (e.g. categories of danger, hazard classes) a minimum increment of five is chosen and the last digit of the respective main item is either a 0 or a 5 (e.g. ***320***, ***325***, ***330***, …). Accordingly, the numbering of the individual items belonging to that main item starts with either a 1 or a 6. If a main item comprises more than four individual items (e.g. R-phrases, hazard categories), the increment is raised to ten and the last digit of that main item is a 0 (e.g. ***250***, ***310***). If in sections I and II of the synopsis individual items are addressed as a group, the complete range of the corresponding identifiers is entered (e.g. ***341 – 344***).

Structure of internal identifier numbering

Section / sub-section	**Internal identifier range**	**Comments**
Structural elements	1 – 99	
methodological elements	1 – 9	one-digit numbers
classification elements	10 – 49	two-digit numbers
test methods	10 – 19	
classification system	20 – 39	
EU system	21 – 29	
GHS	31 – 39	if not correspondence with element in EU system
classification rules for mixtures	40 – 49	
hazard communication elements	50 – 99	two-digit numbers
labelling elements	60 – 89	
EU system	61 – 69	
GHS	70 – 79	if not correspondence with element in EU system

[9] For example: the hazard pictogram exists only in the GHS. The second column of the line is left empty (EU reference), whereas the third column contains information on the chapter where the item is addressed in the GHS.

Section / sub-section	Internal identifier range	Comments
consumer product labelling	80	
packaging etc.	84 – 89	
SDS elements	90 – 99	
Elements	100 – 999	three-digit numbers
classification criteria	100 – 899	
general classification criteria	100 – 199	
physical hazards	200 – 499	
EU system	210 – 299	
GHS	310 – 499	
health hazards	500 – 699	
EU system	510 – 599	
GHS	610 – 699	
environmental hazards	700 – 899	
EU system	710 – 799	
GHS	810 – 899	
classification criteria for mixtures	900 – 999	

3.3 Synopsis – Section II

In *Synopsis Section II* the results of the analysis of documents and of the expert interviews are presented.

In the second column the items of the two classification systems are listed. This list corresponds directly in both structure and content to *Synopsis Section I*. The scope of the synopsis covers both the provisions on classification and those on the hazard communication elements (labelling, safety data sheets).

The differences between the two systems are described for the items as named and contained in the GHS. Analogous items in the EU system which differ only in terminology (e.g. 'hazard class' vs. 'category of danger') are listed as separate items, and reference to the respective GHS item is made in the third column to avoid any duplication of assessment. Only for those cases where an item exists solely in the EU system is the assessment given at the level of items pertaining to the EU system.

The information provided in column 3 (Assessment) has been formulated in standardised sentences. Five different cases are foreseen:

- Reference to analogous items in the GHS
- Agreement à the item is covered in both systems in a similar manner and with the same meaning. For some items, the level of agreement is specified[10].
- Addressed in EU system only à the item is fully absent from the GHS.
- Addressed in the GHS only à the item is new to the EU system of classification and labelling
- Addressed in both systems, yet in different ways à both systems contain the item, but it is regulated in a different manner. The differences are specified either in column 5 (Comments) or in column 4 (Consequences) by referring to proposals and/or recommendations identified.

In column 4 (Consequences) the way forward in the GHS implementation is specified. Here, six different standard answers are foreseen:

- No further work necessary à applies to the items with "agreement" in column 3
- Approach identified à in the documents analysed, no discussions or questions were identified regarding the adoption of the item; the item has either been included in, or omitted from, Annex X or Y. Inclusion or omission is assessed as an implicit recommendation for either adopting or not adopting the item, respectively. Any comments on the item, either made by experts interviewed, or otherwise identified are listed in column 5 (Comments).
- Proposal identified à in the documents analysed, discussions or questions were identified regarding the adoption of the item, and there is an expert recommendation on how to address it in the future system. The recommendation is not binding on the Commission. Reference to the document containing the recommendation is given. Usually, the most recent document addressing the item is quoted. The main information sources here are the Annexes X and Y, as well as the summary of recommendations by the White Paper Working group (ECB1/03/02).
- Options identified à the item has been discussed and experts have identified options for implementation, however no agreement has been reached. The options are not binding on the Commission. Reference to the document containing the options is given. Usually, the most recent document is quoted.
- No proposal identified à in the documents analysed, no information has been found on how the issue should be dealt with.
- Work in progress at international level à indication that the item is being discussed at international level. If it is published in UN or OECD documents, information is given as to when the adoption of the respective element in the GHS is foreseen.

4 Classification

Conclusions on the comparison of the two systems regarding the classification of substances and preparations (GHS: mixtures) will be drawn from *Synopsis Section II* in the following sections:

- Overall system
- Physical hazards
- Health hazards
- Environmental hazards
- Conclusions on Classification

In the last chapter the conclusions are summarised according to the type of job and/or decision to be made.

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[10] 'Agreement: conceptual level' means, for example, that the concept is the same in both systems but differences exist when the concept is examined in detail. The system of dividing hazardous properties into standard hazard classes/categories of danger is applied in both systems (agreement at conceptual level), however the types of hazard classes/categories of danger differ (à addressed in both systems, yet in different ways).

4.1 Overall system

The basic structural elements of the two systems exhibit no real differences as such, if differences in terminology are not considered. In both systems, classification is based on tests and criteria, and also encompasses physical, health, and environmental hazards. For all three areas categories of danger (EU) / hazard classes (GHS) exist, some of which are subdivided, and for preparations (EU) / mixtures (GHS) specific classification rules apply. Differences become visible at a lower structural level, i.e. when comparing the corresponding structural elements in the two systems with each other, as is described in the subsequent sections 4.2 to 4.4.

In contrast to the structural elements, the legal structures of the two systems present a major difference: In the current EU system the provisions for classification and labelling are contained in the same directives, yet separated according to substances and preparations (i.e. 67/548/EEC and 1999/45/EC, respectively), while in the GHS the provisions for classification and for hazard communication (i.e. labelling, SDS) are separated, yet substances and mixtures are dealt with in the same sections of the legal text. No proposals have been identified that object to, or qualify this structural change, which is reflected by the Annexes X (Classification) and Y (Labelling).

As the decision logic, which is employed for all hazard classes, features explicitly as additional guidance but not as part of the harmonized classification system itself, it has not been incorporated in Annex X. Guidance, which is employed for all physical and for some of the health hazard classes, has the same legal status and, thus, has also not become part of Annex X.

On the other hand, the conservation of the current EU-harmonized classification elements compiled in Annex I of the DSD (67/548/EEC) is as yet not foreseen.[11] Under the proposed REACH regulation[12], a harmonised classification is planned for CMR substances and respiratory sensitizers only.

4.2 Classification of physical-chemical hazards

The biggest changes that will occur are going to take place in the classification of physical hazards. However, as for this sector the GHS is based on the existing system for the Transport of Dangerous Goods (TDG), no major problems are envisaged.

4.2.1 Tests and criteria

The classification for physical hazards in the GHS is based on the existing TDG Manual of Tests and Criteria, which is already used world-wide for the classification of dangerous goods. This will result in various differences to the current EU methods. However, as the TDG system encompasses many additional methods, no gaps should open up when switching from the current EU system to the GHS.

