COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 27.6.2007
COM(2007) 355 final

2007/0121 (COD)

Volume I

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006

(presented by the Commission)

[SEC(2007) 853]
[SEC(2007) 854]

EXPLANATORY MEMORANDUM

BACKGROUND TO THE PROPOSAL

Reasons and objectives

This proposal builds on existing chemicals legislation and establishes a new system on classification and labelling of hazardous substances and mixtures by implementing in the EU the international criteria agreed by the United Nation Economic and Social Council (UN ECOSOC) for the classification and labelling of hazardous substances and mixtures, called the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Chemicals are manufactured and traded globally, and their hazards are the same around the world. Therefore the description of hazards should not differ between countries if the product is the same.

Enterprises will save costs if they do not have to assess hazard information for their chemicals against different sets of criteria.

If the same criteria are used to identify the hazards of chemicals and the same labelling is used to describe them, the level of protection of human health and the environment becomes more consistent, transparent and comparable throughout the world. Professional users of chemicals and consumers all over the world benefit from such a harmonisation.

Global Context

In December 2002, the 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]. It was formally adopted by UN ECOSOC[2] in July 2003 and revised[3] in 2005. In its Plan of Implementation, adopted in Johannesburg on 4 September 2002, the **World Summit on Sustainable Development** encouraged countries to implement the GHS as soon as possible, to have the system fully operational by 2008.

EU Context

Besides participating in the UN work to develop the GHS, the Commission announced its aim to propose the implementation of the GHS into Community legislation on several occasions, e.g. in the 2001 White Paper 'Strategy for a future Chemicals Policy'[4], and the Explanatory Memorandum to the amendment to Directive 67/548/EC[5], adopted at the same time as the REACH proposal. The present proposal fulfils that commitment.

---

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
5 2003/0257(COD)

Current EU System and GHS

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

– the Dangerous Substances Directive (67/548/EEC)[6];

– the Dangerous Preparations Directive (1999/45/EC)[7];

– the Safety Data Sheet Directive (91/155/EEC)[8].

They pursue internal market objectives, i.e. the establishment of a Single Market in chemicals. The Directives are based on a high level of protection concerning health, safety, environmental and consumer protection (Article 95 (3) EC Treaty).

The first two Directives set out rules on the classification, packaging and labelling of dangerous substances and preparations. The Safety Data Sheet Directive ensures that suppliers of substances and preparations provide information about the hazards of their chemicals and guidance on safe use to professional customers. These provisions have been taken up in REACH[9].

The current EU system and the GHS are conceptually similar. Both cover classification, packaging and hazard communication through labelling and safety data sheets. The GHS is a common approach that provides criteria for harmonised classification and hazard communication for 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 having regard to the various target audiences in different legal areas. As the GHS provides a common system of the classification and labelling for transport, supply and use, this proposal aims to ensure coherence with EU transport legislation, where relevant. EU transport legislation will incorporate relevant GHS criteria by 2007 and 2009, in line with the timetable for adoption of the UNECE Model Regulation.

This proposal addresses supply and use of chemicals and, therefore, the main target audience are workers and consumers, as is the case for the current EU system.

---

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

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

8 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], repealed and replaced by Regulation (EC) No 1907/2006 as of 1 June 2007.

9 Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European chemicals agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [OJ L 396, 30.12.2006, p. 1]

Experts have identified the differences between the current EU system for supply and use and the GHS system[10]. The Commission has based this proposal on their work. The number of classified substances resulting from the application of the new system is estimated to be approximately the same as under the current system.

Due to changes of cut-off values and calculation methods, more preparations – now called mixtures - will probably be classified under the new system. The application of the new criteria may result in a different classification compared to the current one.

As safety data sheets are the main tool for communication under the REACH Regulation, the provisions on safety data sheets remain there.

