EXPLANATORY MEMORANDUM

BACKGROUND TO THE PROPOSAL

Reasons for and objectives of the proposal

This proposal aims at implementing within the EU the criteria that have been agreed on the international level by the United Nation Economic and Social Council (UN ECOSOC) for the classification of substances and mixtures as hazardous and the labelling of such hazardous substances and mixtures, called the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Chemicals are manufactured and traded globally, and the hazards of substances and mixtures remain the same when they are manufactured in different countries around the world. Therefore the description of these hazards should not differ from country to country if the product is the same.

Enterprises will save costs if they do not have to assess their information on the hazard of their substances and mixtures against different sets of criteria.

Different descriptions of the same facts do not improve the level of protection of human health and the environment. On the contrary, if the same criteria are used to identify the hazards of substances and mixtures and the same labelling elements are used to describe them, the level of protection becomes more consistent, transparent and comparable throughout the world. In the end, professional users of chemicals and consumers all over the world will benefit from such a harmonisation.

The Global Context

During the last 30 to 40 years, a number of different classification and labelling (C&L) systems for chemicals (substances and preparations, GHS term: mixtures) have been elaborated by different jurisdictions in the world such as the European Union, Australia, Canada, Japan, the USA, China and Korea, which has lead to dissimilar C&L systems giving different Health and Safety (H&S) information for the same chemicals which originate in different countries, but which are traded internationally.

In 1992, the UN Conference on Environment and Development (UNCED) in Rio de Janeiro identified the harmonisation of classification and labelling systems for chemicals as one of its action programmes in Chapter 19 of UNCED Agenda 21.

The aim of this work was to bring together the major world classification and labelling systems (effectively the US, Japanese, Australian, Canadian, EU supply systems and the international transport systems) into one single new system with the goal to promote sustainable development and to facilitate international trade. Three main elements were identified:

– a globally harmonised classification system for chemical substances

– a globally harmonised classification system for mixtures/preparations;

– and a globally harmonised system for hazard communication for workers, consumers and in transport which includes labelling and safety data sheets (SDS).

Since the middle of the 90ies the system has been developed in co-operation with various international organisations. EU Member States, the Commission and a high number of industry stakeholders were heavily involved in this development work since its onset.

In December 2002, the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) was agreed by the UN Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labelling of Chemicals (CETDG/GHS)[1] in Geneva. The GHS was then formally adopted by UN ECOSOC[2] in July 2003 as was its first revised edition[3] in 2005. Hence it became available for implementation.

In its Plan of Implementation, adopted in Johannesburg on 4 September 2002, the **World Summit on Sustainable Development** encouraged countries to implement the new GHS as soon as possible with a view to having the system fully operational by 2008. The Strategic Approach to International Chemicals Management that was adopted by the International Conference for Chemicals Management in Dubai on 6 February 2006 recognises the importance of the GHS and one of its objectives is "to promote implementation of the common definitions and criteria contained in GHS".

The adoption of GHS at the UN level did not take place in form of an international Convention but it provides *de facto* for a voluntary international standard. It was necessary to adopt such a voluntary approach at the start of the process to get all the key parties involved. In the meantime, many countries have expressed their willingness to implement the agreed harmonised system into their legal systems.

The EU Context

A globally harmonised system for classification and labelling of chemicals contributes to the harmonious development of world trade and to the progressive abolition of restrictions on international trade as expressed in Article 132 of the Treaty.

Besides participating in the work to develop the GHS at UN level, the Commission has announced on several occasions its aim to come forward with a proposal for the implementation of the GHS into Community legislation.

Already in 2001, the White Paper, 'Strategy for a future Chemicals Policy'[4] proposed as Action 7C:

"To simplify the current labelling system and improving comprehensibility through Globally Harmonised System (sic). The current negotiations on the elaboration of a Globally Harmonised System provides an opportunity to fundamentally review the current labelling provisions, to consider simplification and to improve comprehensibility of the labels".

---

1 An ECOSOC subsidiary body serviced by the UNECE secretariat.
2 Economic and Social Committee of the UN
3 http://www.unece.org/trans/danger/publi/ghs/ghs_rev00/00files_e.html
4 COM(2001) 88 final

The Council Conclusions of 2001[5] (7 June 2001, para 47) on the White Paper:

"Invites the Commission, when drawing up its proposals, to … coordinate in cooperation with Member States the input into the international work on the Globally Harmonised Classification and Labelling System (GHS) and also analyse its implications for the Community legislation and consider, as appropriate, the need to submit proposals for its implementation".

The Plan of Implementation[6] of the World Summit on Sustainable Development adopted at the 17th plenary meeting, on the 4 September 2002 states the following:

"23. Renew the commitment, as advanced in Agenda 21, to sound management of chemicals….This would include actions at all levels to: …

(c) Encourage countries to implement the new globally harmonized system for the classification and labelling of chemicals as soon as possible with a view to having it fully operational by 2008;"

The Plan of Implementation of the World Summit on Sustainable Development which was signed up to by all now 25 EU Member States, the Council Conclusions and the statement in the White Paper, demonstrate that there is general agreement that the GHS should be implemented in the EU.

On 29 October 2003, the Commission stated in the explanatory memorandum to the amendment to 67/548/EC[7], adopted at the same time as the REACH-Proposal, that:

"it is the intention of the Commission to propose the inclusion of the internationally agreed GHS into Community law as soon as possible"

and, more specifically, that:

"the Commission will come forward with the necessary proposals for having it adopted at the same time as the final adoption of the REACH legislation".

The present proposal fulfils that commitment.

The Current EU System and the GHS

The current EU classification and labelling system for chemicals is set out in three key legal instruments:

– the Dangerous Substances Directive (67/548/EEC)[8];

– the Dangerous Preparations (i.e. mixtures of chemicals) Directive (1999/45/EC)[9];

---

5 2355th Council meeting, 7 June 2001, §47

6 http://www.johannesburgsummit.org/html/documents/summit_docs/131302_wssd_report_reissued.pdf

7 2003/0257(COD)

8 Council Directive 67/548/EEC relating to the classification, packaging and labelling of dangerous substances, as amended [OJ 196, 16.8.1967, p. 1]

9 Council Directive 1999/45/EC relating to the classification, packaging and labelling of dangerous preparation, as amended [OJL200, 30.7.1999, p.1]

– the Safety Data Sheet Directive (91/155/EEC)[10].

The Directives are very closely linked. They are based on Article 95 of the EC Treaty as they pursue internal market objectives, i.e. the establishment of a Single Market in the trade of chemicals in the EU. Preparations make up about 95% of all chemicals on the market. The Directives take as a basis a high level of protection concerning health, safety environmental and consumer protection (Article 95 (3) EC-Treaty).

The first two Directives mentioned above set out rules on the classification, packaging and labelling of dangerous substances and preparations respectively. This system has been developed over the last 40 years. The Safety Data Sheet Directive of 1991 ensures that suppliers of such substances and mixtures provide available information about the hazard of their substances and preparations and some guidance on safe use to professional customers. These provisions have lately been transferred to the REACH-proposal.

The current EU system and the GHS system are conceptually similar and cover the same structural elements: classification, packaging and hazard communication including labelling and safety data sheets. Some of the criteria for classification will however change with the new system.

The GHS is a common approach that provides the criteria for harmonised classification and hazard communication for the different target audiences including consumers, workers and emergency responders, and in transport. Therefore, it includes a "building block" approach to enable countries to adopt the system with regard to the various target audiences and thus in different legal areas. This "building block" approach enables the legislator to choose the hazard classes and hazard categories in order to determine the level of protection for the various target audiences. This concept requires that if a hazard class or category is chosen, the criteria shall be those set out in the GHS, but the legislators in the different jurisdictions have a certain choice of which hazard classes and/or categories to implement. This "building block" approach was developed to facilitate agreement on the GHS while still promoting the highest possible global harmonisation of the criteria for classification.

As one of the aims of the GHS is to provide a common system of the classification and labelling for transport and for supply and use, this proposal strives for coherence with the EU transport legislation, where relevant. EU transport legislation will incorporate those GHS criteria for hazard classes and categories that correspond to the specific needs for transport by 2007 and 2009 which is in line with the timetable for adoption of the UNECE Model Regulation.

This proposal addresses supply and use of chemicals and the main target audience are therefore workers and consumers. This is the same as in the current EU system for classification and labelling of substances and preparations.

Substantial work of identifying the differences of the current EU system for supply and use and the GHS systems has been carried out[11]. Based on this work the Commission has come forward with the present proposal.

---

[10] Council Directive 91/155/EEC relating to defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations and dangerous substances, as amended [OJL 076, 22.03.1991, p. 35]

The number of classified substances resulting from the application of the new system is estimated to be approximately about the same as under the current system.

Regarding preparations, now called mixtures, due to changes of the generic concentration limits and of the calculation methods, overall probably more mixtures will be classified. The application of the new criteria might however result in a different classification of a substance or a mixture compared to the current system.

As safety data sheets will be used as the main tool for the communication in the REACH Regulation, the provisions on safety data sheets being implemented through the REACH Regulation will remain in that Regulation.

Future Development

The Sub-Committee of the Experts on the Globally Harmonised System of Classification and Labelling of Chemicals (UNSCEGHS) is responsible for the technical aspect related to the maintenance of the GHS for health and environmental hazards. Whereas the Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) is responsible to keep the system up-to-date regarding physical hazards. The main functions of the parent committee, the Committee of the Experts on the Transport of Dangerous Goods and the Globally Harmonised System of Classification and Labelling of Chemicals (UNCETDG/GHS), are to coordinate strategic and policy issues, to give formal endorsement to recommendations of the sub-committees and to provide the mechanism for channelling these to the UN ECOSOC. Future revisions of the GHS document will get formal adoption by UN ECOSOC on a biennium basis[12].

Coherence with other policies

The classification of substances and preparations in the current directives triggers many other obligations in Community legislation, referred to as "downstream legislation".

Substantial work of assessing the potential effects on downstream legislation due to implementation of the GHS criteria into Community legislation has been carried out by the Commission services. The "Analysis of the Potential Effects of the Proposed GHS Regulation on Its EU Downstream Legislation" is available for information on the website as follows: http://ec.europa.eu./enterprise/reach/ghs_consultation_en.htm

The assessment shows that references in downstream legislation to classifications do not mean that they will always automatically trigger further legal obligations. The reason is that in many cases obligations in "downstream legislation" are risk based. Therefore, exposure has to be considered as a second trigger for any obligations.

---

[11] ECBI/03/02: White Paper Working Group on Classification and Labelling: Summary of Recommendations from Technical Working Group on Tasks 1 and 2.
Final report: Technical Assistance to the Commission on the implementation of the GHS. Ökopol Institute for Environmental Strategies, July 2004.
Final project report: Technical support for the preparation of Annexes for the draft legislation implementing the Globally Harmonised System for Classification and Labelling of Chemicals (GHS). Milieu Environmental Law & Policy, January 2006.

[12] GHS ST/SG/AC.10/30/Rev. 1, 2005, 1.1.3.2

The assessment also shows that different approaches in the downstream legislation need to be distinguished: references to selected classifications or R-Phrases or general references to classification as dangerous.

The Commission will address the interfaces to downstream legislation in two ways:

A number of pieces of such legislation will be amended through this Regulation.

For other pieces of legislation the Commission will prepare specific proposals for amendments of the Directives or Regulations to address necessary changes due to the implementation of GHS into Community legislation.

For public stakeholder consultation

For example a number of Directives, like the Cosmetics Directive or the Directive on the protection of workers from the risk related to exposure to carcinogens or mutagens at work, refers to certain categories of danger or R-Phrases for which the GHS contains corresponding or comparable criteria. Therefore they can be easily replaced by references to the GHS specific hazard classes or categories in this Regulation as set out in the table of correspondence, e.g. classification as "carcinogenic, mutagenic or toxic to reproduction, Category 1 and 2" under the current legislation will be construed as references to "carcinogenicity, mutagenicity or reproductive toxicity, Category 1A and 1B" in this Regulation.

Another example of a Regulation that is amended by this Regulation is the REACH Regulation. In the REACH Regulation, there are different references to classifications. For example in the authorisation system, there are references to the classification as carcinogenic, mutagenic and toxic to reproduction, Category 1 and 2. They can easily be replaced, as explained above, by references to the classification as carcinogenic, mutagenic and toxic to reproduction, Category 1A and 1B. Other obligations under the REACH Regulation, like the steps 5 and 6 of the chemical safety assessment, are generally triggered by reference to the classification of a substance or mixture as "dangerous". Hazard classes and categories which have been included by the GHS in addition to the current EU system but which are not relevant for the exposure situations addressed by REACH should therefore not trigger the obligations under REACH. This would alter the scope and impact of REACH. Therefore those hazard classes and categories that will not trigger obligations under REACH are specified in this Regulation.