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[11] In interview 5 it was recommended that the future legal role of Annex I should be considered, particularly whether it could be used as recommendations or as guidance.

[12] COM(2003) 644

A test approach currently not existing in the EU system is the testing of substances in their packaging. Compared to the present situation, different classification could result, which is of particular relevance for the workplace setting, where substances are usually used outside any packaging.[13]

Since both test methods and criteria are different for most physical hazard classes, a detailed comparison between individual hazard classes in the two systems is possible for only a minority of classes.

4.2.2 Items in agreement

Due to differences in the delimitations of hazard categories of classes with identical test methods and criteria, no items with full agreement were identified.

4.2.3 Items addressed in EU system only

The so-called “other physical-chemical properties” which do not lead to classifications in themselves, yet can be applied additionally to otherwise classified substances, are not covered by the GHS. For two properties their inclusion in the hazard classes currently under discussion on water-activated toxicity is considered. If they are not included, it is recommended that they, like most other properties, should be transformed into the GHS precautionary statements. Only one of the whole group of properties is considered as redundant.

4.2.4 Items addressed in the GHS only

The physical hazard classes in the GHS cover a wider range of properties than the corresponding classes in the current EU system. In particular, the GHS encompasses hazard classes without current EU counterparts of flammable aerosols, self-heating substances, substances corrosive to metals, and gases under pressure. For all GHS hazard classes the adoption by the EU is recommended, yet for flammable liquids not the adoption of the full set of hazard categories for all settings, and for substances corrosive to metals the adoption for the transport use setting only.

4.2.5 Items addressed in both systems, yet in different ways

4.2.5.1 Classification of substances

One apparent difference between the two systems is a more differentiated subdivision of several hazard classes into hazard categories, divisions or types in the GHS than in the corresponding EU unit. This is the case for explosives, flammable gases, liquids, and solids; self-reactive substances; substances which, in contact with water, emit flammable gases; and organic peroxides. As mentioned in section 4.2.1, above, due to the differences for tests and criteria, a more detailed comparison between corresponding hazard classes in general would have to be very differentiated for most of them and, thus, would be beyond the scope of this overview. A difference which could be of particular relevance was identified for flammability: the EU classification “flammable” is limited to an upper flash point of 55° C, while in the GHS the corresponding value (flammable liquids, cat. 3) is 60° C. Thus, in the GHS additional substances would be classified for the supply and use setting, even if cat. 4 were not applied to that setting.

[13] In interview 8, detailed recommendations were given to overcome this problem.

4.2.5.2 Classification of preparations

For most physical hazard classes, in both systems substances and preparations are classified in the same way. Deviations from this approach exist in both systems for mixtures containing organic peroxides, and for oxidising and flammable properties of gaseous mixtures. Whereas in the EU system the classification as “oxidising” of preparations containing organic peroxides is based on calculations, in the GHS the classification of the mixture is determined by the classification of the most dangerous organic peroxide component. For gaseous mixtures, in the EU system the classification as “oxidising” is based on calculations, and in the GHS such an approach is permitted as an alternative to testing. Similarly, in the GHS classification of gaseous mixtures as “flammable gases” can be based either on calculations or on testing. In contrast, in the EU system a calculation-based classification as “highly flammable” is permitted for only small amounts of gaseous mixtures.

4.2.6 Items addressed in neither system

In one of the interviews it was stressed that two classes of physical hazards have not yet been included in the GHS process which are also not covered by the current EU system: ammonium nitrate and desensitized explosives. According to the interviewee, an inclusion of the two hazards in the GHS and, thus, in the future EU system is recommendable since it would complete the coverage of the area of physical hazards. At least for ammonium nitrate the relevance can be discerned from the fact that it is covered by the Seveso II directive of the EU and by national chemicals legislation in some Member States, as in Germany. For ammonium nitrate the inclusion in the GHS process has already been proposed, whereas for desensitized explosives this step is still to be taken.[14]

4.3 Health hazards

4.3.1 Tests and criteria

In contrast to physical hazards, no test methods have been specified for the determination of health and environmental hazards. It is only demanded that tests are conducted according to internationally recognised scientific principles. In other words, “the GHS criteria for determining health and environmental hazards are test method neutral, allowing different approaches as long as they are scientifically sound and validated according to international procedures and criteria already referred to in existing systems for the hazard of concern and produce mutually acceptable data.”[15]

4.3.2 Items in agreement

Most health hazards are covered in both systems. Nevertheless, due to differences at various levels, only for a few hazard classes can agreement between the two systems be noted. This is the case for **respiratory or skin sensitization**, if immunological contact urticaria is considered separately (see section 4.3.5.1, below).

Structurally, the hazard categories of **germ cell mutagenicity** are identical to the ones of mutagenic substances, while the verbal descriptions of them do not coincide. However, the

[14] Cf. interview 8

[15] Cf. GHS, 1.3.2.4.3, p. 19

criteria and the available guidance seem to result in equivalent classifications for this hazard. It has to be left to further case-by-case comparisons to determine whether this assessment of agreement between the two systems is justified.

4.3.3 Items addressed in EU system only

Two specific health hazards that result in classifications in the EU system have as yet not been included in the GHS. For “R65, aspiration hazard” discussions are under way at international level, which are expected to lead to decisions by the end of this year. Similarly, “R37 – respiratory tract irritation” might be included in the hazard class of TOST, single exposure, which is presently under revision.

Furthermore, most of the so-called “other toxicological properties” which do not lead to classifications in themselves, yet can be applied additionally to otherwise classified substances, are not covered by the GHS. Two of them are the object of on-going discussions at international level and might be covered by revised or additional parts of the GHS (the current “R67, narcotic effects” as part of TOST, single exposure; and the current R29 as part of water-activated toxicity, respectively). For a further one, “R66, skin effects”, different proposals were identified that ranged from taking it forward to the GHS process to omitting it from the future EU legislation. For both properties of acid-activated toxicity (i.e. R31, R32) the recommendation of retaining them in the future EU legislation was identified, while the omission of “R33, danger of cumulative effects”, which it is hardly used at present, was proposed.

4.3.4 Items addressed in the GHS only

In contrast to the EU system, the GHS differentiates between acute toxicity and systemic toxicity, which is reflected in the introduction of two new hazards classes, TOST, single exposure, and TOST, repeated exposure. However, as there are classifications in the EU system that correspond to these hazard classes, both will be discussed in the following section.

4.3.5 Items addressed in both systems, yet in different ways

4.3.5.1 Classification of substances

Regarding the subdivision of hazard classes into hazard categories, the GHS exhibits a more differentiated structure than does the EU system for acute toxicity, skin corrosion / irritation, and serious eye damage / eye irritation.

For **acute toxicity**, the GHS categories 1 – 4 cover the same LD_{50}- or LC_{50}-range, as do the three acute toxicity categories of the EU system. However, only for the inhalation of gases and vapours can a direct correspondence between the individual categories be discerned, whereas for the inhalation of dust this is only the case for a single category (EU harmful vs. GHS acute cat. 4). For the dermal route, too, for only a single category does such a direct correspondence exist (EU very toxic vs. GHS acute cat. 1). In contrast, for the oral route, direct correspondence is lacking.