Future Development

Two UN Expert Sub-Committees keep the technical aspects regarding health and environmental hazards and physical hazards of the GHS up-to-date. The Committee of the Experts on the Transport of Dangerous Goods and the Globally Harmonised System of Classification and Labelling of Chemicals endorses recommendations of the sub-committees and channels these to the UN ECOSOC, which will adopt revisions of the GHS on a biannual basis[11].

Coherence with other policies

Classification of substances and preparations triggers other obligations in EU legislation, referred to as downstream legislation.

The Commission services have assessed the potential effects of the implementation of the GHS criteria on downstream legislation. Their analysis concludes that effects are either minimal or can be minimised by appropriate changes to particular downstream acts. This draft Regulation includes such changes to Regulation (EC) No 1907/2006. For the Seveso II Directive[12], where the implementation of GHS is expected to have a substantial impact, necessary measures have to be introduced in a separate amendment. Other separate amendments implementing the GHS for other EU downstream acts will be part of an upcoming Commission proposal.

During the stakeholder consultation, some parties mentioned the lack of analysis of national legislation referring to EU classification. However, the assessment of the effects on national legislation is within the competence of Member States. It may be worthwhile for them to analyse national downstream acts along the lines of the study on EU legislation.

---

[10] 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.

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

[12] Council Directive 1996/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances, as amended [OJ L 10, 14.1.1997, p. 13]

RESULTS OF PUBLIC CONSULTATIONS AND IMPACT ASSESSMENTS

Public stakeholder consultation

Internet consultation

The Commission launched a stakeholder consultation on the internet from 21 August to 21 October 2006. All responses were published on the Internet. Some 370 contributions were received. 82% were sent by industry - companies or associations; of the 254 company responses, 45% came from enterprises with less than 250 employees. 10 NGOs and one trade union responded.

18 Member State governments and/or public authorities sent comments. Non-EU public authorities (Iceland, Norway, Switzerland, Romania) gave input as well. No international organisation sent comments. **97% of the responses supported the implementation of the GHS in the EU and 96% of these by means of a Regulation.** Overall the draft proposals of the Commission services were well appreciated by Member State authorities and industry.

Issues raised and how they are addressed

Scope: 59% supported not changing the level of protection in comparison with the current EU system, except to be consistent with transport legislation or the GHS. 5% had no opinion, including most of the NGOs. 36% favoured a different approach. Of these, one group (governmental bodies in Denmark, Sweden, Norway, Iceland), wanted to go beyond the scope of the current system; the second group (associations and companies) proposed to include all GHS categories, but not to include the "EU left-overs" not yet part of the GHS.

The majority of respondents supported maintaining the current level of protection and the Commission has not changed the proposal in this regard. However, flammable gases Cat. 2 was included as requested by some Member States and industry.

Transitional period: No specific comments were made on the two stage structure (substances then mixtures) of the transitional period. A clear majority of respondents (around 60%) supported a three-year transition period for substances after entry into force of REACH. This would require all enterprises to register the first wave of phase-in substances and notify the classification and labelling of their substances to the Chemicals Agency. Fixing the transition period for substances in line with the relevant period in REACH avoids double work as confirmed by the impact assessment. Some stakeholders preferred a longer deadline allowing to postpone the work until after the last registration deadline in REACH.

For mixtures, almost half of the responses supported the 5 year option. Nearly equal numbers of the remaining responses preferred either a longer period or a shorter period. Industry responses were divided, with significant support for 5 years for mixtures, sometimes coupled with a demand for a longer period for substances. Member States looked for a shorter period, typically 3 years.

The Commission therefore proposes a transition period for substances of three and a half years after the entry into force of REACH. As the length of the transition period for mixtures is less evident and the impact assessment does not show clear enough results to give preference for either four or five years, a transition period of 4.5 years is proposed.

Specific comments: Around 15% of the respondents provided specific comments.