This approach [could be / is] extended to other downstream acts.

Therefore, the impact on many pieces of legislation can be kept to a minimum with the changes introduced in this Regulation.

An example of a Directive for which the "translation" of particular hazards might not be so straight forward, is the Seveso-II-Directive[13]. It will therefore need more consideration; in particular as it will not only be the GHS Regulation to bear upon the Seveso-II provisions, but also the UNECE Convention on Transboundary Effects of Industrial Accidents. The Convention will also adapt various classification criteria of the GHS. The Commission will therefore propose to amend the Seveso-II-Directive to take account of both this Regulation and the Convention.

---

[13] Council Directive 1996/82/EC of 9.12.1996, OJ

RESULTS OF PUBLIC CONSULTATIONS AND IMPACT ASSESSMENTS

Public stakeholder consultation

Internet consultation

The Commission has launched a public stakeholder consultation on the internet on 21 August 2006.

[after the consultation*:* main concerns and how they were addressed]

Impact assessments

Specific studies, notably in relation to the likely impact of the changed criteria for the classification of substances and mixtures, were performed. The outcome of these has been taken into account in preparing the impact assessment.

[after the consultation: main conclusions and how they were addressed]

Collection and use of expertise

The GHS has been developed by various international organisations and a vast variety of stakeholders were invited to participate in the GHS process. Also at the EU level there has been continuously technical discussions with Member States and other stakeholders during the last years. Following the publication of the White Paper "Strategy for a future Chemicals Policy", the Commission consulted widely with experts. This was done in the course of conferences, stakeholder working groups and in bilateral contacts between the services and stakeholders. One of the eight technical working groups convened by the Commission in 2001-2002 in preparation of REACH has dealt with classification and labelling. The results of that working group[14] have been taken into account in the drafting process of this Regulation, especially with regard to the development of the Annexes and the choice which hazard classes and categories need to be selected to provide an equivalent level of protection as the current system and to ensure consistency with the transport legislation. Throughout this process the consultation of relevant experts continued and studies have been launched to seek for technical support for the preparation of the implementation[15]. On 18 November 2005, an informal stakeholder discussion on the implementation of the GHS in Community legislation has taken place with the primary aim to seek guidance on key issues surrounding the development of Community legislation on GHS.

---

14 ECBI/03/02: White Paper Working Group on Classification and Labelling: Summary of Recommendations from Technical Working Group on Tasks 1 and 2.

15 Final report: Technical Assistance to the Commission on the implementation of the GHS. Ökopol Institute for Environmental Strategies, July 2004.
Final project report: Technical support for the preparation of Annexes for the draft legislation implementing the Globally Harmonised System for Classification and Labelling of Chemicals (GHS). Milieu Environmental Law & Policy, January 2006.

LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

Article 95 of the EC Treaty is the appropriate legal basis for this Regulation because the main aim of this Regulation is to ensure a level playing field for all suppliers of chemical substances and mixtures in the internal market and, is moreover, based on the globally harmonised criteria for trade of substances and mixtures. At the same time the proposal is based on a high level of protection of health, safety, environmental and consumer protection.

The choice of this legal basis ensures that the requirements for substances and mixtures are harmonised and that substances and mixtures complying with those requirements benefit from free movement throughout the internal market. This rewards the efforts which will be required from economic actors to reclassify substances and mixtures which they already supply and which are classified according to the current system. It also rewards the efforts from those actors which supply substances and mixtures for the first time after the entry into force of this Regulation.

Moreover, Article 95 paragraph 3 requires a high level of protection to be sought for proposals concerning health, safety, environmental and consumer protection. This Regulation falls within this remit; hence the use of this legal basis does not compromise the level of protection.

Principles of subsidiarity and proportionality

Subsidiarity

With regard to the issue of subsidiarity in the sense of Article 5 of the EC Treaty, it should be taken into account that the present Directives on the classification and labelling of substances and preparations already provide for an extensive control by Community legislation in that respect. The new Regulation will replace the existing Directives. Classification and labelling provisions contain technical details which, to enable trade without barriers in the internal market, need to be exactly the same in all Member States, and should therefore be regulated on the Community level. This ensures for the EU the greatest contribution to the aim of the globally harmonised system, thus that global trading partners will have to follow the same rules in all Member States in the EU.

Proportionality

The criteria for the classification of substances and mixtures as hazardous have been developed on the international level, including the building block approach that invites the legislator to choose the appropriate hazard classes and categories. To ensure proportionality of this Regulation, the Commission selected those hazard classes and categories which are comparable with the current system.

Therefore, firstly, this proposal does not include the categories as follows as they are not part of the current EU system and are not needed for consistency with transport legislation: “flammable gases category 2”, “flammable liquids category 4”, “skin corrosion/irritation category 3”, “aspiration hazard category 2” and “acute aquatic toxicity category 2 and 3”.

Secondly, this proposal does not include the hazard class “acute toxicity category 5” as it is not part of the current system.

Thirdly, those elements which have been part of the current EU system and which have not yet been included in the GHS are also part of this proposal, e.g. "ozone depletion". This is however, no change with respect to the provisions of the current legislation, and no additional elements have been added.

To be consistent with the GHS, those elements which have only lead to additional labelling requirements under the current EU system but which are now part of the GHS classification system will now lead to classification, e.g. for "effects on or via lactation" and "narcotic effects". However, hazard classes or categories added in addition to the current EU system are specified in this Regulation as they should not trigger for example obligations under REACH such as "gases under pressure", "corrosive to metals" or "narcotic effects".

For consistency with the transport legislation some hazard classes or categories have been incorporated which were not included in the current EU system for supply and use, but were part of the existing EU transport system or will be implemented by transport. These are "gases under pressure", "self-reactive substances and mixtures, Type C to G"; "self-heating substances and mixtures"; "oxidising liquids category 3"; oxidising solids category 3"; and "corrosive to metals".

Therefore this proposal for a Regulation is proportionate.

Choice of legal instrument

The choice of a Regulation for this proposal is justified. Not only that it replaces 2 existing and rather old Directives (including 10 Amendments and 30 Adaptations to Technical Progress), but this proposal contains mainly technical details which have been agreed on the UN level, and which cannot be changed. Thus, the Regulation will be directly applicable in all Member States. In the area of technical legislation, the choice of Regulations is a widely used technique that has already met with the support of Member States in other areas of Community competence[16].

INTRODUCTION TO THE PROPOSAL

This Regulation sets out rules and criteria for the classification of substances and mixtures as hazardous, for the labelling of such hazardous substances and mixtures as well as rules for the packaging of them.

1. REASONS AND OBJECTIVES

1.1. General Issues: Subject matter, scope and definitions, hazardous substances and mixtures and specification of hazard classes

The first part of the Regulation sets out the scope of the classification and labelling rules, which is consistent with the REACH system and other pieces of specific Community legislation. There are no changes in scope compared to the current classification and labelling

[16] See the recent Regulation (EC) No 178/2002 on Food Law, as well as the Commission's recent proposals for Regulations on Fertilisers (COM(2001) 508), Detergents (COM(2002) 485) and Drug Precursors (COM(2002) 494).

legislation. Furthermore, the terms used throughout the Regulation are defined. It should be noted that the term "preparation" in the current legislation is replaced by "mixture" in GHS as the majority of jurisdictions in the world use the latter term. For reasons of convenience, some definitions already included in the REACH Regulation are repeated here. The hazard classes that have been agreed upon on the UN level and those originating from the existing EU legislation and not yet covered by the GHS are listed. The Commission is proposed to be empowered to update the Annexes, for example when more hazard classes have been agreed upon on the UN level. Finally, the general obligation for suppliers of substances and mixtures to self-classify and label their substances and mixtures that meet the criteria of this Regulation is set out. If a harmonised classification for a hazard class or part of it for a substance is included in Annex VI to this Regulation, the substance must be classified according to that entry.

1.2. Identification of information

Suppliers have to identify which information is relevant to describe the hazards of their substances and mixtures. Suppliers are not obliged to generate new test data for that purpose alone but they shall use all information available to them, thus in particular information that they have generated under other pieces of Community legislation, e.g. the REACH-Regulation or the Biocides-Directive[17].

If suppliers decide themselves, however, to generate information, this information has to fulfil certain quality standards, set out in the relevant Community legislation or agreed upon on the international level. Wherever possible, animal tests should be avoided.

For mixtures, available test data on the mixtures itself should generally be used, except for mixtures containing one or more substances with CMR properties. For the latter, the classification of the mixtures shall normally be based on the information on those substances.

If no test data are available on the mixture itself, the Regulation specifies in its Annex I a number of "bridging principles" which enable the supplier to derive a sound classification of the mixture.

1.3. Evaluation of Hazard information and classification

Rules are set out on how to evaluate available data for the purpose of hazard classification, and in which cases refinement of the results derived from available data might be necessary.

Classifications of substances are important as such to protect workers and other people using those substances. Furthermore, they form the basis for many obligations in Community legislation. Therefore classifications have to be of good quality and should be harmonised as far as possible throughout Europe. As the responsibility for the classification generally lies with the suppliers, the classification and labelling inventory as a tool to establish a harmonised industry self derived classification system has been introduced by the REACH Regulation, and the provisions are now transferred to this Regulation. To support the harmonisation, majority views on the classifications in that inventory are given special weight, in that they should be followed, unless the supplier has a justification for different results.

---

[17] Directive 98/8/EC of the European Parliament and of the Council, OJ L 123, 24.4.1998, p.1

To ensure that the system is workable and not disproportionate, concentration limits are set out both for the classification of substances with regard to impurities, additives or individual constituents and for the classifications of mixtures with regard to the individual components of the mixtures.

Finally, to ensure that classification of mixtures takes into account changes to the composition and thereby to ensure the protection of human health and the environment, it is specified under which conditions classifications of mixtures have to be re-evaluated.

1.4. Hazard Communication in form of labelling

Hazard Communication as agreed on the UN level consists of two parts: labelling and safety data sheets. The label includes the most important information about the hazards of a substance or mixture. It is the first step which draws attention to the more detailed information in the safety data sheets for professional users of substances and mixtures.

1.4.1 The Content of the label

To implement the labelling rules that were agreed on the UN level, the individual label elements are set out and described in detail. They are pictograms, signal words, hazard statements, product identifiers and precautionary statements.

For specific substances and mixtures in the current EU system there were additional label elements. These are kept and set out in Annex II to this Regulation as well as the additional R-phrases for which no equivalent exists so far on the UN level.

To protect confidential business information it is possible, as today, to apply for a permission to use a name for the substance that does not specify the chemical identity of it. The Chemicals Agency, established under the REACH Regulation, will be responsible for taking decisions on those applications.

To make the system workable, specific exemptions from some of the labelling provisions are set out in the Annex I.

To avoid confusion, labelling should always point out that substances or mixtures are hazardous, opposite statements like “non harmful” etc. shall not be allowed if they are inconsistent with the classification.

Further additional information on labels shall only be allowed if it does not distort the information in accordance with the requirements implementing the GHS.

As the surface of labels is limited, if substances or mixtures have many hazardous properties, rules are needed to avoid duplication or, finally, superfluous information on the label. It should be ensured that those hazards that will determine the consequences for the use of the substance or mixture determine also the information on the label.

Whenever new information becomes available that leads to changes in the classification, labels will have to be updated.

1.4.2 The application of labels

To ensure that customers can easily take notice of the hazard information on packages, general rules are set out to determine the colours, and size of labels, formats, legibility and location of label elements.

Rules are also needed to determine which labels are needed in case of inner and outer packages.

1.5. Packaging

To ensure the protection of human health and the environment, some general rules determine the safety of containers and other packages.

1.6. Harmonisation of classification

The provisions of the Classification and Labelling Inventory of the REACH Regulation, Title XI, have been moved to this Regulation and the technical changes needed to adapt to this Regulation were made without altering the meaning of the Political Agreement on REACH.

Enterprises shall be primarily responsible not only for classifying but also for working towards agreeing on classifications. The instrument to be used is the classification and labelling inventory. This ensures that classifications (and consequent labelling) of all dangerous substances manufactured in, or imported into, the EU are available to all supplier of substances and mixtures. Suppliers are required to notify their classifications to the Agency for it to include all classifications on the inventory. This will be done in a registration under the REACH-Regulation or in a separate notification. Any divergences between classifications of the same substance will become transparent and should be removed over time primarily through co-operation between notifiers and registrants.

EU harmonised classifications in an Annex to this Regulation should be limited as a consequence of the above. Generally only the following properties should be harmonised in this way: Substances that are category 1A, 1B or 2 carcinogens, mutagens or toxic to the reproductive system; or respiratory sensitisers. Resources of the authorities should only be spent to harmonise other properties in justified cases.