Various experts interviewed recommended that the additional GHS category 5 not be adopted, as it is completely above the current EU acute toxicity range.[16]

[16] Cf. interviews 2, 5, 6, 7

For **skin corrosion / irritation** three subcategories for corrosion are foreseen in the GHS, as are two categories for irritancy and mild irritancy. The delimitation between the latter two categories is above the lower end of the current EU category “inflammation of the skin”. Opposing views on the adoption of the GHS category “mild irritancy” have been identified.

For **serious eye damage / eye irritation** two categories are foreseen in the GHS, the latter being subdivided into two subcategories, i.e. irritation and mild irritation. Due to different values for the test scores that are relevant for classification, no direct correspondence between EU and GHS categories exist. Recommendations against an adoption of the subdivision have been identified.

For substances which cause immunological **contact urticaria**, the GHS recommends the consideration of their classification as contact sensitizers, irrespective of their properties as respiratory sensitizers. In contrast, in the EU system only for substances that are not classified as respiratory sensitizers is this to be considered.

Despite the fact that the hazard categories of **carcinogenicity** are structurally identical to those of carcinogenic substances, the criteria employed are assessed as being at different levels of concreteness.[17] Hence, it will depend on the guidance given in the GHS whether equivalent classifications for this hazard will result. As the available guidance in the GHS is considered as insufficient, particularly for incomplete or poor quality data[18], the outcome of the ongoing revision has to be awaited before, based on further case-by-case comparisons, the level of agreement between the two systems can definitely be assessed.

For **reproductive toxicity** the situation is similar to that for carcinogenicity: on the one hand the hazard categories are structurally identical in both systems, yet on the other, clarification of the terminology used in the GHS is still under development. Again, it will depend on the outcome of this work whether equivalent classifications for this hazard will result. Only then can the level of agreement between the two systems be reliably assessed. It should be noted that the additional category of “effects on or via lactation” can lead to classification in itself, whereas in the EU system the corresponding “R64, may cause harm to breastfed babies” can only be allocated to substances already classified otherwise.

For both **target organ systemic toxicity (TOST)** hazard classes, i.e. single exposure and repeated exposure, corresponding classifications in the EU system exist which are subsumed under acute toxicity: Structurally, “R39, danger of very serious irreversible effects”, and “R68, possible risk of irreversible effects” correspond to TOST, single exposure, categories 1 and 2, respectively. However, initial tests of the GHS criteria have not corroborated this correspondence. Instead, urgent need for greater clarity in the guidance was identified.[19] A similar structural correspondence can be found for “T (toxic) R48, danger of serious damage to health by prolonged exposure”, and “Xn (harmful) R48, danger of serious damage to health by prolonged exposure” to TOST, repeated exposure, categories 1 and 2, respectively. For this hazard class, too, the need for additional guidance was indicated.[20]

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[17] Cf. interview 1

[18] Cf. Preliminary Report: Informal Working Group Testing the GHS Criteria for Carcinogenicity (ECB1/06/03 Add. 14)

[19] Cf. GHS Acute toxicity and single dose TOST Group, Document 2 (ECB1/24/03 Add. 2)

[20] Cf. interview 2

4.3.5.2 Classification of preparations

Before the classification of preparations / mixtures is discussed, it should be pointed out that in the GHS a provision on the concentration of impurities that legally transforms a substance into a mixture[21] is lacking.

At a structural level, a correspondence in the two systems between the classification rules for mixtures is apparent: classification can be based on testing of the mixture as a whole; it can be based on conclusions drawn from similar mixtures (Art. 6 (1) of directive 1999/45/EC, bridging principles of the GHS), or it can be based on the ingredients of the mixture. However, in the GHS the sequence listed prescribes an order which is to be followed, whereas in the EU system the three approaches are not part of a hierarchy.

A further difference between the two systems is the fact that in the EU system testing of preparations for classification of CMR hazards is not permitted. According to an expert interviewed, the permission in the GHS for these hazards might be of a more theoretical nature due to the rather strict requirements that have to be met.[22] A detailed overview on which element of the different approaches can be applied for which hazard class is given in Annex 10 of this report.

The rather complex nature of some of the calculation rules was explained by one expert with the different “philosophies” of the respective classification systems in the US and in the EU: whereas the former is only meant to provide the basis for hazard communication, the calculation approach in the latter is considered as a “surrogate test”.[23]

An important detail for the classification based on the ingredients of the mixture are the cut-off values or concentration limits that determine the allocation to a certain category. A detailed comparison of the cut-off values for the various hazard classes can be found in Annex 9 of this report. Assuming a structural correspondence as outlined in the previous section, differences were found for skin corrosion / irritancy (R34: 10 % vs. GHS cat.1: 5 %; R 38: 20 % vs. GHS cat. 2: 10 %), serious eye damage / eye irritation (R35: 5 %, R34: 10 %, R41: 10 % vs. GHS cat.1: 3 %; R36: 20 % vs. GHS cat. 2: 10 %), and reproductive toxicity (R60, R61: 0.5 % vs. GHS cat. 1: 0.3 %; R62, R63: 5 % vs. GHS cat.2: 3 %). For all differences found, the cut-off values in the GHS are below those in the EU system, which means that under the GHS more preparations have to be classified if the criteria for the respective hazard classes are in agreement.

For several hazard classes, options are foreseen for the choice of the cut-off values, as is the case for respiratory or skin sensitization, carcinogenicity, cat. 2, reproductive toxicity and both TOST classes. For all of them the option with the higher value corresponds to the respective value in the EU system, or is slightly below it, as in the case of reproductive toxicity.

For some hazard classes, differences exist for the concentration limit above which ingredients of a mixture have to be considered when determining the classification by summation over the ingredients: for acute toxicity in the GHS this limit is 1 % (w/w, and v/v, respectively)

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[21] Cf. directive 67/548/EEC, Annex VI, No 1.7.2.1

[22] Cf. interview 1

[23] Cf. interview 1

for all hazard categories, while in the EU system the corresponding values are 0.1 % v/v, and 0.02 % w/w, respectively, for very toxic and toxic substances; and 1 % v/v, and 0.2 % w/w, respectively, for harmful substances. For corrosives and irritants, both to the skin and to the eyes, the weight-related concentration limits are identical (i.e. 1 %), whereas the volume-related ones differ: in the GHS for all categories their value is 1 %, while in the EU system the limit is 0.02 % for corrosives, and 0.2 % for irritants.

Furthermore, specific problems for individual hazard classes have been identified: For acute toxicity, the tool of "acute toxicity estimate" (short: ATE) has been introduced, the values of which, however, can be selected from three options.[24] If options 2 or 3 are chosen, the resulting summation results resemble those under the conventional method of the EU system, whereas option 1 leads to structurally different summation results.

For both corrosion / irritancy classes (skin corrosion / irritancy, serious eye damage / eye irritation) different rules apply for additive and non-additive effects. As transparency on selecting the adequate rule is lacking, the need for guidance was remarked upon.[25]

For the additional category of "effects on or via lactation" in the reproductive toxicity class no classification criteria for mixtures have as yet been developed. This deficit is reflected by the lack of corresponding criteria in the EU system.