A large majority of these comments from industry and Member States were technical, seeking more clarity and consistency. Issues repeatedly pointed out are:

– align the definition of mixtures with that of REACH;

– describe the general obligations of Article 4 to classify, label and package more clearly;

– allow the use of an international chemical name beside the name of the IUPAC Nomenclature, limit the names on a label for a mixture in line with the requirements of the current legislation, include a provision to allow the use of shorter names;

– clarify that the content of the publicly accessible part of the classification and labelling inventory is consistent with Article 119 of the REACH Regulation;

– include the specific rule of current legislation with regard to advertising mixtures;

– specify more clearly the body responsible for receiving information relating to health in line with the current legislation;

– reconsider the provision for small packaging to counterbalance the bigger space demand of the GHS label information.

Another request from the majority of Member States and downstream users was the "translation" of the current Annex I of Directive 67/548/EEC (list of harmonised classification and labelling of substances) into the new Annex VI, so as to maintain the results of efforts to build up Annex I.

All these points were considered and taken up in the revised proposal.

Impact assessments

The impact assessment made use of the impact assessment consultant reports prepared by RPA and London Economics as well as the responses to the Internet Consultation. The responses from companies on costs led to further efforts to quantify significant cost items. The overall analysis demonstrates that the implementation costs need to be kept in check so as to arrive at the net benefits of the GHS in the foreseeable future.

Collection and use of expertise

The GHS was developed by international organisations, with participation of various stakeholders. Similarly, in the EU there have been continuous technical discussions with Member States and other stakeholders over the past years. Following the publication of the White Paper "Strategy for a future Chemicals Policy", the Commission consulted widely with experts. The results of the technical working group on classification and labelling convened by the Commission in preparation for REACH[13] have been taken into account in drafting this

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

proposal. Further studies were carried out[14] and an informal stakeholder discussion on the implementation of the GHS in the EU took place on 18 November 2005.

LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

Article 95 of the EC Treaty is the appropriate legal basis. The aim is to ensure a level playing field for all suppliers of substances and mixtures in the internal market, as well as a high level of protection of health, safety, environment and consumers.

This legal basis ensures that the requirements for substances and mixtures are harmonised and that substances and mixtures complying with them can move freely throughout the internal market. This rewards the efforts required from economic actors to reclassify substances and mixtures.

Moreover, Article 95(3) requires a high level of health, safety, environmental and consumer protection. This Regulation falls within this remit.

Subsidiarity and proportionality

Subsidiarity

Existing Directives on the classification and labelling of substances and preparations already set forth an extensive system. The new Regulation will replace the existing Directives. Classification and labelling provisions need to be exactly the same in all Member States, and should therefore be regulated at Community level.

Proportionality

The criteria for the classification of substances and mixtures as hazardous, including the building block approach that invites the legislator to choose the appropriate hazard classes and categories, have been developed at international level. To ensure proportionality, the Commission selected those hazard classes and categories which are comparable with existing legislation. Therefore, this proposal does not include certain categories not part of current EU legislation. Elements which are part of current EU legislation, but have not yet been included in the GHS, are also part of this proposal, e.g. "ozone depletion".

To be consistent with the GHS, those elements which were only subject to additional labelling requirements under the current EU system, but which are now part of the GHS classification system, will now have to be classified. However, for those hazard classes or categories which are added in comparison to the current EU system, no obligations should be triggered under other legislation, e.g. REACH. For consistency with transport legislation, this proposal incorporates some hazard classes or categories which are not included in current EU

[14] 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.

legislation for supply and use, but are part of the existing EU transport system or will be implemented in transport legislation.

Therefore this proposal for a Regulation is proportionate.

Choice of legal instrument

The choice of a Regulation is justified, as it will lead to the direct application of the rules throughout the Community. It replaces 2 existing and dated Directives (with 10 Amendments and 30 Adaptations to Technical Progress). It also contains mainly technical details agreed at UN level, which it is not appropriate to change, as this would defeat the purpose of global harmonisation. In the area of technical legislation, Regulations are a widely used technique that has already met with the support of Member States in other areas[15]. It is even more justified in a Community of 27 Member States that will certainly benefit from homogeneous and directly applicable rules throughout its territory.