1.7. Competent authorities

These provisions require that there are authorities in each of the Member States for the application and enforcement of this Regulation, including one body that is responsible to receive all information related to health effects to strengthen the protection of human health. Member States will also have to adopt measures to ensure adequate sanctions.

1.8. Common and final provisions

No advertisements shall be made for substances and mixtures in the scope of this Regulation without the mention of any hazards identified. Information used for the application of this Regulation shall be kept and made available to authorities on request.

To ensure coherence in the application of Community Chemicals Legislation, the Committee established under the REACH Regulation shall also assist the Commission in the adaptations to technical progress of the Annexes to this Regulation.

The transitional provisions ensure that the Regulation enters into force in both a practical and an effective way. As for the classification of mixtures, results of the classifications of substances are needed, the re-classification according to the new criteria shall first be required for substances, and only thereafter also for mixtures. In the transitional period, a system with two sets of criteria is unavoidable. By allowing industry maximum flexibility, giving enterprises the choice which of the two systems to apply in that period, maximum encouragement shall be given to reclassify as quickly as possible the substances and mixtures that have already been on the market. Further help for the re-classification of substances is given by a "table of equivalence" in the Annex.

1.9. Technical Annexes

This Regulation consists of a number of technical Annexes which set out in detail the criteria for the classification into all hazard classes and categories, the label elements, a list of hazard and precautionary statements, an overview about the pictograms to be used, the list of substances with harmonised classifications for certain hazard classes or parts thereof, and a table of equivalence to facilitate the reclassification of substances.

2. CONTENT OF THE REGULATION

2.1. General Issues

Article 1 – Subject matter and scope

Radioactive substances are excluded from the scope of this Regulation because they are addressed by other legislation. For reasons of clarity, substances and mixtures which are subject to customs supervision are also excluded, provided that they do not undergo any treatment or processing and that they are in temporary storage, or in a free zone or free warehouse with a view to re-exportation or in transit, as such substances or mixtures are not supplied in the EU. Non-isolated intermediates are not supplied, either. Substances and mixtures for scientific research and development not placed on the market can also be excluded from the scope under controlled conditions minimising exposure.

Article 2 - Definitions

The essential terms in this Regulation are defined. For reasons of convenience, some of the definitions of the REACH-Regulation are repeated here. To globally harmonise legislation, the term "preparation" is now replaced by "mixture".

Article 3 – Hazardous substances and mixtures and specification of hazard classes

The hazard classes as agreed upon in the GHS are listed in this Article. If a substance or a mixture fulfils the criteria for any hazard class set out in this article, it is considered to be hazardous. Hazard categories and detailed criteria are specified in Annex I.

The Commission is empowered to update the information for the different hazard classes in Annex I and to include new hazard classes that will be agreed on the UN level. Necessary adaptation should follow the biennium working rhythm at the UN level.

Article 4 – General obligations to classify, label and package

Before a substance or mixture is placed on the market, the supplier has to identify and describe the hazards of that substance or mixture. The classification and labelling consists of a three step approach: the identification of relevant information, the evaluation of this information and the comparison of that information with the criteria set out in this Regulation. However, where harmonised classifications for a hazard class or parts of it for a substance are included in this Regulation, the supplier has to classify the substance in accordance with that entry, and must not deviate from it on the basis of his available information.

Distributors have to ensure that they pass on the information with labels as they receive them or they need to apply the rules of this Regulation themselves.

Article 5 – General rules for the hazard identification of substances and mixtures

The procedure for the identification of the relevant information for the purposes of hazard classification is described. Paragraph 2 states the general rule that no new testing has to be generated for the purpose of classification only. This means that available information from public sources as well as information generated under other pieces of Community legislation like REACH, the transport, biocides or plant protection product legislation, may be used.

If the supplier decides to generate new information, certain conditions for the quality of such information have to be fulfilled. This is to ensure that the classifications are based on sound data. International standards are accepted as well as data that fulfil the requirements under REACH or under the transport, biocides and plant protection products legislation. Testing on animals shall be avoided wherever possible and alternative test methods always have to be considered first. Animal tests will of course have to comply with the Directive on animal testing[18]. Testing on humans should not be performed, only available experience on effects on humans may be used.

Article 6 – Information basis for the hazard identification of mixtures

For mixtures, generally available test data on the mixtures themselves should be used, except for mixtures with substances e.g. with CMR properties. For the latter, the classification of the mixtures shall normally be based on the information on those substances.

If no test data are available on the mixtures themselves, the Regulation specifies in its Annex I a number of "bridging principles" which enable the suppliers to derive a sound classification of the mixtures. If the available information is not sufficient for the application of those general principles, for health and environmental classes, it will be specified in the individual chapters what needs to be done for estimating the hazards based on the information known[19].

Article 7 – General rules for evaluation of hazard information and classification of substances and mixtures

The identified relevant information needs to be evaluated for the purpose of classification which consists of a comparison of the criteria in Annex I with the identified information. In some cases, the criteria are easy to apply, and the result will be a "yes" or "no" decision. In

[18] Directive 86/609/EEC, OJ L

[19] GHS 1.3.2.3 (c)

other cases, it will be more difficult to derive the classification. In these cases a weight of evidence determination using expert judgment may be necessary.

Paragraph 4 allows a refinement of the classification, if the classification differs for different forms or physical states. In these cases, the form or physical state in which the substance or mixture is used or is supplied for shall be decisive, for example, phenol shall be classified for its more hazardous properties in the melted form if it will be used in that form.

Article 8 – Classification of substances included in the REACH database

Classifications for substances in the classification and labelling inventory by more than one supplier shall be seen as harmonised classifications. They shall be followed, unless the supplier has sufficient evidence to justify a different classification.

[relationship to transport/international conventions]

Article 9 – Specific rules for the classification of mixtures

The classification of mixtures shall take account of all available information about potential occurrence of synergistic among the ingredients of the mixtures. The classification may be lowered on the basis of antagonistic effects if the supplier has sufficient data.

Article 10 – Concentration limits for the evaluation and classification of substances containing impurities, additives or individual constituents of mixtures

As today and to ensure that the system is workable and proportionate, concentration limits are set out both for the classification of substances with regard to impurities, additives or individual constituents and for the classifications of mixtures with regard to the individual components of the mixtures. Suppliers may define other concentration limits in accordance with criteria and accepted guidance in justified cases, unless specific concentration limits are included in Annex VI together with harmonised classifications for that substance.

Article 11 – Review of classification in case of change of composition of a mixture

A new hazard evaluation is required when the composition of a mixture is changed to an extent that is outside specified limits, unless it is evident that the change of the composition has no effect on the classification of the mixture.

HAZARD COMMUNICATION IN FORM OF LABELLING

Content of the label

Article 12 – General rules

The label elements following from the GHS are hazard pictograms, signal word(s), hazard statements, product identifiers, the name, address and telephone number of the supplier, and precautionary statements. Furthermore, as today, the nominal quantity of a substance or mixture in the packages as placed on the market to the general public has to be indicated, unless this quantity is specified elsewhere on the package.

Article 13 – Exemptions and derogations from the general rules for labelling

To protect confidential business information, it is possible, as today, to apply for a permission to use a name for the substance that does not specify the chemical identity of it. This could also be used in a manner that simplifies the name of a substance or mixture for communication purposes. The Chemicals Agency, established under the REACH Regulation, will be responsible for taking decisions on those applications.

To make the system workable, exemptions from some of the labelling provisions are set out in the Annex for specific substances and mixtures.

Article 14 – Supplemental information on the label

To maintain the level of protection as set out under the current EU law, requirements for supplementary information on the label about hazards that have not yet been included in the GHS are kept.

Suppliers are allowed to include additional information on the label only if this does not interfere with the labelling information following from the application of Article 12, and thereby from the GHS.

Substances and mixtures shall not be labelled as "non-toxic", "non-harmful", "non-polluting", or "ecological" as the labelling provisions aim at indicating hazardous properties only, and not the opposite.

Article 15– Precedence rules for labelling of substances and mixtures classified for multiple hazard classes and according to different legislation

Precedence rules for physical hazards shall follow the UN transport provisions, and Annex I specifies the rules for other hazards.

Article 16 – Updating information on labels

The supplier of a substance or a mixture shall update the label without delay after receipt of any new scientific or technical information which results in a change to the classification and labelling of the substance or mixture, unless the labels are part of an approval decision. In the latter case, that decision will have to be changed first. This applies in the cases of biocides, Directive 98/8/EC, or plant protection products, Directive 91/414/EEC[20].

Application of labels

Article 17 – General rules for the application of labels

To ensure that customers are aware of the hazard information on packages, general rules are set out to determine the colours, and size of labels, formats, and legibility of label elements.

[20] OJ L 230, 19.08.1991, p. 1

Article 18 – Location of information on the label

To enable those who use substances and mixtures to develop a routine for finding the essential information on hazards while at the same time allowing for sufficient flexibility, there are rules on the location of information on labels. Whereas the label elements hazard pictogram(s), signal word and hazard statement(s) shall be located together on the label, the supplier may generally choose the order of the hazard and precautionary statements on the label.

Article 19 – Labelling of outer packages, inner packages and single packages according to transport rules and this Regulation

To reduce the burden on enterprises and to avoid the duplication of transport labels, rules are set out to determine which labels are needed in case of inner and outer packages.

PACKAGING

Article 20 – Packaging

Safety measures for containers and other packages are set out in this Article.

HARMONISATION OF CLASSIFICATION

The provisions of the classification and labelling inventory of the REACH Regulation, Title XI, have been moved to this Regulation. Changes are made to adapt to this Regulation, but these changes do not change the content of the Political Agreement of the Council on REACH.

Classification and Labelling Inventory

Article 21 – Harmonised classification and labelling of substances for specific hazard classes or categories

This Article specifies the hazard classes and parts of them for which harmonised classifications shall be included in Annex VI to this Regulation and allows for the harmonisation of other hazard classes if there is a need for Community wide action.

Furthermore, it sets out that specific concentration limits may be set if a substance is included in the Annex.

Article 22 – Procedure to include a substance into Annex VI

This Article sets out the procedure that needs to be followed for the harmonisation of the classification of a substance in Annex VI. It ensures that sufficient expert opinion is sought, and that stakeholders get an opportunity to comment to ensure transparency of the process.

Article 23 – Content of opinions and decisions for harmonised classification and labelling in Annex VI

To ensure legal certainty the content of decisions to be included in Annex VI in case of harmonised classifications is set out in this Article.

Article 24 – Obligation to notify the Agency

This Article specifies the information that must be provided by all those who place substances on the market to the Agency for it to include it in the inventory. As classification and labelling data are part of the information requirements for registration under the REACH Regulation, there is no need to notify the information, if a registration has been submitted.

The added efforts to notify the agency of a hazardous substance that is placed on the market is small compared to the efforts of collecting available data, assigning a classification, packaging, labelling and preparing the safety data sheets. They are already part of the REACH requirements.

Subsequently, if further information comes to light, as a result of the REACH system or otherwise, the entry shall be updated. It is anticipated that for some substances the classifications notified or registered will vary. Over time it is expected that notifiers and registrants will work together to agree an entry.

Article 25 – Industry agreement on entries

This Article specifies that where the entries in the inventory differ, enterprises shall make every effort to come to an agreed entry to ensure a uniform classification. This provision reflects the principle of industry self-responsibility and enables authorities to concentrate resources on looking at the classification of those substances with properties of very high concern. The Article further specifies what information has to be reported to the Agency for any agreement reached.

Article 26 – The classification and labelling inventory

This Article details the information that will be included in the inventory. This inventory will be widely available as a source of information on substances and also act as an encouragement to industry to agree on their classification and labelling proposals when entries for the same substance differ.

COMPETENT AUTHORITIES

Article 27 – Appointment of authorities and bodies

For the application and enforcement of this Regulation Member States will need to appoint a competent authority or competent authorities. It is also essential that Member States ensure a good cooperation and coordination between all competent authorities that are responsible for legislation related to chemicals.

Article 28 – Appointment of bodies responsible for receiving information on human health

To bundle information on human health, as under the current legislation, there should be one body in each Member State that is responsible for receiving information on human health.

Article 29 – Enforcement and reporting

This Article requires Member States to take all necessary measures, including maintaining a system of official controls, to ensure that this Regulation is applied correctly, and to report the

results of the official controls, and other enforcement measures taken to the Agency that will use this information to provide input the Commission for its public report under the REACH Regulation.

To enhance the exchange of practical experience, the Forum established as part of the Agency under the REACH Regulation to exchange information between enforcement authorities shall also exchange information about the enforcement of this Regulation.

Article 30 – Sanctions for non-compliance with this Regulation

This Article requires Member States to establish sanctions for non-compliance with this Regulation. The sanctions imposed must be proportionate to the extent and impact of the non-compliance.