4.3.6 Guidance

Both in the documents analysed and in the expert interviews, the need for additional guidance beyond that already included in the GHS was stressed. For carcinogenicity and for reproductive toxicity, such guidance is currently being developed at international level. For the two TOST classes which were also named, no such work has as yet been identified. Additional issues that need guidance include the choice of the LD_{50}-/LC_{50}-value for the ATE calculation, and the selection of the adequate rule in the ingredients-based classification of mixtures containing corrosives / irritants.

Two experts addressed the question of conceivable EU guidance, since awaiting harmonized guidance at GHS level would be too time-consuming. A pragmatic rather than a formal solution was advocated, as it is a delicate matter which could lead to non-harmonisation and create complications at the level of the GHS and within the GHS Subcommittee.[26]

4.4 Environmental hazards

The EU system of classification and labelling covers both terrestrial hazard classes and hazard classes for aquatic toxicity, whereas at the moment the GHS covers hazard classes for the aquatic environment only. The classification and labelling system for the aquatic environment in the GHS reflects the current EU system. Both systems use two hazard classes: acute aquatic toxicity and chronic aquatic toxicity, with similar classification criteria.

[24] Cf. GHS, 3.1.3.3 (b), p. 113

[25] Cf. interview 1

[26] Cf. interviews 1, 2

4.4.1 Tests and criteria

The classification for the aquatic environment is based on toxicity data of three species and information on the degradability and bioaccumulation potential of substances and preparations. Whereas the EU system defines test methods in Annex V of Directive 67/548/EEC, the GHS opens up a wider range of test methods. Both systems allow the use of existing test data and QSARs, however the GHS is more explicit in respect of the latter.

4.4.2 Items in agreement

The following items are in agreement in both systems and can be implemented as drafted in Annex X[27] without further work:

- definition of, and test requirements for, rapid/ready degradability and bioaccumulation (substances)
- principle of division into acute aquatic toxicity and chronic aquatic toxicity, yet the GHS is more explicit (substances / preparations)
- criteria for “acute toxicity 1” (R50) (substances)
- use of other data than those specified in the text for classification (use of existing data / best available data allowed) (substances)
- use of QSARs (substances)
- testing of mixtures/preparations not possible for bioaccumulation and degradability, yet possible for acute toxicity (preparations / mixtures)
- principle of calculation of environmental toxicity for preparations - summation method / conventional method - (preparations / mixtures), not including the additivity formula
- the hazard symbol for environmental hazards

4.4.3 Items addressed in EU system only

The GHS contains neither hazard classes nor criteria for terrestrial environmental toxicity, hence the R-phrases R54-58 are not covered. The White Paper Working Group recommended these hazard classes not to be implemented in the new regulatory system[28]. Annex X does not contain any definitions of terrestrial hazard class.

In contrast to that, an adoption of the classification with regard to ozone depletion (R59) in the new legislation has been clearly recommended. At UN-level, the inclusion of this hazard class into the GHS is being discussed in the SCE GHS at the moment, but it is expected that the GHS will be implemented in the EU before this hazard class is included in the GHS. Therefore a decision needs to be taken about the mode of implementation. Here no clear recommendation could be discerned on whether the EU should a) maintain the current system, or b) adapt the label and hazard statement in order to conform to the “layout” of the GHS.

The hazard class “harmful to aquatic organisms” (R52), which represents a safety net classification in the EU system, does not exist in the GHS[29]. According to Annex X, no adoption of this specific hazard class / category has been recommended so far and its omission seems to be accepted.

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[27] However, it still needs to be checked whether there have been relevant changes in GHS after the drafting of Technical Annex X. Cf. Annex 11 to this report

[28] Cf. ECB1/03/02

[29] According to expert opinion the chronic aquatic toxicity category 4 represents this safety net in the GHS.

The indication of danger “Dangerous for the environment” does not exist in the GHS either. This problem is described further in section 5.1 of this report.

4.4.4 Items addressed in the GHS only

Categories 2 and 3[30] in the hazard class of acute aquatic toxicity do not exist in the EU system. The classification of inorganic compounds and metals is especially addressed in the GHS, with a guidance document provided. There is no such guidance document in the EU system, and the provision of one is seen as desirable by the experts.

The above mentioned items are proposed for inclusion in the new legislation and are not objected to by the experts. Nevertheless, there are different opinions on the application of the acute categories 2 and 3 in the supply and use setting.

Regarding the classification of preparations, the GHS adds new items to the current system in the EU, namely the use of a multiplication factor for highly toxic substances and the possibility to classify mixtures with components of unknown aquatic toxicity. These two elements were approved of as improvements of the current system and have been included as a proposal for adoption in Annex X.

The additivity formula in the environmental classification of preparations is an element which does not exist in the current EU system. The experts commented that the additivity formula would make the system too complicated. It provided another parallel option to classify and make use of test data, which, however, are not always available. Additionally, the additivity formula applied only to the toxicity criteria, thus summation is to be applied anyway for the classification of chronic toxicity. At the moment, Annex X includes the additivity formula.

4.4.5 Items addressed in both systems, yet in different ways

One structural difference in the classification systems is the clear division between acute and chronic aquatic toxicity in the GHS compared to the current EU system, which has no such division. Apart from this structural difference, there are several issues which are addressed in different ways. For most of these items proposals are identified (Annexes X and Y) which seem to be accepted by the experts.

4.4.5.1 Classification of substances

The introduction of the hazard classes “acute” and “chronic aquatic toxicity” is seen as an extension and clarification of the EU system and its implementation is recommended. A classification of a substance in both hazard classes at the same time is possible.

The test species recommended in the GHS differ from the EU system as laid down in Directive 67/548/EEC. Nevertheless, due to the possibility of using “best available data” according to EU-legislation, it is already common practice to use data of other test species, thus the adoption of the GHS constitutes a formalisation of existing practice. Additionally, the use of QSARs is encouraged much more explicitly in the GHS than in the EU system.

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[30] Two experts commented that the implementation of the acute aquatic toxicity categories 2 and 3 should only take place for the transport system and only category 1 should be applied for the supply and use system. Another expert commented that categories 2 and 3 are also relevant to storage and thus should be applied in the supply and use system too. The draft technical annexes do not make any specific recommendation as to which categories should be used in supply and use and the transport system.

The thresholds for the criteria for bioaccumulation potential (Log Kow and BCF) are higher[31] in the GHS than in the EU system. This results in differences in the definition of the hazard classes for chronic aquatic toxicity and the combined R-phrases in the EU. The raised values have been evaluated as of little relevance regarding the level of protection and are thus accepted by the experts.

It was mentioned by one expert that the ***connection*** between the description and purpose of chronic aquatic toxicity, category 4 (paragraph 1.4.3.14) should be explicitly linked to Table 1.4.3.1 listing the criteria to classify for this hazard category in Annex X.

The GHS provides the possibility to refrain from a classification for chronic aquatic toxicity by means of an escape clause (NOEC > 1 mg/l, or NOEC > solubility of the substance). This is also possible under EU legislation but for fewer hazard classes. This issue is also not seen as critical.

4.4.5.2 Classification of preparations

The cut-off values for considering components in the classification of preparations ('relevant components') is set at 1% in the GHS, whereas the preparations directive foresees a value of 0.1 % for very dangerous substances (R50, R50/53, R51/53). Implementation of the GHS provisions has been recommended and no special concerns[32] were identified in the documents analysed or mentioned by the experts interviewed.

4.4.6 Items addressed in neither system

Neither system has separate criteria for the classification of chronic aquatic toxicity, however this is foreseen for future work at international level (not with high priority, not to be finalised during the current biennium). Additionally, the ECB working group recommended the continuation of a cost-benefit analysis regarding the development and inclusion of terrestrial hazard classes [ECB1/03/02]. It recommended that ongoing work on the development of criteria for PBT and vPvB substances, and classification criteria based on these, be continued and included in the GHS, if appropriate, at a later stage. Furthermore, an inclusion of a hazard class for greenhouse gases has been discussed, but no agreement has been reached on whether this should be realised or not.

According to the results of the discussion in the ECB working group, the inclusion of new hazard classes and classification criteria should be possible in the new regulatory framework in the form of an 'adaptation to technical progress'.

4.4.7 Guidance

The GHS Annexes 8 and 9 contain detailed guidance on the environmental classification of substances and the classification of metals and metal compounds, respectively. It is more extensive than the corresponding one in Annex VI of Directive 67/548/EEC. For the classification of preparations, no separate guidance is provided by the GHS in addition to chapter 3.10. According to expert comments, Annexes 8 and 9 should be implemented as a guidance

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[31] Cut-offs for Log Kow: EU system -- 3, GHS -- 4. Cut-offs for BCF: EU system -- 100, GHS -- 500

[32] It was mentioned that the wording of the respective paragraph should be improved in order to achieve more clarity in what is meant. See Synopsis Section II, relevant components à 945

document rather than as part of the future legal text[33].

5 Hazard communication

Analogous to the structural similarities addressed for classification (cf. section 4.1, above), a close correspondence between the structural hazard communication elements is visible. In the two systems, hazard communication is based on both labelling and safety data sheets (SDS). The principal labelling elements, i.e. symbols and text information, exist in both systems, and the structure and content of SDS are principally the same. However, differences were identified on the issue of confidentiality.[34]

5.1 Labelling

For most label elements a direct correspondence can be seen, despite the fact that they are termed differently.

Counterpart of the EU danger symbol is the GHS **hazard symbol**. Whereas the EU symbols for extremely / highly flammable, oxidizing, (very) toxic, corrosive and environmental hazard are retained unchanged or nearly unchanged in the GHS, the EU symbols for explosive and irritant / harmful are not part of the GHS symbols. Instead, in the GHS three new symbols are introduced, i.e. exploding bomb, exclamation mark, and health hazard. Different to the EU system, on the GHS label a **hazard pictogram** appears which is composed of the hazard symbol and other graphic elements, such as a border, background pattern or colour that is intended to convey specific information.

In this context, one complication in the system as a whole has to be addressed: no harmonization between the pictograms under the transport regulations and under the GHS has been achieved. In order to avoid the duplication of information the GHS gives precedence to the TDG pictogram: where a TDG pictogram appears on a label, a GHS pictogram for the same hazard should not appear.[35] As a consequence, transport labels as an additional labelling system have to be both understood and relied on by occupational health and safety experts.[36]

In contrast to the EU system, in which the hazard symbol is accompanied by the indication of danger, no such additional verbal information is given in the GHS. Instead, a **signal word** is introduced which can consist either of the word “danger” or of the word “warning”, and serves as a graduation for some hazard symbols, e.g. for flame, flame over circle, health hazard. Precondition for the allocation of a signal word is not the allocation of a hazard pictogram, as can be seen for example in acute toxicity, cat. 5, or skin corrosion / irritation, cat. 3. On the other hand, a hazard pictogram is always accompanied by a signal word.

[33] There was also one different opinion, stating that parts of the guidance may have to be included as part of future legislation.

[34] Cf. interviews 7, 8

[35] Cf. GHS, 1.4.10.5.1, p. 30

[36] Cf. interview 8

Corresponding structural element to the EU nature of special risk (short: R-phrase) is the GHS **hazard statement**. No agreement between the wording of most of the individual R-phrases and the corresponding hazard statements was found. A hazard statement is allocated to each hazard category, even if no hazard symbol or no signal word is allocated.

Counterpart of the EU safety advice (short: S-phrase) is the GHS **precautionary statement**. As the harmonization of precautionary statements into fully standardized label elements is still under development at OECD level, a more detailed assessment of this structural element should await the outcome of that work.

In the GHS, the possibility of **supplemental label elements** is foreseen. It has been recommended that use be made of this option for certain labelling requirements that follow from other EU legislation, e.g. from directive 76/769/EEC[37].

The option of **consumer product labelling** which is envisioned in the GHS[38] was unanimously rejected by all experts who addressed this issue.[39]

Provisions on **packaging** are not contained in the GHS except for tactile warnings, which are in agreement with the corresponding provisions in the EU system.[40]

Currently, a GHS Correspondence Group is developing additional **guidance** to clarify labelling provisions and to achieve more consistent implementation for all sectors.

5.2 Safety data sheets

Regarding the safety data sheet (SDS), the GHS provides only a framework. The GHS format, i.e. the number of sections and their headings, is identical to the EU format. In contrast to the EU system, in which detailed guidance on the content of the SDS is provided[41], no such guidance is available as yet in the GHS, which, however, contains an extensive list of minimum information required.[42] Currently, a Correspondence Group is working on such guidance, which should be available by the end of this year. According to an expert the forthcoming proposals will not cover all aspects.[43] For some items options are foreseen which can be made use of by individual countries. Thus, specific EU guidance will be necessary in this area.

On the issue of comprehensibility of SDSs, which so far has not been addressed by the EU, progress could be achieved under the GHS: this issue is specifically addressed[44], and testing methodology is included in an annex.[45]

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[37] It is foreseen that directive 76/769/EEC will be replaced by the REACH regulation; cf. COM(2003) 644, Title VIII and Annex XVI

[38] Cf. GHS, Annex 4

[39] Cf. interviews 2, 7, 9

[40] Cf. GHS, 1.4.10.5.5.3, p. 34

[41] Cf. directive 91/155/EEC, Annex; it is foreseen that directive 91/155/EEC will be replaced by the REACH regulation; cf. COM(2003) 644, Title IV, and Annexes Ia and Ib

[42] Cf. GHS, Table 1.5.2, pp. 38 ff

[43] Cf. interview 9

[44] Cf. GHS, 1.4.4, p. 25

[45] Cf. GHS, Annex 5

In the GHS, the obligations for the provision of an SDS are less detailed than the corresponding EU obligations.[46] No limitation of the latter by the GHS text was identified. In particular the EU obligation to provide SDS for unclassified preparations[47] is contained in the GHS as an option.[48]

6 Summary of conclusions sorted according to action needs of the Commission

The following flow chart shows the hierarchy of action needs for the Commission. The very basic decision to be taken or affirmed is that on the adoption of the GHS with its structural differences regarding the separation of classification and labelling as well as the joining of provisions on substances and preparations in one piece of legislation.

For all items which can be adopted in accordance with the GHS and which have already been included in Annexes X and Y it is still necessary to compare the details of changes applied to the GHS after the drafting of the Annexes[49]. The items which are supposed to be adopted in accordance with the GHS are not addressed further in this chapter.