COMMON AND FINAL PROVISIONS

Article 31 – Advertisement

To avoid that customers are mislead, advertisements for substances and mixtures shall only be allowed if mention is made therein of the classification for any hazard class and/or category.

Article 32 – Obligation to keep information and requests for it

To be able to retrace, reconstruct and reproduce decisions taken in the application of this Regulation, suppliers of substances and mixtures shall keep the information on which they apply this Regulation together with any information they are required to keep under the REACH Regulation. Authorities may request this information.

Article 33 – Free Movement Clause

This Article is the explicit complement to the various requirements in the Regulation and guarantees the free movement of substances and mixtures, as such or in articles, that comply with the provisions of the Regulation. It is an essential provision in each Regulation that aims at harmonising the internal market.

Article 34 – Safeguard clause

This Article enables Member State to address risks to human health and the environment due to reasons of classification, labelling or packaging, by appropriate provisional measures. Such measures have to be distinguished from any further changes of this Regulation.

Article 35 – Amendments to the annexes

This Article enables the Commission to revise Annexes I to VII to the Regulation through a Committee procedure and to adapt them to technical progress, as these relate to scientific and technical matters and do not touch the fundamental rules established in the body of the Regulation.

Article 36 – Committee procedure

The Committee established under the REACH Regulation shall also assist the Commission to take decisions under this Regulation on the adaptation of the Annexes to technical progress. The committee procedure proposed in the articles of the regulation depends on the measure to be taken, which are measures of general application. Therefore the regulatory procedure has to be applied for as the adaptation to technical progress of the annexes to this Regulation.

Article 37 – Repeal

This Articles establishes that Directives 67/548/EEC and 1999/45/EC are to be replaced by this Regulation at the end of the last transitional period set out in Article 38.

Article 38 – Amendment of Community legislation

This Article sets out the general rules that references to the repealed Directives are to be replaced by reference to this Regulation and, more specifically, the consequences of this Regulation for cases in which these references are made to specific hazard classes.

It specifies furthermore which hazard classes or categories shall trigger obligations under the REACH Regulation.

There is a need to amend Article 31 (3) in the REACH regulation, the change is based on the agreements in GHS. This is a deviation from the agreement obtained in REACH based on the current legislative requirements under the Preparations Directive, as currently there is only an obligation to report in the SDS substances classified as toxic to reproduction, carcinogenic category 2[21] present in concentrations equal to or above 1 percent.

Article 39 – Entry into force and application

This Regulation enters into force on the twentieth day following its publication in the official journal. This is common practice in EU legislation.

This Article establishes furthermore when the obligations under this Regulation apply for the supply of substances. Not all duties apply when the Regulation first enters into force. As the classification of mixtures depend on the classification of substances, the new criteria will have to be applied first for substances, before they have to be applied for mixtures.

The deadline for mixtures is chosen to strike the balance between avoiding too much confusion on the market from the use of a dual system during the transitional period and the need to allow enterprises sufficient time to learn the new criteria and to manage the workload that will arise from having to reclassify the substances and mixtures that have already been on the market in addition to those that are newly supplied.

For the transitional period, maximum flexibility is given to enterprises; they are free to use either of the two systems. This is to encourage enterprises to make the most efficient use of their resources to align their practice to the new system.

[21] Category 2 in the meaning of Directive 67/548/EEC

For some hazard classes and hazard categories, for substances that have already been on the market, during the transitional period the table of equivalence in Annex VII may serve as a first orientation for the results that might follow from the application of the new criteria. In most cases, verification by identifying and evaluating the available information and comparing it with the criteria set out in the Annex, is advisable or necessary. This is indicated in the table in Annex VII.

3. ANNEXES

Annex I – Classification and labelling requirements for hazardous 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 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 will contain guidance for the application of Precautionary Statements, which will be included as soon as the ongoing work at the UN level has reached a stable stage, probably July 2006. However an amendment might be needed to adapt to the final UN decision envisaged for December 2006.

Annex II – Special rules for labelling and packaging of certain substances and mixtures

This Annex contains 5 Parts. In Part 1 it includes the extra labelling provisions from Annex VI (sections 2.2.6 and 3.2.8) to Directive 67/548/EEC which are not yet covered by the GHS; Part 2 includes the special rules for the labelling of certain substances or mixtures mainly from Annex V to Directive 1999/45/EC.

Part 3 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.

Finally, Part 4 sets out some general rules for the workplace, and Part 5 sets out the rules on consumer information.

Annex III – List of hazard statements

The Annex III is a list of hazard statements. It is intended to include a multilingual version of the hazard statements similar to that ones we have in the Annex III of Directive 67/548/EEC. The core of this is drawn from those statements set out in the GHS text.

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

A codification system for GHS Hazard Statements is under discussion in the UN Committee of Experts and will be included as soon as the discussion is more advanced.

Annex IV – List of precautionary statements

The Annex IV will include a list of precautionary statements. It is intended to include a multilingual version of the hazard statements similar to that ones we have in the Annex IV of Directive 67/548/EEC. The precautionary statements and a codification system can only be included at the stage when the going work at the UN level has reached a stable stage, probably October 2006. However an amendment might be needed to adapt to the final UN decision envisaged for December 2006.

Annex V – Pictograms

This Annex reproduces the standard pictograms and signal words from the GHS document. The principle of pictograms and signal words reflects the approach used in the current EU system with pictograms and indications of danger.

Annex VI – Harmonised classification

The Annex contains a list of Community harmonised classification of substances for a specific hazard class or parts of a hazard class. As resources of the authorities should be focused on substances of the highest concern, mainly substances will be added to this Annex if it is classified for carcinogenicity, mutagenicity or reproductive toxicity categories 1A or 1B, and for respiratory sensitisation, or in respect of other effects on a case-by case basis where this is justified. In addition, the allocated hazard statements should also be listed.

As a start this Annex will include the substances which are in the current Annex I of Directive 67/548/EEC and which are classified for carcinogenicity, mutagenicity or reproductive toxicity categories 1A or 1B, and for respiratory sensitisation and other classes and categories where the criteria are equivalent. This ab initio translation is justified as the criteria for these hazard classes or parts of hazard classes are equivalent in both systems the GHS and the current EU system.

Annex VII – Conversion table

This Annex will include conversion tables to be used for the self-classification by suppliers of substances and mixtures already evaluated under the current criteria for those hazard categories where a simple equivalence is possible.

These conversion tables 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 use the tables for any reason, he must then re-evaluate the substance or mixture using the GHS criteria.

Annex VIII – Reference table and adaptation of references to GHS criteria according to Article 37 (2) (b)

This Annex includes in Part 1 a table with references to specific categories of danger and risk phrases according to Directive 67/548/EEC which should be read as references to specific hazard classes, parts of hazard classes and hazard categories in this Regulation. In Part 2 of

this Annex appropriate adaptations of the references for specified Directives and Regulations are proposed.

200x/0xxx(COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Classification and Labelling of Substances and Mixtures based on the Globally Harmonised System

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[22],

Having regard to the opinion of the European Economic and Social Committee[23],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[24],

Whereas:

(1) The trade with chemical substances and mixtures is not only an issue of the internal market but of the global market. Enterprises would therefore benefit from harmonised rules on the global market for the classification and labelling of substances and mixtures as hazardous and from consistency with the rules for classification and labelling for supply and use with those for transport; harmonised criteria for classification and labelling have been carefully developed over 12 years on the international level, within the United Nation (UN) structure, with a view to facilitate a world wide trade while protecting human health and the environment.

(2) This Regulation puts into action various statements by the EC to contribute to this global harmonisation of criteria for classification and labelling for substances and mixtures, not only on the UN level but also by implementing the internationally agreed criteria into Community law. Such announcements include, for example, the explanatory memorandum to the Commission's proposal to amend Directive 67/548/EEC from 29.10.2003 to enter into force at the same time as Regulation (EC) No …/2006 {REACH} concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals … and amending Directive 1999/45.

(3) Within the Community, this Regulation contributes to the health and well-being of workers and consumers, and to the protection of the environment as well as to the competitiveness of the chemical industry.

---

22 OJ C

23 OJ C

24 OJ C

(4) The benefits for enterprises will increase the more countries in the world adopt the globally harmonised criteria in their legislation; the EU should be involved in the start of this process to encourage other countries to follow.

(5) Therefore it is essential to harmonise, now based on the GHS, the provisions for the classification and labelling of substances and mixtures on the internal market within the European Community.

(6) Workers and consumers worldwide would benefit from a globally harmonised hazard communication tools in the form of labelling and safety data sheets. In particular it would increase the understanding of these hazard communication tools.

(7) While this Regulation should replace Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[25], and Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the law, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[26], it should maintain the overall current level of protection of human health and the environment provided by those Directives and should not unnecessarily increase the associated burden on enterprises. Therefore, some hazard classes which have been part of the EU legislation prior to this Regulation and are not yet included in the GHS should be included in this Regulation.

(8) The objective of this Regulation is to determine which properties of substances and mixtures should lead to a classification as hazardous, in order for suppliers of substances and mixtures to identify and communicate those properties of their substances and mixtures. These properties should include physical hazards as well as hazards to human health and to the environment.

(9) Substances and mixtures classified as hazardous should be packaged and labelled according to the classification to give relevant protection and to provide the essential information to their customers and draw their attention to the hazards of the substance or mixture.

(10) The two components of the hazard communication system are labels and safety data sheets; the label is the only tool for communication to consumers. The label may also serve to draw attention of a worker to the more comprehensive information on substances or mixtures provided to downstream users and distributors in safety data sheets; as the provisions on safety data sheets (SDS) are included in the REACH-Regulation where the SDS serve as a main communication tool within the supply chain of substances, it is appropriate not to integrate those provisions in this Regulation but only to stress here the connection between these two Regulations.

(11) Responsibility for the identification of hazards of substances and mixtures should mainly lie with the suppliers of substances or mixtures; however, classifications of

---

[25] OJ 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

[26] OJ L 200, 30.7.1999, p. 1. Directive as amended by Commission Directive 2001/60/EC (OJ L 226, 22.8.2001, p. 5).

substances of high concern as justified by authorities should be harmonised for specified hazard classes or parts of a hazard class which should be legally binding and applied by all suppliers of such substances and of mixtures containing such substances.

(12) This Regulation should generally apply to all substances and mixtures supplied in the EU; except where there are more specific rules for the same purpose.

(13) The definitions of terms in this Regulation should be consistent with those set out in the REACH-Regulation and with those definitions agreed on the UN level in the GHS, to ensure maximum consistency for the application of chemicals legislation in the European Community and for global trade; to facilitate the application of this Regulation, some of the terms defined in REACH should be included in this Regulation as well.

(14) The hazard classes already agreed on the UN level should be set out in this Regulation to provide a stable framework, while there should be means for the Commission to follow adaptations to technical progress on that level by amending the technical Annexes to this Regulation in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[27]; adaptations to technical progress should follow the biennium working rhythm at the UN level.

(15) While the supplier of any substance or mixture should not be obliged to generate new information for the purpose of this Regulation, he should identify all relevant information available to him on the hazards of his substance or mixture and evaluate its quality for the purpose of classification; he should furthermore compare that information with the criteria set out in this Regulation to arrive at a conclusion whether or not the substance or mixture should be classified as hazardous.

(16) In cases where a decision on the classification of a substance for a specific hazard class or parts of a hazard class, has been included in Annex VI to this Regulation, the supplier should apply this harmonised classification, and only self-classify for the remaining, non-harmonised hazard classes or parts of them.

(17) To ensure that customers receive information on the hazards, manufacturers, importers and downstream users should package and label substances and mixtures according to the classification derived, and distributors should ensure that they transfer the information received by either leaving the labelling unchanged or by labelling themselves in accordance with this Regulation.

(18) To ensure information on hazardous substances included in mixtures, mixtures should be labelled, where appropriate, also when they contain at least one substances that is classified as hazardous, even if the mixtures are not classified as hazardous themselves.

(19) While the classification of any substance or mixture may be carried out based on available information, to ensure quality and comparability of the results and

[27] OJ L 184, 17.7.1999, p. 23.

consistency with other provisions set out at international or Community level, information to be used for the purposes of this Regulation should comply with relevant parts of the REACH-Regulation, transport provisions or international principles or procedures for the validation of information; the same should apply where the supplier chooses to generate information for the purposes of this Regulation.

(20) To protect vertebrate animals, where the supplier chooses to generate information for the purposes of this Regulation, he should consider other means than testing on vertebrate animals first.

(21) To facilitate the hazard identification of mixtures, suppliers should base this identification on the data for the mixtures itself, where available, except for mixtures with e.g. carcinogenic, mutagenic, reproductive toxic substances or sensitisers, where normally the data of the individual substances of the mixture should be used as a basis for the hazard identification of the mixture to arrive at adequate results.