Those parts of classification which will be implemented differently than foreseen in the GHS have different action needs, depending on the state of play. For those items which are to be implemented making use of the building block approach, a decision needs to be taken on how the provisions are to be modified. The same applies for all items which do not yet exist in the current EU system.
For those items where provisions are missing in the GHS, the decision on a possible implementation depends on whether work is ongoing or not, and when a decision will be taken at international level. Issues which have been identified as relevant but are not addressed in either system also fall into this category of action needs, or may lead to a decision that work should be initiated, either in the EU alone or at international level.

The following figure shows the different types of action needs identified by the contractor. In the chapters below, the jobs are summarised[50] according to recommendations and options identified in the analysis of documents and during expert interviews.

[46] Cf. directive 91/155/EEC, Art. 1

[47] Cf. directive 91/155/EEC, Art. 1 (1) b)

[48] Cf. GHS, 1.5.2, p. 35

[49] An overview of types of changes and of documents produced at international level on changes is given in Annex 11 to this report.

[50] The summary is based on Synopsis Section II on classification and labelling.

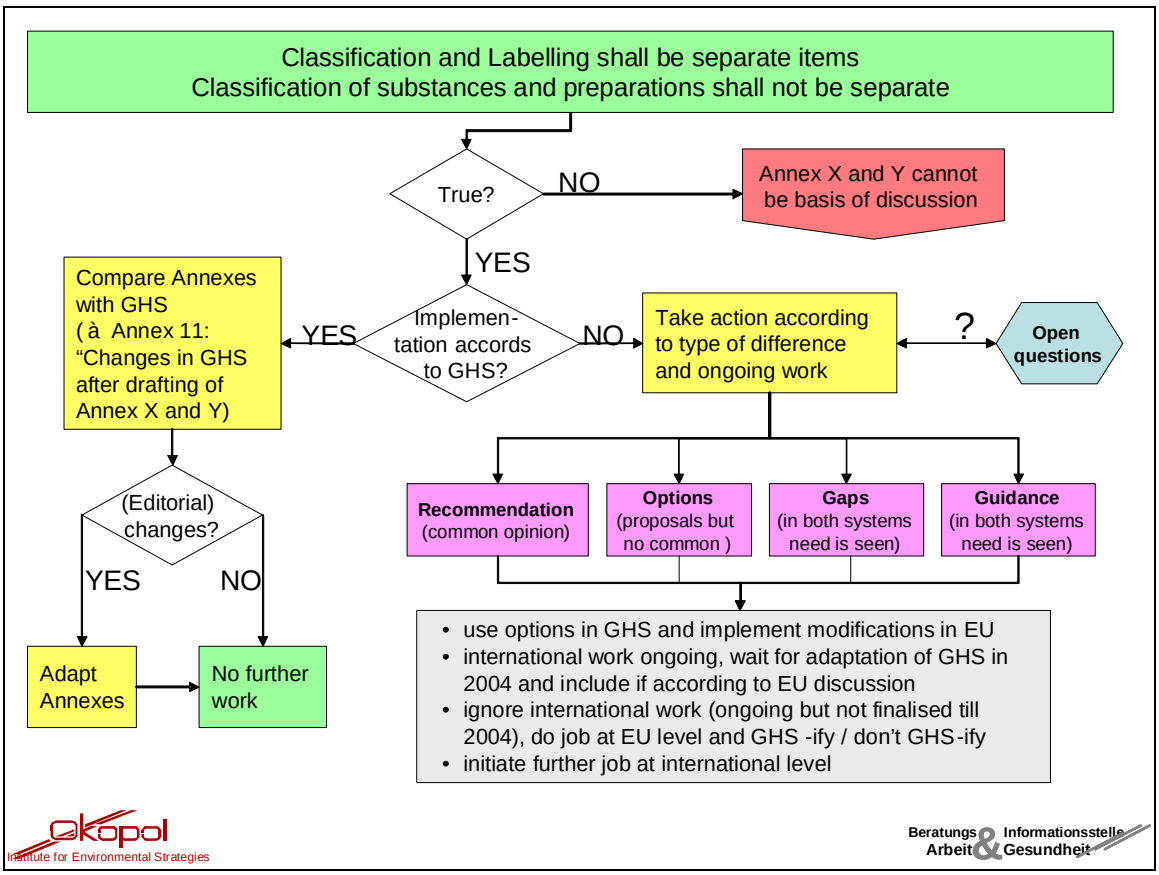

Figure 6.1: Flowchart of action needs for the implementation of the GHS in the EU

6.1 Use of options in the GHS for modifications in the EU system

6.1.1 Recommendations

Classification elements

Decision logic (***34***): not to be adopted;
rationale: no explicit arguments identified; in the GHS text, decision logic features explicitly as additional guidance outside the harmonized system itself

Specific cut-off-values / concentrations limits (***47***): to be set in the future EU legislation;
rationale: retain options for various purposes [ECB1/03/02]

Expert judgement (***102***): adopt the GHS and combine with text from Annex VI;
rationale: the two approaches are comparable; retain as much as possible from current EU system as it works without obvious problems [ECB1/03/02]

Classification of physical hazards

Oxidising properties (***215*** / ***380***, ***385***): specific recommendations for classification of current R8 and R9 substances;
rationale: no explicit reasons given [ECB1/84/01.rev.2]

Other physical-chemical properties (***250***): transform current risk phrase into GHS precautionary statement and provide more information in the SDS;
rationale: no explicit reasons given [ECB1/75/01-Part C]

Flammable gases (***320***): specific recommendations for classification of Ammonia and Methyl Bromide;
rationale: cover derogations under both current EU system and UN transport system [ECB1/75/01-Part A]

Flammable liquids (***340***): adopt hazard category 4 for storage;
rationale: potentially large volumes could be involved [ECB1/03/02]

Corrosive to metals (***400***): apply for the transport use setting only;
rationale: for hazard communication, to avoid confusion with labelling for skin corrosion or serious eye damage which uses the same pictogram but different hazard statement, since substances corrosive to metals are predominantly skin irritants [ECB1/75/01-Part A]

Classification of health hazards

Acute toxicity (***610*** – ***611***, ***612***): in a future fully harmonized system encompassing both the use and supply setting and the transport setting do not separate cat. 1 and 2 for the use and supply setting;
rationale: toxicity values in the range of category 1 currently used primarily by the transport sector [ECB1/79/01]; in view of the broad application of the supply and use system and also recognising the needs related to the transport system, no combination of the two categories recommended in a system not fully harmonized [ECB1/03/02]

Serious eye damage / eye irritation – reversible effects on the eye, cat. 2 (***632*** – ***633***, ***634***): in classification for eye irritancy use only cat. 2, no sub-division into 2A and 2B in the future EU system for supply and use;
rationale: as criteria for cat. 2 correspond almost completely to current EU criteria for Xi, R36, further sub-division considered as unnecessary [ECB1/79/01]

Germ cell mutagenicity (***650*** – ***651***, ***652***): cat. 1A and 1B should be combined to cat. 1;
rationale: identical hazard communication elements for the two sub-categories [ECB1/79/01]

Carcinogenicity (***660*** – ***661***, ***662***): cat. 1A and 1B should be combined to cat. 1;
rationale: identical hazard communication elements for the two sub-categories [ECB1/79/01]

Reproductive toxicity (***670*** – ***671***, ***672***): cat. 1A and 1B should be combined to cat. 1;
rationale: identical hazard communication elements for the two sub-categories [ECB1/79/01]

Classification of mixtures

Testing of mixtures (***911***): recommendations on the preferred sequence of methods to be applied;
rationale: contraindicate testing of mixtures in general by recommending a preferred sequence of methods different to the GHS hierarchy [ECB1/79/01]

Testing of mixtures (***911***): recommendations on the non-testing of CMR chemicals;
rationale: contraindicate testing of mixtures for CMR effects by employing the strict criteria to be fulfilled concerning the test methods [ECB1/03/02]

Cut-off values / concentration limits (***947***): use options foreseen in the GHS for several end-points that correspond to the values in the current EU system;
rationale: no explicit arguments identified; use of options foreseen allows retaining of current EU practice

Relevant components – environment (**701**): modify text of Annex X regarding the use of the M-factor for determining relevant components;
rationale: M-factor is an improvement; the GHS text is as yet not fully comprehensible [ECB1/03/02; interviews]

Labelling

Hazard pictograms (***72***): requirement for transport pictograms on supply packages;
rationale: use of TDG pictograms for physical hazards instead of GHS-pictograms should be acceptable, as this practice would harmonize labelling requirements between transport and supply systems as far as possible [ECB1/84/01.rev.2]

Supplemental label element (***67*** / ***77***): make use of this GHS provision for certain EU labelling requirements that follow from other Community legislation;
rationale: use of tool foreseen allows retaining of existing EU requirements [ECB1/03/02; interviews]

Consumer product labelling (***80***): do not adopt; do not allow reduced hazard information on labels;
rationale: no separation between consumer and work place chemicals is justified; risk-based labelling does not cover information needs for the whole life cycle and would not satisfy right-to-know-principle; consumer products cannot be excluded from professional uses [ECB1/84/01.rev.2]

Skin corrosion / irritation – corrosive, cat.1 (***621*** – ***622***, ***623***, ***624***): apply labelling for undivided cat. 1 only, do not introduce separate labelling for sub-categories;
rationale: identical hazard communication elements for the three sub-categories [ECB1/79/01]

Safety Data Sheets

Cut-off values / concentration limits (***94***): use options foreseen in the GHS for several end-points that correspond to the values in the current EU system;
rationale: these cut-offs would correspond better to the test results if mixtures were tested for classification purposes; the cut-offs used in the USA and Canada are in general meant for hazard communication purposes only [ECB1/84/01.rev.2]

SDS provision for certain non-dangerous preparations (***96***): retain current EU requirements;
rationale: requirements of recently adopted Directive 2001/58/EC should be kept in force [ECB1/78/01]

6.1.2 Options

Classification of health hazards

Acute toxicity, category 5 (***615***): adopt cat. 5 / do not adopt cat. 5;
considerations – adoption: advantages being extension of protection, maximisation of harmonisation; disadvantages being additional assessments required in a low priority area,

pressure for further testing;
considerations – non-adoption: advantages being that this reflects current EU approach with no loss of protection, does not incur extra testing and evaluation burden; disadvantages being that the opportunity to extend protection is lost [ECB1/03/02]

Skin corrosion / irritation – mild irritant, cat.3 (***626***): use both cat. 2 and 3 in the future EU system for supply and use / use only cat. 2 in the future EU system for supply and use;
considerations – use of both categories: additional cat. 3 would extend range of current EU criterion for irritant; could be useful for pesticides and for consumer products; still to be assessed whether R66 substances would fit better into cat. 3 than into cat. 2 [ECB1/79/01];
considerations – use of cat. 2 only: no explicit arguments identified

Respiratory or skin sensitization – skin sensitization, cat.1 (***642***): do not classify substances causing immunological contact urticaria as contact sensitizers in the future EU system for supply and use / if immunological contact urticaria is the only effect, then consideration should be given to classifying the substance as contact sensitizer (contrary to current Annex VI);
considerations: no explicit arguments identified for either option [ECB1/79/01]

Classification of environmental hazards

Acute aquatic toxicity, categories 2 and 3 (**822, 823**): apply categories for transport only / apply categories for supply and use as well;
rationale: categories 2 and 3 are not relevant, as such high concentrations are not reached during normal supply and use [interviews]

6.2 Probable inclusion of elements in the GHS, to be decided by the end of 2004

6.2.1 Recommendations

Classification of physical hazards

Other physical-chemical properties: may cause fire – R7 (***255***); reacts violently with water – R14 (***256***): take results on Water-Activated Toxicity Hazard Class (WAT) into consideration;
rationale: no explicit arguments identified; forthcoming GHS proposal might constitute viable alternative to previously quoted recommendation of transforming current risk phrase into GHS precautionary statement and providing more information in the SDS [cf. ECB1/75/01-Part C]

Classification of health hazards

Aspiration hazard – R65 (***523***): take results on classification criteria into account;
rationale: no explicit arguments identified; forthcoming GHS proposal might constitute viable alternative to currently foreseen solution of including this endpoint separately in Annex X

Respiratory tract irritation – R37 (***539*** / ***680***): take results on additional module in TOST, single exposure, on classification for respiratory tract irritation into consideration;
rationale: no explicit arguments identified; forthcoming GHS proposal might offer solution of covering this endpoint

Other toxicological properties: contact with water liberates toxic gases – R29 (***551***): take results on Water-Activated Toxicity Hazard Class (WAT) into consideration;
rationale: no explicit arguments identified; forthcoming GHS proposal might constitute viable alternative to currently foreseen solution of including this endpoint separately in Annex X

Vapours may cause drowsiness and dizziness – R67 (***557*** / ***680***): take results on classification criteria for narcotic hazards as part of TOST, single exposure, into consideration;
rationale: not covered by acute toxicity cat. 5 dermal and inhalation criteria [ECB1/03/02]; forthcoming GHS proposal might constitute viable alternative to currently foreseen solution of including this endpoint separately in Annex X

Acute toxicity (***610***): take results into consideration on revision of classification criteria for taking account of experimentally obtained acute toxicity range estimates to point estimates

Acute toxicity (***610***): take results on definition of terms for dust, mist and vapour in relation to inhalation toxicity into consideration

Respiratory or skin sensitization – skin sensitization, cat.1 (***642***): take results on examination of sensitization-induction and elicitation into consideration, which might lead to proposal of amendment of the criteria

Carcinogenicity (***660***): take results on development of guidance on the importance of different factors addressed in the GHS into consideration;
rationale: guidance considered necessary [interview]

Reproductive toxicity (***670***): take results on clarification of the following terms into consideration: reproductive toxicity, developmental toxicity, reproductive ability and capacity, class and category;
rationale: guidance considered necessary [interview]

Labelling

Labelling (***60***): take results on development of additional guidance for the clarification of labelling provisions and the achievement of more consistent implementation of the GHS for all sectors into consideration;
rationale: clarifies labelling provisions and achieves more consistent implementation of the GHS for all sectors [SCE GHS, Programme]

Precautionary statements (***75***): take results on harmonization of precautionary statements into fully standardized label elements into consideration;
rationale: relates precautionary statements to criteria – precautionary statements will be determined by hazard classes and categories, which, in turn, are determined by criteria [interview]