(22) Where no test data are available for the mixture itself, suppliers should follow a hierarchy of principles set out in this Regulation to ensure adequate comparability of results of the classification of such mixtures.

(23) For the purpose of classification, data on humans should not be generated; available, reliable epidemiological data and experience on the effects of chemicals on humans should be taken into account and generally be given priority over data derived from animal studies; results of animal studies should be weighed against results of data from humans and expert judgement should be used to ensure the best protection of human health when evaluating both the animal and human data.

(24) Recognising that the comparison of information with the criteria for the different hazard classes set out in this Regulation is not always straightforward and simple, suppliers should apply weight of evidence determinations involving expert judgment to arrive at adequate results.

(25) Different suppliers, should make every effort to agree on a single classification for the same substance if not in Annex VI.

(26) To avoid confusion, contradictions between classifications for hazard classes that are relevant for both supply and use and for transport should be avoided.

(27) To ensure adequate classification of mixtures, available information on synergistic effects should be taken into account for the classification of mixtures. To allow correct classification of mixtures, while avoiding risks of under-classification, antagonistic effects may be taken into account only where there is clear evidence.

(28) For reasons of proportionality and workability, general concentration limits are defined, both for impurities, additives and individual constituents of substances and for substances in mixtures.

(29) Specific concentration limits which deviate from the general concentration limits should be assigned to a substance by a supplier in accordance with the criteria referred to in this Regulation or Community wide accepted guidance provided he is able to justify it and inform the Agency accordingly; however to ensure uniformity, specific

concentration limits should be included, where appropriate, in cases of agreed or harmonised classifications, both in the inventory and in Annex VI, and such limits should then take precedence over any other concentration limit.

(30) To harmonise the hazard communication, the label elements should be specified in this Regulation, and pictograms, signal words, hazard statements and precautionary statements which should form the core information of the GHS system; additional information should be limited to a minimum and should not call into question the specified label elements.

(31) It is essential that the product placed on the market is well identified, however, the Chemicals Agency should allow enterprises, where necessary, to describe the chemical identity in a way that does not put at risk the confidential nature of their businesses or in a manner that simplifies the name of the substance or mixture for communication purposes.

(32) To limit the information on the label to the most essential information, there should be precedence rules for label elements for cases in which substances or mixtures possess several hazardous properties.

(33) To ensure up to date information, suppliers should re-evaluate their classifications if they change the composition of their mixtures, unless there is sufficient evidence that the classification would not change; suppliers should also update the labels accordingly.

(34) To facilitate the understanding of the information on labels, there should also be rules for the application of labels and the location of information on labels.

(35) To ensure the safe supply of hazardous substances and mixtures, this Regulation should also fix general packaging standards.

(36) Resources of the authorities should be focused on substances of the highest concern. A substance should therefore be added to Annex VI of this Regulation if it is classified for carcinogenicity, mutagenicity or reproductive toxicity categories 1A or 1B, for respiratory sensitisation, or in respect of other effects on a case-by-case basis where this is justified; specific concentration limits might be set if a substance is included in the Annex;

(37) To include a substance into the Annex VI competent authorities or a supplier should be prepared to submit a dossier that should be discussed by the Agency's risk assessment committee to prepare any Commission decision in accordance with Council Decision 468/1999/EC;

(38) The content of decisions to be included in Annex VI in case of harmonised classification should be described;

(39) For purposes of enforcement and evaluation and for reasons of transparency, suppliers of substances should submit information on the classification of their substances to the Agency to be included it in a public inventory, unless they have already done so in their registration dossiers according to the REACH Regulation;

(40) As the main responsibility for the classification and labelling lies with industry, industry should strive to harmonise entries between suppliers if they differ; if the classification differs for the same substance between suppliers, to that end the inventory should also record any divergences between suppliers on the classification of the same substance, and the suppliers should make every effort to come to an agreed entry to be included in the inventory.

(41) To ensure availability of hazard information to the general public, and, in particular, for persons who come into contact with certain substances at work, a publicly accessible inventory should record the classification in accordance with this Regulation, as well as decisions taken at Community level to harmonise the classification and labelling of some substances;

(42) If the interpretation or application of the classification criteria, or the classification of same substances differ between supply and transport for the same hazard classes or categories at the international level [United Nations], the Commission should take all reasonable steps for an agreement to be reached to harmonise the criteria or their application, unless the difference is justified by reasons of supply or transport.

(43) Member States should appoint the competent authority or competent authorities responsible for proposals for harmonised classification and labelling and for the enforcement of the obligations set out in this Regulation and in order to ensure compliance with this Regulation, Member States should put in place effective monitoring and control measures.

(44) In order for the system established by this Regulation to operate effectively, it is important that there should be good co-operation and co-ordination between the Member States, the Agency and the Commission.

(45) To establish focal points for information on hazardous substances and mixtures, Member States should appoint bodies responsible for receiving information on human health in addition to the competent authorities for the application and enforcement of this Regulation.

(46) The Forum for the exchange of information on enforcement in the Chemicals Agency as established under the REACH Regulation should also exchange information about the enforcement of this Regulation.

(47) In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary for Member States to set up an appropriate framework for sanctions with a view to imposing effective, proportionate and dissuasive sanctions for non-compliance, as non-compliance can result in damage to human health and the environment.

(48) Regular reports by the Member States and the Agency on the operation of this Regulation will be an indispensable means of monitoring the implementation of chemicals legislation as well as trends in this field; conclusions drawn from findings in the reports will be useful and practical tools for reviewing the Regulation and, where necessary, for formulating proposals for amendments.

(49) To protect customers, including consumers, any advertisement for a substance or a mixture meeting the criteria for classification according to this Regulation should be prohibited if no mention is made therein of the concerned hazards.

(50) To follow the progress made at the international level, the measures necessary for the adaptation to technical progress by amending the Annexes to this Regulation should be conferred to the Commission supported by the Committee established by the REACH-Regulation, and those amendments should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[28].

(51) To ensure a consistent approach to the updating of chemicals legislation, the Committee established by Regulation (EC) No …/2006 {REACH} concerning … and amending Directive 1999/45 to assist the Commission for the purpose of that Regulation, should also assist the Commission for the purposes of this Regulation.

(52) Other pieces of community legislation base their rules on the results from the application of this regulation and may consider exposure to determine appropriate risk management measures and conditions of use. Such provisions may be needed to be reviewed with a view to assessing whether the change of the classification criteria would lead to consequential changes therein.

(53) While many of the obligations on enterprises established by the REACH Regulation are triggered by classification, this Regulation should not alter the scope and impact of the REACH Regulation.

(54) It is appropriate for the provisions of this Regulation to enter into force in a phased manner to smoothen the transition to the new system; moreover, a gradual entry into force of the provisions should allow all parties involved, authorities, enterprises as well as stakeholders, to focus resources in the preparation for new duties at the right times; therefore the provisions for the classification of mixtures should only have to applied after the reclassification of all substances.

(55) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of this Regulation to contribute to the global harmonisation of the classification and labelling of substances and mixtures to lay down very specific technical rules to be applied for that purpose. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty.

(56) Since the objective of the action to be taken to contribute to the global harmonisation of the classification and labelling of substances and mixtures cannot be sufficiently achieved by individual Member States as […], and can therefore, by reason that the technical criteria have to be exactly the same in all Member States, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of proportionality, as set out in that Article, this Regulation on the Classification and Labelling of substances and mixtures based on the globally

---

[28] OJ L 184, 17.7.1999, p. 23.

harmonised system does not go beyond what is necessary in order to achieve those objectives.

(57) The Regulation observes the fundamental rights and principles which are acknowledged in particular in the Charter of Fundamental Rights of the European Union[29].

HAVE ADOPTED THIS REGULATION:

TITLE I
GENERAL ISSUES

Article 1
Subject matter and Scope

1. This Regulation shall apply to substances and mixtures. It lays down provisions on the classification of substances and mixtures for their hazards within the meaning of this Regulation and on the labelling and packaging of hazardous substances and mixtures. It also lays down provisions on the classification for physical hazards of certain substances and mixtures in articles as laid down in Annex I Part 2 and on the labelling and packaging of these.

2. This Regulation shall not apply to:

   (a) radioactive substances and mixtures within the scope of Council Directive 96/29/Euratom;

   (b) the carriage of substances and mixtures by rail, road, inland waterway, sea or air[30];

   (c) substances and mixtures which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;

   (d) non-isolated intermediates;

   (e) substances and mixtures for scientific research and development, which are not placed on the market, provided they are used under such controlled conditions minimising exposure as if they were classified as carcinogenic, mutagenic or toxic to reproduction (CMR category 1A or 1B) according to Annex I.

3. Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council is not a substance, mixture or article within the meaning of Article 2 of this Regulation[31].

---

29 OJ C 364, 18.12.2000, p. 1.
30 Aligned with REACH, version 27.06.2006
31 Aligned with REACH, version 27.06.2006

4. This Regulation shall not apply to the following substances and mixtures in the finished state, intended for the final user[32]:

   (a) Medicinal products for human or veterinary use, within the scope of Regulation (EC) No 726/2004 and Directive 2001/82/EC[33] and as defined in Directive 2001/83/EC[34];

   (b) Cosmetic products as defined in the scope of Directive 76/768/EEC;

   (c) Medical devices within the scope of Directives 90/385/EEC, 93/42/EEC or 98/79/EC[35];

   (d) food or feeding stuffs according to Regulation (EC) No 178/2002 of the European Parliament and of the Council including use:

      (i) as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC[36];

      (ii) as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC and Commission Decision 1999/217/EC[37];

      (iii) as an additive in feeding stuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council;

      (iv) in animal nutrition within the scope of Council Directive 82/471/EEC.

Article 2
Definitions

For the purpose of this Regulation:

1. *GHS* means the "Globally Harmonised System of Classification and Labelling of Chemicals";

2. *Hazard class* means the nature of the physical, health or environmental hazard;

3. *Hazard categories* means the division of criteria within each hazard class;

4. *Pictogram* means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information;

5. *Signal* word means a word that indicates the relative level of severity of hazards to alert the potential reader of the hazard; the following two levels are distinguished:

---

32 Aligned with REACH, version 27.06.2006
33 OJ L 311, 28.11.2001, p. 1.
34 OJ L 311, 28.11.2001, p. 67.
35 Not aligned with REACH, version 27.06.2006
36 OJ L 40, 11.2.1989, p. 27.
37 OJ L 84, 27.3.1999, p. 1.

(a) *Danger* means a signal word indicating the more severe hazard categories;

(b) *Warning* means a signal word indicating the less severe hazard categories.

6. *Hazard Statement* means a phrase assigned to a hazard class and category that describes the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard;

7. *Precautionary statement* means a phrase and/or pictogram that describes recommended measure(s) to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use;

8. *Competent authority* means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

9. *REACH Regulation* means the Regulation (EC) No… concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals;

10. *The Agency* means the European Chemicals Agency established under the REACH Regulation;

11. *REACH* database means the classification & labelling inventory established under Article 113 of the proposed REACH Regulation;

12. *UN RTDG* means the United Nations Recommendations on the transport of dangerous goods.

13. *Substance*[38] means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

14. *Mixture* means a mixture or solution of two or more substances which do not react;

Note: Mixture and preparation are synonymous

15. *Alloy*[39] means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means; alloys are considered to be mixtures for the purposes of this Regulation;

16. *Article*[40] means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

17. *Polymer*[41] means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a

---

38 Aligned with REACH, version 27.06.2006

39 GHS definition, aligned with REACH, version 27.06.2006.

40 Aligned with REACH, version 27.06.2006

range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;

18. *Monomer*[42] means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

19. *Registrant*[43] means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

20. *Intermediate*[44] means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis");

21. *non-isolated intermediate*[45] means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

22. *Scientific research and development*[46] means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year;

23. *Supplier*[47] of a substance or a mixture means any manufacturer, importer, downstream user or distributor placing on the market a substance or a mixture;

24. *Manufacturer*[48] means any natural or legal person established within the Community who manufactures a substance within the Community;

25. *Manufacturing*[49] means production or extraction of substances in the natural state;

---

41 Aligned with REACH, version 27.06.2006
42 Aligned with REACH, version 27.06.2006
43 Aligned with REACH, version 27.06.2006
44 Aligned with REACH, version 27.06.2006
45 Aligned with REACH, version 27.06.2006
46 Aligned with REACH, version 27.06.2006
47 Aligned with REACH, version 27.06.2006
48 Aligned with REACH, version 27.06.2006

26. Importer[50] means any natural or legal person established within the Community who is responsible for import;

27. *Import*[51] means the physical introduction into the customs territory of the Community;

28. *Downstream* user[52] means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) REACH Regulation shall be regarded as a downstream user;

29. *Use*[53] means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

30. *Distributor*[54] means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance or a mixture for third parties;

31. *Placing on the market*[55] means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

Article 3

Hazardous substances and mixtures and specification of hazard classes

1. A substance or a mixture fulfilling the criteria for any hazard class set out in this article is hazardous. The same shall apply to substances and mixtures in articles for which a hazard class is defined in paragraph 2.