Safety Data Sheets

SDS content (***91***): take results on development of guidance on the preparation of the SDS under the GHS into consideration;
rationale: guidance considered necessary as GHS provides only a framework for SDS [interview]

6.3 Elements in the GHS under discussion, not to be decided by the end of 2004

6.3.1 Recommendations

Classification of health hazards

Acute toxicity (***610***): take results into consideration to be expected from Correspondence group on suggestions that additivity formula is not appropriate for toxic gases and may lead to serious underestimation of the hazard

Respiratory or skin sensitization (***640***): take results on examination of information concerning strong vs. weak sensitizers into consideration, which might lead to revisions to the classification criteria for respiratory and/or dermal sensitization

Carcinogenicity (***660***): take results on examination of methods for potency estimation into consideration

Reproductive toxicity (***670***): take results into consideration on the amendment of classification criteria for toxic to reproduction to consider cut-off dose levels related to the potency of a chemical

Classification of environmental hazards

Substances dangerous for the ozone layer, R59 (***726***): take results of work on ozone depleting substances into consideration;
rationale: ODS classification should not be dispensed with ,implementation in EU should be carried out although international work will not be finalised by the end of 2004 [ECB1/76/01; ECB1/03/02; interviews]

Chronic aquatic toxicity (***830***): take results of planned inclusion of test methods of,and data requirements for, chronic aquatic toxicity in the GHS into consideration;
rationale: actual chronic toxicity data would form a better basis for classification; work does not have the highest priority [ECB1/03/02]

6.4 Elements to be forwarded to the GHS

6.4.1 Recommendations

Classification of physical hazards

Ammonium nitrate (***405***): introduce it to the GHS process;
rationale: neither covered by current EU chemicals legislation nor by GHS [interview]

Desensitized explosives (***410***): introduce it to the GHS process;
rationale: neither covered by current EU chemicals legislation nor by GHS [interview]

Classification of health hazards

Other toxicological properties: repeated exposure may cause skin dryness or cracking – R66 (***556***): introduce it to the GHS process;
rationale: not covered by acute toxicity cat. 5 dermal and inhalation criteria [ECB1/03/02]; potential GHS proposal might constitute viable alternative to currently foreseen solution of including this endpoint separately in Annex X

Classification of environmental hazards

Work on new hazard classes and criteria: consider inclusion of hazard classes for PBTs / vPvBs and for terrestrial hazards.
rationale: ongoing EU work on PBTs and vPvBs in the scope of REACH should be used for the classification system; the new system will not contain terrestrial hazard classes; new classes and criteria should undergo a cost-benefit analysis before being elaborated [ECB1/76/01; ECB1/03/02; interviews]

6.5 Elements to be addressed by the EU, irrespective of GHS process

6.5.1 Recommendations

Classification of physical hazards

Other physical-chemical properties: explosive when mixed with oxidising substances – R16 (***257***): do not retain in the new system;
rationale: no explicit arguments identified, neither for recommendation of omitting R16 [Annex X] nor for converse recommendation of retaining R16 [ECB1/75/01-Part C]

Classification of health hazards

Other toxicological properties: contact with acids liberates toxic gases – R31 (***552***); contact with acids liberates very toxic gases – R32 (***553***): include separately in Annex X;
rationale: no explicit arguments identified

Other toxicological properties: danger of cumulative effects – R33 (***554***): do not retain in the new system;
rationale: was hardly used within the current EU system and had been replaced more or less by R48 [interview]

Other toxicological properties: repeated exposure may cause skin dryness or cracking – R66 (***556***): include separately in Annex X;
rationale: not covered by acute toxicity cat. 5 dermal and inhalation criteria [ECB1/03/02]; cf. complementary proposal of introducing this endpoint to the GHS process (above)

Classification of environmental hazards

Substances dangerous for the aquatic environment, R52 (***714***): do not retain in the new system, rather improve the description of the 'safety net' function of chronic toxicity category 4 in Annex X;
rationale: chronic toxicity categories 3 and 4 cover the safety net function of R52; particularly the description of category 4 does not, as yet, clearly show this [interviews];

Substances dangerous for the non-aquatic environment, R54 – 58 (***721 – 725***): do not retain in the new system;
rationale: these R-phrases are confusing in the current system and regarded as unlikely to be those actually developed in a future classification system [ECB1/03/02]

Substances dangerous for the ozone layer, R59 (***726***): decide on design layout of hazard pictogram and on the way of implementing the current indication of danger;
rationale: as the international work will not be finalized during this biennium, the EU needs to implement the classification of ODS independently; the question of how to formulate the criteria and to design respective pictograms is a question applicable to various items [discussion with Commission representatives]

Labelling

Child-resistant fastenings (***85***): retain the current EU provisions;
rationale: outside scope of GHS [interview]

Safety Data Sheets

SDS provision (***95***): retain current EU obligations;
rationale: specific provisions not part of the GHS [interviews]

6.5.2 Guidance

Weight of evidence (***103***): further interpretation needed for some health endpoints;
rationale: inclusion of clarifications in format of legal text instead of guidance could lead to international complications [interview]

Classification of health hazards

Acute toxicity (***610***): guidance on expert judgement (cf. ***102***) needed;
rationale: need for guidance on expert judgement with regard to methaemoglobinaemia addressed [ECB1/24/03 Add.1]

Carcinogenicity (***660***): further guidance needed; cf. results on development of guidance on the importance of different factors addressed in the GHS to be expected by the end of 2004;
rationale: IARC criteria used by the GHS considered from an EU viewpoint as too general [interview]

TOST (***680*** / ***690***): further guidance is needed for both classes

TOST, single exposure (***680***): guidance on expert judgement (cf. ***102***) needed

Classification of environmental hazards

Guidance (Annex 8 and 9 of the GHS) on environmental classification (**870**): implementation as part of legislation or as guidance document referenced to in legislation;
rationale: mode of implementation influences flexibility in changing the guidance [interviews]

Classification of mixtures

Acute toxicity estimate - ATE (***943***): guidance needed;
rationale: resolves open problems with formula for mixtures [ECB1/84/01.rev.2]

Non-additivity approach for corrosives / irritants (***944***): further guidance needed;
rationale: resolves lack of clarity on when to assume an additive effect and when to assume a non-additive one in order to select the appropriate rule [interviews]

Safety Data Sheets

SDS content (***91***): additional guidance needed, as guidance under the GHS (cf. section 6.2.1, above) will not cover all areas

6.5.3 Open questions

Classification of health hazards

Reproductive toxicity – effects on or via lactation (***674***): criteria for classification of mixtures containing substances which have effects on lactation have not yet been developed

7 Identified issues beyond the scope of the contract

Several issues were identified in the expert interviews and the analysis of documents which are beyond the scope of this study contract. They focus on the following main aspects:

1) updating of Annexes X and Y according to the latest developments in the GHS and REACH à checking of consistency
2) taking account of the current work at UN-level when implementing the GHS
3) consequences of classification under the GHS for
    a. number of classified substances and preparations
    b. industry with regard to time, resources, and capacities
    c. need for transitional periods
    d. support and training
4) compatibility with REACH
5) discretions of competent authorities
6) relation to, and possible harmonization with, transport system
7) consequences for / impacts on downstream legislation
8) problems for new Member States

Details of the various aspects mentioned are compiled in Annex 7 of this report.