2. In accordance with Annex I Part 2 for substances and mixtures the following hazard classes for physical properties are defined:

   (a) Explosives;

   (b) Flammable gases;

   (c) Flammable aerosols;

   (d) Oxidising gases;

---

49 Aligned with REACH, version 27.06.2006
50 Aligned with REACH, version 27.06.2006
51 Aligned with REACH, version 27.06.2006
52 Aligned with REACH, version 27.06.2006
53 Aligned with REACH, version 27.06.2006
54 Aligned with REACH, version 27.06.2006
55 Aligned with REACH, version 27.06.2006

(e) Gases under pressure;

(f) Flammable liquids;

(g) Flammable solids;

(h) Self-reactive substances and mixtures;

(i) Pyrophoric liquids;

(j) Pyrophoric solids;

(k) Self-heating substances and mixtures;

(l) Substances and mixtures which, in contact with water, emit flammable gases;

(m) Oxidising liquids;

(n) Oxidising solids;

(o) Organic peroxides;

(p) Substances and mixtures corrosive to metals;

(q) Other hazard classes included in Annex I Part 2 in accordance with paragraph 5.

3. In accordance with Annex I Part 3 for substances and mixtures the following hazard classes for effects to human health are defined:

(a) Acute toxicity;

(b) Skin corrosion/irritation;

(c) Serious eye damage/eye irritation;

(d) Respiratory or skin sensitisation;

(e) Germ cell mutagenicity;

(f) Carcinogenicity;

(g) Reproductive toxicity;

(h) Specific target organ systemic toxicity from single exposure;

(i) Specific target organ systemic toxicity from repeated exposure;

(j) Aspiration hazards;

(k) Other hazard classes included in Annex I Part 3 in accordance with paragraph 5.

4. In accordance with Annex I Part 4 and 5 for substances and mixtures the following hazard classes for effects to the environment are defined:

(a) Hazardous to the aquatic environment:

(i) Acute aquatic hazard;

(ii) Chronic aquatic hazard;

(b) Ozone depletion;

(c) Other hazard classes included in Annex I Part 4 in accordance with paragraph 5.

5. The Commission may include other hazard classes in Annex I for physico-chemical properties and effects to human health or the environment in accordance with the procedure referred to in Article 36.

Article 4
General obligations to classify, label and package

1. Subject to paragraph 2, a substance or a mixture shall not be placed on the market in the Community, unless its supplier has performed the following steps:

(a) the supplier has identified relevant information regarding the hazards of the substance or mixture in accordance with Articles 5 and 6; and

(b) the supplier has evaluated this information to ascertain the hazards associated with the substance or mixture; and

(c) the supplier has taken a decision on whether the hazard information on the substance or mixture meets the criteria for classification as hazardous, and, where specified, the hazard categories in accordance with Article 7, 8 and 10.

2. Paragraph 1 shall not apply to a hazard class for a substance where a decision on the classification of the substance covering the whole of that hazard class is included in Annex VI. The substance shall be classified according to the entry in Annex VI before it is placed on the market.

In cases where a decision on the classification of a substance is included in Annex VI which partially covers a hazard class, paragraph 1 shall only apply to the part of that hazard class which is not covered by the decision/ entry in Annex VI. For the part of the hazard class covered by the decision in Annex VI the substance shall be classified according to that entry.

3. A substance or a mixture classified as hazardous in accordance with this Regulation shall not be placed on the market, unless

(a) its manufacturer, importer, or downstream user has labelled and packaged the substance or mixture in accordance with this classification according to Title III and IV; or

(b) its distributor has ensured that its labelling or packaging in accordance with subparagraph (a) remains unchanged or has labelled and packaged the substance or mixture again in accordance with subparagraph (a).

4. A mixture not classified as hazardous but containing at least one substance classified as hazardous shall not be placed on the market in the Community, unless it is labelled and packaged in accordance with Titles III and IV.

TITLE II
HAZARD IDENTIFICATION, HAZARD EVALUATION AND CLASSIFICATION

Chapter 1
Identification of Information

Article 5

General rules for the hazard identification of substances and mixtures

1. For the identification of the hazards of a substance or mixture referred to in Article 4 (1) (a) the supplier shall perform the following steps:

(a) the supplier shall consider all available and relevant information concerning hazard;

(b) the supplier shall examine the available data to ascertain whether they are adequate and reliable for the purpose of hazard identification;

(c) the supplier shall take into account available evidence from humans e.g. epidemiological data, occupational data or data from accidents.

Such information can be used for the purpose of hazard identification, where they have been generated under the conditions set out in paragraph 4 and 5 or where the conditions set out in Annex XI Section 1 of the REACH Regulation are met.

2. The supplier shall not be required to carry out new testing[56] on substances and mixtures for the purpose of hazard identification and classification under this Regulation. He shall not carry out testing on humans[57] for the purpose of this Regulation.

3. Where the supplier chooses to generate information for the purpose of hazard identification and classification, he shall use, where possible, tests that do not use vertebrate animals. He shall consider generating information by means other than tests on vertebrate animals, provided the conditions set out in Annex XI of the REACH-Regulation are met[58].

---

[56] GHS 1.1.2.5 (ii)/1.3.2.4.1
[57] GHS 1.1.2.5(i)/1.3.2.4.7
[58] REACH Article 13.1

4. Where the supplier decides to carry out a new test, he shall conduct that test in accordance with one of the following test methods:

   (a) test methods in the current revised edition of the United Nations Recommendations on the Transport of Dangerous Goods [UN RTDG] Manual of Tests and Criteria ST/SG/AC.10/11[59];

   (b) the test methods referred to in Article 13 (2)[60] REACH Regulation;

   (c) for health or environmental hazards to internationally recognised scientific principles or methods validated according to international procedures[61].[62]

5. Where the supplier decides to carry out a new ecotoxicological or toxicological test and analyses, they shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable[63].

6. Where tests are carried out only for the purpose of hazard identification and classification under this Regulation, generally they shall be carried out on the substance or on the mixture as it is used or may be used after it is placed on the market[64].

Article 6
Information basis for the hazard identification of mixtures

For the hazard identification of mixtures the following shall apply:

(a) Where adequate and reliable test data are available to the supplier for the mixture itself, the supplier shall base the hazard identification and the classification on this information[65].

The classification of mixtures for certain hazard classes or parts of hazard classes shall be based on the available data for the individual substances of the mixture applying the criteria as specified in Annex I, Part 3, and test data from the mixture itself may only be used under the conditions as further specified in the same Annex [66] [67].

(b) Where no test data are available for a hazard identification and classification of the mixture itself,

---

59 of which contains details of screening procedures to determine if further testing shall be undertaken in certain hazard classes.
60 Note: reference to test method Regulation
61 GHS 1.1.2.5 (b)(i)
62 Note: Needed for PPP testing
63 REACH Article 13.3
64 DPD Article 3.1; GHS especially in phys-chem part
65 GHS 1.3.2.3 (a)
66 GHS Chapter 3.5/3.6/3.7
67 Note: different to current legislation

(i) the supplier shall apply bridging principles set out in each Chapter in Annex I to identify the hazards of the mixture; and[68]

(ii) if the available information is not sufficient to apply bridging principles, for health and environmental classes, the supplier shall apply the method(s) described in Annex I for estimating the hazards based on the information known[69].

Chapter 2
Evaluation of Hazard Information and Classification

Article 7

General rules for evaluation of hazard information and classification of substances and mixtures[70]

1. The supplier of a substance or mixture shall take the decision whether to classify the substance or mixture as hazardous as referred to in Article 4 (1) (c) after a comparison of the identified and evaluated information on physical, human health and environmental hazards with the criteria for classification in Annex I.

2. The criteria set out in Annex I are directly applicable when the test data have been obtained from test methods referred to in Article 5 (4). In other cases, the available data shall be evaluated by comparing the test methods employed with those indicated in Article 5(4) and the rules specified in Annex I for determining the classification[71].

3. Where a classification cannot be directly made on the basis of the available identified information, a weight of evidence determination using expert judgement shall be applied[72].

4. The supplier shall consider additional information, like the form and /or physical state in which the substance or mixture is used or may be used after it is placed on the market and may refine the classification accordingly; for example, phenol is classified for its more hazardous properties in the melted form[73].

5. Annex I, Part 1 contains further specific rules.

---

68 GHS 1.3.2.3(b)
69 GHS 1.3.2.3 (c)
70 Modification REACH Annex I paragraph 1 to 1.2; 2; 3 to 3.1 might be needed
71 DSD Annex VI 1.7.2
72 GHS1.3.2.4.8/GHS1.3.2.4.9.1/GHS1.3.2.4.9.2
73 Note: to cover cases like phenol

Article 8

Classification of substances included in the REACH database [and in international conventions]

1. Any substance included in the database established under Article 76 (2) (d) REACH Regulation, for which an entry in the classification and labelling inventory is recorded that is agreed between two or more notifiers or registrants of the substance shall *prima facie* be classified accordingly. A supplier may classify such a substance differently, provided he submits the reasons for his classification to the Agency together with the notification according to Article 24 of this Regulation.

2. [Placeholder: Precedence rule needed for cases where a classification is required by an International Convention e.g. Transport of Dangerous Goods and by this Regulation][74].

Article 9

Specific rules for the classification of mixtures

1. The classification of a mixture shall take account of all available information about potential occurrence of synergistic effects among the ingredients of a mixture. The classification may only be lowered to a less hazardous category on the basis of antagonistic effects, provided the supplier has sufficient adequate and reliable data[75].

2. Annex I, Part 1 contains further specific rules for the classification of mixtures.

Article 10

Concentration limits for the evaluation and classification of substances containing impurities, additives or individual constituents and for the classification of mixtures

1. The supplier of a substance shall take into account for the classification of the substance impurities, additives or individual constituents of substances that meet the criteria for classification themselves[76], if their concentration is greater than or equal to the limits specified in Annex I Part 1; unless specific concentration limits have been set in Annex VI. Instead of the limits specified in Annex I Part 1 a supplier of a substance may set a specific concentration limit that he has derived in accordance with the relevant sections of Annex I.

2. The supplier of a mixture shall take into account for the classification of the mixture, substances classified as hazardous on the basis of their health and/or environmental effects, also if they are only present as impurities or additives, when their concentrations are equal to, or greater than

   (a) specific concentration limits that have been set in Annex VI; or

---

74 Note: precedence of classifications covered by International Conventions e.g. Transport of Dangerous Goods: possibly further discussion with DG TREN needed

75 GHS 1.3.3.3; DPD Article 6.3

76 GHS 1.3.3.1.3

(b) if no specific concentration limits have been set in Annex VI, generic concentration limits/cut-off values defined in Table 1.1 in Part 1 of Annex I, unless the generic cut-off values or other concentration limits for the classified substances in the mixture have been set for specific hazard classes in the other Parts of Annex I. Annex I sets out derogations from this paragraph.

Article 11
Review of classification for substances and mixtures[77]

1. The supplier of a substance shall carry out a new evaluation of a human health or environmental hazard according to Annex I if he becomes aware of new scientific or technical information that warrants a change in the classification of the substance.

2. For a mixture of a known composition, unless covered by Directive 91/414/EEC, classified as hazardous in accordance with the criteria in Annex I, the supplier shall carry out a new evaluation of a human health or an environmental hazard according to Annex I if:

   – the supplier introduces changes of the composition of the initial concentration of one or more of the hazardous constituents in concentrations outside the limits in table 1.2 of Part 1 of Annex I; or

   – the supplier introduces changes of composition involving the substitution or addition of one or more constituents, in concentration above the limits referred to in the table 1.1 of Part 1 of Annex I.

3. A new evaluation referred to in paragraphs 1 and 2 need not be performed if there is valid scientific justification that a re-evaluation of the hazard will not result in a change of classification.

TITLE III
HAZARD COMMUNICATION IN FORM OF LABELLING

Chapter 1
Content of the Label

Article 12
General rules

1. The label referred to in Article 4 (3) for a substance or mixture classified as hazardous according to this Regulation shall include the following elements in accordance with Annex I:

[77] DPD Article 6 and 7

(a) The hazard pictograms assigned to each hazard category within each hazard class in accordance with Annex I;

(b) Signal word(s) assigned to each hazard category within each hazard class in accordance with Annex I;

(c) Hazard statements assigned to each hazard category within each hazard class in accordance with Annex I and III;

(d) Product identifiers for the substance or mixture matching those included in the safety data sheet:

(i) for a substance one of the following product identifiers[78]:

– One of the designations given in Annex VI; or

– If there is no designation in Annex VI, the identity of the substance as listed in the classification and labelling inventory in accordance with Article 26 of this Regulation; or

– If there is no identifier neither in Annex VI nor in the classification and labelling inventory both of the following:

– the CAS number, if available;

– the name in the IUPAC Nomenclature or a common name, if allowed in accordance with Article 13;

(ii) For a mixture, including an alloy, the following product identifiers:

– The trade name or the designation of the mixture and

– An indication of the identity of all substances in the mixture that contribute to the classification of the mixture as acute toxic, skin corrosive or causing serious eye damage, germ cell mutagen, carcinogenic, toxic for reproduction, skin or respiratory sensitising, or specific target organ systemic toxicity[79] (STOST). If the above requirement would lead to the provision of multiple chemical names, the supplier may choose a generic chemical name that identifies the nature of the substances concerned;

(iii) For a substance or mixture the UN proper shipping name in addition if the substance or the mixture is regulated for transport;

(e) The name, address and telephone number of the supplier;

(f) Precautionary statements, taking account of the nature of the hazard(s) and the recommended measures, in the following way:

---

78 GHS 1.4.10.5.2 (d)(i)

79 GHS 1.4.10.5.2 (d)(ii)

(i) For hazard classes or parts of hazard classes of substances included in Annex VI, the precautionary statements included in this Annex shall be used;

(ii) If a hazard class or parts of a hazard class of the substance is not included in Annex VI any appropriate precautionary statement included in Annex I and IV;

(g) The nominal quantity of a substance or mixture in the packages as placed on the market to the general public unless this quantity is specified elsewhere on the package.

2. For hazard classes which are included in Part 5 of the Annex I

(a) the label element in paragraph 1 (a) shall not be included on the label;

(b) label elements in paragraph 1 (b), (c) and (f) shall be placed in a section for supplemental information as referred to in Article 14.

Article 13

Exemptions and derogations from the general rules for labelling

1. Where the supplier of a substance or a mixture can demonstrate that the disclosure on the label of the chemical identity of a substance puts at risk the confidential nature of his business, in particular his intellectual property, he may request to the Agency to be allowed to refer to that substance either by means of a name that identifies the most important functional chemical groups or by means of a common name[80]. Any request shall be made in a format referred to in Article 110 REACH Regulation and shall be accompanied by a fee.

The Agency may require further information from the person making the request if such information is necessary to take a decision. The Agency shall notify the applicant of its decision within 6 weeks of the request or the receipt of further required information[81]. If the Agency does not take any decision within the time specified, the use of the requested name is deemed to be allowed[82].

2. Annex I, Part 1 contains specific derogations from Article 12.

---

80 consistent with GHS 1.4.8

81 Similar provisions are in DSD Art 19, DPD Article 15

82 Note: Need to include reference to REACH-IT for all communication to and from the Agency. In the spirit of REACH.

Article 14

Supplemental information on the label

1. The label on the packaging of substances and mixtures shall include any additional or supplementary information about hazards specified in Annex I Part 5 and Annex II[83] [84].

2. The supplier may include additional information on the label, provided this information does not impede the identification of information specified in Article 12 and it provides[85] further details and does not contradict or cast doubt on the validity of the standardised hazard information[86].

3. Indications such as "non-toxic", "non-harmful", "non-polluting", "ecological" or any other statements that are inconsistent with the classification shall not appear on the label or packaging of any substance or mixture subject to this Regulation[87].

4. Additional information related to the hazard, such as physical state or route of exposure shall be included in the hazard statement rather than in the supplementary information section on the label[88].

5. For substances for which a classification is included in Annex VI to this Regulation, the word "Annex VI - harmonised" shall be added.

Article 15

Precedence Rules for labelling of substances and mixtures classified for multiple hazard classes and according to different legislation

1. If a substances or mixture is classified in more than one hazard class, the rules of precedence for labelling elements laid down in 1.3.2 of Part 1 of Annex I shall apply to the label elements referred to in Article 12 (1) (a) to (c) and (f).

2. The precedence of symbols for physical hazards shall follow the rules of the UN Model Regulations[89].

3. [Placeholder[90]: Precedence rules needed for cases where labelling is required under both transport and this Regulation[91].]

---

83 DPD Annex V; in current draft in Annex II

84 GHS 1.4.6.3.1 (b)

85 GHS 1.4.10.5.4.2

86 GHS 1.4.6.3.1 (a)

87 DSD VI 7.1.2/DPD Art 10.5

88 GHS 1.4.6.3.2

89 GHS 1.4.10.5.3.1

90 Note: Provision of the GHS 1.4.10.5.1, after discussion with transport provision might need to be included again

91 GHS 1.4.10.5.1

Article 16
Updating information on labels

1. The supplier of a substance or a mixture shall update the label without delay after receipt of any new scientific or technical information which results in a change to the classification and labelling of the substance or mixture[92].

2. Without prejudice to the requirements for the transport of dangerous goods, paragraphs 1 shall not apply to labels which are part of an approval decision such as for biocides, Directive 98/8/EC, or plant protection products, Directive 91/414/EEC.

Chapter 2
Application of Labels

Article 17
General rules for the application of labels

1. Any label for a substance or mixture shall be:

   (a) firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture;

   (b) able to be read horizontally when the package is set down normally.

2. The colour and presentation of any label shall be such that the hazard pictogram and its background stand out clearly from it.

3. The information in accordance with Chapter 1 to 3:

   (a) shall be clearly and indelibly marked;

   (b) shall stand out clearly from its background;

   (c) shall be of such size and spacing as to be easily read.

4. Any label shall be supplied in an official language of the Member State(s) where the substance or mixture is placed on the market, unless the Member State provides otherwise[93]. This shall not prevent the use of several languages provided that the same particulars appear in all the languages used without prejudice to paragraph 3.

5. The dimensions of the label as set out in 1.3.3.2 of Part 1 of Annex I shall be applied.

---

92 Aligned with REACH Article112.4 (a)
93 Aligned with REACH 31.5

6. All hazard pictograms shall be in the shape of a square set at a point. Each pictogram shall cover at least one-twentieths[94] of the minimum surface area specified for the label but shall not be less than $1cm^2$ [95].

7. A label shall not be required when the particulars are clearly shown on the package itself. In such cases, the requirements of this Chapter applicable to a label shall be applied to the information shown on the package.

Article 18
Location of information on the label

1. The label elements hazard pictogram(s), signal word and hazard statement(s) shall be located together on the label[96].

2. The supplier may choose the order of the hazard and precautionary statements on the label, unless specified in this Regulation.

3. Additional labelling requirements imposed by other Community legislation, e.g. REACH Regulation, Directive 91/414/EEC and Article 20 of Directive 98/8/EC shall be placed on the label.

4. The placement of supplemental information shall not impede identification of the harmonised hazard information and shall be placed in a section for supplemental information.

5. In addition to its use in pictograms, colour may be used on other areas of the label to implement special labelling requirements such as the use of the pesticide bands in the FAO Labelling Guide, for signal words and hazard statements or as background to them[97].

Article 19
Labelling of outer packages, inner packages and single packages according to transport rules and this regulation

1. In the case of an outer package containing one or more inner packages,

   (a) if the outer package bears a hazard label in accordance with rules on the transport of dangerous goods, then the inner package or packages shall be labelled in accordance with this Regulation;

   (b) if the outer package does not bear a hazard label in accordance with rules on the transport of dangerous, both the inner and the outermost package or packages shall be labelled in accordance with this Regulation.

---

94 Note: the required space for a square set at a point is double the space needed for a square set at the basis to make it comparable one-tenth has to be replaced by one-twenties

95 DSD Article 24.1

96 GHS 1.4.10.5.4.1

97 GHS 1.4.10.5.4.3

2. In case of a single package, the package shall be labelled in accordance with this Regulation in addition to any label in accordance with provisions on the transport of dangerous goods.

TITLE IV
PACKAGING

Article 20
Packaging[98]

1. Without prejudice to the requirements for packaging for the transport of dangerous goods, the packaging of substances and mixtures classified as hazardous according to this Regulation shall satisfy the following requirements:

   (a) It shall be so designed and constructed that its contents cannot escape, except in cases where other more specific safety devices are prescribed;

   (b) The materials constituting the packaging and fastenings must not be susceptible to attack by the contents, or liable to form dangerous compounds with the contents;

   (c) Packaging and fastenings must be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling;

   (d) Containers fitted with replaceable fastening devices shall be so designed that the packaging can be refastened repeatedly without the contents escaping;

   (e) Containers containing a substance or a mixture sold or made available to the general public and labelled "fatal", "toxic" or "corrosive", as defined in this Regulation, shall have a child-resistant fastening and a tactile warning of danger;

   (f) Containers containing a substance or a mixture sold or made available to the general public and labelled "harmful", or "flammable" as defined in this Regulation shall bear a tactile warning of danger.

   (g) Containers containing a substance or a mixture offered or sold to the general public shall not have:

      (i) either a shape and/or graphic decoration likely to attract or arose the active curiosity of children or to mislead consumers, or

      (ii) a presentation and/or a designation used for foodstuff or animal feeding stuff or medicinal or cosmetic products.

---

98 DSD Article 22; DPD Article 9

2. Where tactile warnings are used, the technical specifications shall conform with the current edition of EN ISO standard [11683] relating to tactile warnings of danger.

TITLE V
HARMONISATION OF CLASSIFICATION

Chapter 1
Community Harmonisation of Classification and Labelling of Substances: Annex VI

Article 21(based on Art 114 REACH)
Harmonisation of classification and labelling of substances for specific hazard classes or categories

1. The Commission shall take decisions to include substances and their classification and labelling in accordance with this Regulation for the following hazard classes and parts of hazard classes to human health into Annex VI:

   (a) Carcinogenicity

   (b) Mutagenicity

   (c) Reproductive toxicity

   (d) Respiratory sensitization.

2. Harmonised classification and labelling for other hazard classes or parts of hazard classes may also be added to Annex VI on a case-by-case basis if justification is provided demonstrating the need for action at Community level.

3. Where appropriate, specific concentration limits may be set for a hazard class or categories when a substance is included in Annex VI.

Article 22 (based on Article 114 REACH)
Procedure to include a substance into Annex VI

1. Member State competent authorities may submit proposals for substances meeting the criteria in Article 21 (1) or the conditions in Article 21 (2) for harmonised classification and labelling by inclusion in Annex VI in the format set out in the relevant sections of Annex XV REACH Regulation to the Agency.

2. Any supplier of a substance may submit a proposal for substances meeting the criteria in Article 21 (1) or the conditions in Article 21 (2) for harmonised classification and labelling by inclusion in Annex VI in accordance with the relevant parts of Section 1 to 3 of Annex I REACH Regulation in the format set out in Part B and C of the Chemical Safety Report in Annex I REACH Regulation to the Agency and in accordance with Article 110 of the REACH Regulation. In his proposal, the

supplier shall demonstrate the need for action at Community level. The supplier may refer to any information already submitted as part of the registration under the REACH Regulation.

3. The Risk Assessment Committee of the European Chemicals Agency shall adopt an opinion on the proposal prepared under paragraph 1 to 2 within 12 months of receipt of the proposal; giving parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission.

4. The Commission shall take its decision on any inclusion in Annex VI within 6 months of receipt of the opinion referred to in paragraph 3 in accordance with the procedure in Article 36 (2).

Article 23(new, not in REACH)
Content of opinions and decisions for harmonised classification and labelling in Annex VI

Any opinion referred to in Article 22 (3) and any decision according to Article 22 (4) shall at least specify for each substance:

– the identity of the substance as specified in Section 2.1 to 2.3.4 of Annex VI REACH Regulation;

– the harmonised classification of the substances in accordance with Article 21;

– the specific concentration limits, where applicable;

– the resulting labelling elements for the substance;

– the registration number for the substance, if available;

– any other parameter enabling an assessment to be made of the health or environmental hazard of mixtures containing the said hazardous substances or substances containing such hazardous substances as impurities[99].

Chapter 2
Industry Classification and Labelling of Substances: Classification and Labelling Inventory

Article 24(based on Art 112 REACH)
Obligation to notify the Agency

1. Any manufacturer or importer, or group of importers or manufacturers, who places on the market a substance meeting the criteria for classification as hazardous, shall notify to the Agency the following information in order for it to be included in the

[99] DSD Article 4.4

inventory in accordance with Article 26 of this Regulation, unless submitted as part of a registration under the REACH Regulation[100]:

(a) The identity of the manufacturer or importer responsible for placing the substance(s) on the market as specified in section 1 of Annex VI REACH Regulation;

(b) The identity of the substance(s) as specified in section 2.1 to 2.3.4 of Annex VI REACH-Regulation;

(c) The hazard classification of the substance(s) in accordance with Title II of this Regulation and the hazard statements allocated in accordance with Article 12.1 (c);

(d) Specific concentration limits, where applicable, in accordance with Title II of this Regulation and their justification, if they are not included in Annex VI to this Regulation;

(e) The resulting labelling elements for the substance(s) in accordance with Title III of this Regulation;

(f) The registration number for the substance allocated in accordance with Article 20 of the REACH-Regulation, if available.

The manufacturer or importer shall submit this information in the format specified pursuant to Article 110 REACH-Regulation.

2. The information listed in paragraph 1 shall be updated by the notifier(s) whenever[101]:

(a) any new scientific or technical information is generated which results in a change to the classification and labelling of the substance;

(b) notifiers and registrants of differing entries for a single substance come to an agreed entry in accordance with paragraph 3.

3. The obligations set out in this Article shall apply from the deadlines established under Article 23 (1) REACH Regulation.

---

100 Aligned with REACH Article 112

101 Aligned with REACH Article 112

Article 25 (based on Article 112 REACH)
Industry agreements on entries

1. Where the obligation in Article 24 paragraph 1 results in different entries on the inventory referred to in Article 26 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory[102].

2. Any agreement shall be notified to the Agency by one of the notifiers or registrants who have reached an agreement, specifying

   (a) the substance as specified in section 2.1 to 2.3.4. of Annex VI REACH Regulation;

   (b) the notifiers and registrants that have agreed;

   (c) the agreed classification in accordance with Title II of this Regulation, including, where applied, specific concentration limits in accordance with Title II of this Regulation and

   (d) the labelling elements in accordance with Title III of this Regulation;

   (e) the registration number(s) assigned in accordance with Article 20 of the REACH-Regulation, if available.

   The notifiers shall submit this information in the format specified pursuant to Article 110 REACH-Regulation.

Article 26 (based on Article 113 REACH)
The classification and labelling inventory

1. The Agency shall establish and maintain a classification and labelling inventory in form of a database, listing the information referred to in Article 24 (1), both for information notified under that Article as well as for information submitted as part of registrations under the REACH Regulation. Information in this database which is also identified in Article 118 (1) REACH -Regulation shall be publicly accessible. The Agency shall grant access to the other information on each substance in the inventory in accordance with Article 117 REACH Regulation.

2. The Agency shall update the inventory when it receives updated information in accordance with Article 24 (2).

3. In addition to the information referred to in paragraph 1, the Agency shall record the following information, where appropriate, against each entry:

---

[102] Aligned with REACH Article 112

(a) whether, in respect of the entry, there was a harmonised classification and labelling at Community level by inclusion in Annex I of Directive 67/548/EEC[103];

(b) whether, in respect of the entry, there is a harmonised classification and labelling at Community level in Annex VI of this Regulation;

(c) whether, in respect of the entry, it is a joint entry between registrants of the same substance as per Article 11 (1) REACH -Regulation;

(d) whether it is an agreed entry of two or more notifiers or registrants in accordance with Article 25;

(e) if the entry differs from another entry on the inventory for the same substance;

(f) the relevant registration number(s), if available.

TITLE VI
COMPETENT AUTHORITIES AND ENFORCEMENT

Article 27
Appointment of authorities and bodies

Member States shall appoint the competent authority or competent authorities responsible for proposals for harmonised classification and labelling and for the enforcement of the obligations set out in this Regulation. Member States shall ensure cooperation and coordination of all authorities competent for legislation related to chemicals.

Article 28
Appointment of bodies responsible for receiving information on human health

Member States shall appoint a body or bodies responsible for receiving information by the suppliers, including chemical composition of the mixtures placed on the market and classified or considered as hazardous on the basis of their health effects or on the basis of their physico-chemical effects[104].

---

103 Note: Depending on how Annex I is used in this Regulation, we may want to delete (a)

104 DPD Art 17

Article 29
Enforcement and Reporting

1. Member States shall take all necessary measures, including maintaining a system of official controls, to ensure that substances and mixtures are not placed on the market, unless they have been classified, labelled and packaged in accordance with this Regulation.

2. Member States shall submit a report to the Agency every 5 years by 1st July on the results of the official controls, and other enforcement measures taken. The Agency shall make these reports available to the Commission which shall take them into account for its report under Article 116 REACH Regulation.

3. The Forum referred to in Article 75 REACH Regulation shall exchange information about the enforcement of this Regulation.

Article 30
Sanctions for non-compliance with this Regulation

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of the present Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than eighteen months after entry into force of this Regulation and shall notify without delay any subsequent amendment affecting them.

TITLE VII
COMMON AND FINAL PROVISIONS

Article 31
Advertisement[105]

Any advertisement for a substance or a mixture meeting the criteria for classification according to this Regulation shall be prohibited if no mention is made therein of the concerned hazard class and/or category.

Article 32
Obligation to keep information and requests for it

1. Any supplier of a substance or mixture shall assemble and keep available all the information he requires to classify and label it under this Regulation for a period of at least 10 years after he last supplies the substance or the mixture. The supplier shall keep this information with the information required by Article 35 REACH Regulation for substances within the scope of the REACH Regulation.

---

105 DSD Article 26

2. The competent authority of a Member State in which a supplier is established or the Agency may require the supplier to submit any information referred to in paragraph 1 on the classification of a substance or mixture to it, unless that information is submitted to the Agency as part of a registration under the REACH Regulation.

Article33
Free movement clause

On grounds relating to the classification, labelling or packaging of substances and mixtures within the meaning of this Regulation, Member States shall not prohibit, restrict or impede the placing on the market of substances or mixtures, which comply with this Regulation.

Article 34
Safeguard Clause

1. Where a Member State has justifiable grounds for believing that a substance or a mixture, although satisfying the requirements of this Regulation, constitutes a risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving the reasons for its decision.

2. The Commission shall take a decision in accordance with the procedure referred to in Article 36 (2) within 90 days of receipt of the information from the Member State. This decision shall either:

   (a) authorise the provisional measure for a time period defined in the decision; or

   (b) require the Member State to revoke the provisional measure with effect for the future.

3. If, in the case of a decision as referred to in point (a) of paragraph 2, the Commission shall consider whether it needs to prepare an amendment of this Regulation, [in particular Annex VI or Annex I] or action at the international level needs to be taken.

Article 35
Amendments to the Annexes

The Annexes may be adapted to technical progress in accordance with the procedure referred to in Article 36 (2).

Article 36
Committee procedure

1. The Commission shall be assisted by the Committee instituted by Article 132 of Regulation (EC) No…/2006 (REACH).

2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article37

Repeal and amendment of Community legislation

1. Directives 67/548/EEC and 1999/45/EC are repealed with effect from [X] [years - end of the transitional period] after the entry into force of this Regulation.

2. From the {end of the transitional period - repeal of Directive(s 67/548/EEC and) 1999/45/EC}, references to the repealed acts referred to in paragraph 1 shall be construed as references to this Regulation, and the following shall apply:

   (a) Unless otherwise specified, references to the "classification as dangerous according to Directive 67/548/EEC" shall be construed as references to the "classification as hazardous according to Regulation … (GHS- Regulation); except for the following hazard classes or categories:

   – Gases under pressure in accordance with Annex I Chapter 2.5

   – Self-reactive substances and mixtures , Type C to G, in accordance with Annex I Chapter 2.8

   – Self heating substances and mixtures in accordance with Annex I Chapter 2.11

   – Oxidising liquids, category 3 in accordance with Annex I Chapter 2.13

   – Oxidising solids, category 3 in accordance with Annex I Chapter 2.14

   – Organic peroxides, Type G in accordance with Annex I Chapter 2.15

   – Corrosion to metals in accordance with Annex I Chapter 2.16

   – Reproductive toxicity, effects on and via lactation in accordance with Annex I Chapter 3.7

   – Specific Target Organ Systemic Toxicity STOST (single exposure), narcotic effects in accordance with Annex I Chapter 3.8."

   (b) Unless otherwise specified, references to specific categories of danger and risk phrases according to Directive 67/548/EEC shall be read as references to specific hazard classes, parts of hazard classes and hazard categories in accordance with the reference table in part 1 of Annex VIII to this Regulation and with any adaptations in part 2 of Annex VIII for specified Directives and Regulation;

(c) the term “preparation” shall be replaced by the term “mixture”.

3. From the {end of the transitional period - repeal of Directive(s) 67/548/EEC and) 1999/45/EC}, unless otherwise specified, references to Article 29 of Directive 67/548/EEC shall be considered as references to Article 132 of Reach, applying the procedure of Article 132(3).

Article 38
Amendment of the REACH Regulation

1. From the entry into force of this Regulation Articles 111 to 115 of the Regulation ….REACH Regulation shall be deleted.

In Article 14 (2) (e), the words “Title XI” are replaced by “Title V of the Regulation … (GHS Regulation);”

2. From the {end of the transitional period - repeal of Directive 1999/45/EC} the following Articles of the Regulation….REACH Regulation are amended as follows:

(a) In Article 14 (2) the subparagraphs (a) to (d) are replaced by the following subparagraphs (a) and (b):

“(a) The specific concentration limits that have been set in Annex VI to Regulation … (GHS Regulation);

(b) The applicable concentration limits/cut-off values defined in each Part of Annex I to Regulation … (GHS Regulation);”

(b) In Article 31 (3)

– The words “Article 5, 6 and 7 of Directive 1999/45/EC” are replaced by “Title I and II of Regulation … (GHS Regulation);”

– In subparagraph (b) after the words “….at least one substance that is” the words “carcinogenic Category 2 or toxic to reproduction Category 2 or” are added.

(c) In Article 55 (6) (b),

– The words “Directive 1999/45/EC or in Annex I to Directive 67/548/EEC” are replaced by “Annex VI or in each Part of Annex I to Regulation … (GHS Regulation);

(d) In derogation from Article 37 (2) (a) of this Regulation, Annex VI section 4[106] of the REACH Regulation is amended as follows:

[106] The effect of this change is that in any notifications and registrations according to Articles 7 (4), 9 (2), 10 (a) (iv), 17 (2), 18 (2) and 22 (1) (f) REACH Regulation the classification for all hazard classes and categories has to be addressed

(i) In section 4.1, the words "Article 4 and 6 of Directive 67/548/EEC" are replaced by "[Title I and II to] Regulation … (GHS Regulation) for all hazard classes and categories in that Regulation;

(ii) In section 4.2, the words "Article 23 to 25 of Directive 67/548/EEC" are replaced by "Title III to Regulation … (GHS Regulation);"

(iii) In section 4.3, the words "Article 4 (4) of Directive 67/548/EEC and Article 4 to 7 of Directive 19999/45/EC" are replaced by "Article 10 to Regulation … (GHS Regulation);"

3. From the respective application dates set out in Article 39, registrants and notifiers of substances as well as applicants for authorisations for the use of substances shall follow the references set out in Paragraph 2 instead of any references to Directive 67/548/EEC or Directive 1999/45/EC. The same shall apply if use is made of Article 39(3).

Article 39
Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2. The provisions of this Regulation shall apply:

(a) for substances 3 years*[107];

(b) for mixtures*[108].

3. From 3 to 7/8[109] years after the entry into force, suppliers of substances shall also classify their substances according to Directive 67/548/EEC. The classification according to both systems shall be included in the safety data sheet, but not on the label.

4. The provisions of this Regulation may be applied from the entry into force of this Regulation for all substances and mixtures placed on the market until the deadlines in paragraph 2. In this case, any supplier shall include the classification according to both Directive 67/548/EEC or 1999/45/EC and this Regulation in the safety data sheet only. The label shall follow the requirements of this Regulation.

5. In derogation from Article 4 (2), suppliers of substances that they have classified according to Directive 67/548/EEC before the entry into force of this Regulation as

---

107 * after the entry into force of the REACH Regulation (aligned with the 1. registration deadline in REACH and with the obligation to notify all classified substances placed on the market to the Classification and Labelling Inventory of REACH, Title XI)

108 * 3+4/5 years after the entry into force of the REACH Regulation. (The proposed duration of the additional transition period for mixtures (4 or 5 years) is to be decided in the light of the internet consultation.)

109 The proposed duration of the additional transition period for mixtures (4 or 5 years) is to be decided in the light of the internet consultation.

carcinogenic, mutagenic, toxic to reproduction or as a respiratory sensitizer, [Placeholder: list of 1:1 - endpoints] may reclassify these substances for these hazard classes by using the conversion table in Annex VII.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

For the European Parliament	*For the Council*
The President	*The President*
[…]	*[…]*