INTRODUCTION TO THE PROPOSAL

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

1. REASONS AND OBJECTIVES

The objective of this Regulation is to ensure a high level of protection of human health and the environment, while guaranteeing the free movement of substances and mixtures within the internal market. To this end, the Regulation takes a fivefold approach based on the GHS.

First, it harmonises the classification, labelling and packaging rules for substances and mixtures. Second and third, it obliges enterprises to classify their substances and mixtures themselves and to notify the classifications. Fourth, it establishes a harmonised list of substances classified at Community level in Annex VI. Finally, it establishes a classification and labelling inventory, made up of all notifications and harmonised classifications referred to above.

2. GENERAL ISSUES

The Regulation applies to substances and mixtures. However, since the physical hazards of substances or mixtures are to some extent influenced by the way in which they are released, the Regulation also covers release by aerosols through a specific hazard class. Radioactive substances are excluded from the scope, as they are covered by other rules. Substances and mixtures subject to customs supervision are also excluded, subject to certain conditions, as they are not supplied in the EU. Non-isolated intermediates are not included for the same reason. Substances and mixtures for scientific research and development not placed on the market are also excluded when used under controlled conditions minimising exposure.

---

[15] See Regulation (EC) No 178/2002 on Food Law [OJ L 31, 1.2.2002, p. 1, Regulation (EC) No 2003/2003 on Fertilisers [OJ L 304, 21.11.2003, p. 1], Regulation (EC) No 273/2004 on Drug Precursors [OJ L 47, 18.2.2004, p. 1] and Regulation (EC) No 648/2004 on Detergents [OJ L 104, 8.4.2004, p. 1].

The essential terms are defined. Following the GHS, the term "preparation" is replaced by "mixture".

Annex I lists the hazard classes of the GHS, as well as the relevant hazard categories and criteria. If a substance or a mixture fulfils the criteria for any hazard class, it is hazardous. The Commission is empowered to update Annex I and to include new hazard classes agreed at UN level. The concept of "dangerous" is also laid down, in order to allow minimising effects on downstream legislation.

Before a substance or mixture is marketed, the supplier must classify it. This means he must identify and describe its hazards, evaluate this information and compare it with the criteria of the Regulation. Suppliers may define other concentration limits which differ from the generic concentration limits in justified cases, unless Annex VI contains specific concentration limits. However, where harmonised classifications for a hazard class or differentiation within a hazard class are included in this Regulation for a substance, the supplier must classify in accordance with that entry, and must not deviate from it on the basis of available information.

Distributors must ensure that they pass on the relevant information, either by keeping the labels on the substances or mixtures they receive or by applying the rules of this Regulation themselves.

The procedure for identifying information relevant for hazard classification is described. No new testing needs to be done for the purpose of classification only. Thus, available information from public sources and information generated under other EU legislation like REACH, the transport, biocides or plant protection product legislation, may be used.

If the supplier generates new information, certain quality conditions must be met, to ensure that classification is based on sound data. International standards are accepted as well as data that fulfil the requirements of REACH or other legislation. Testing on animals must be avoided wherever possible and alternative methods always must be considered first. Animal tests must comply with the relevant Directive[16]. Testing on humans is not permitted; only available experience on effects on humans may be used.

For mixtures, there is a general obligation to use available test data on the mixtures themselves, except for mixtures containing substances with e.g. CMR properties. For the latter, the classification of the mixtures is normally based on the information on those substances. If no test data are available on the mixtures themselves, Annex I specifies "bridging principles", which enable suppliers to derive a sound classification of mixtures. If the available information is not sufficient for the application of those principles, the individual chapters of Annex I specify what needs to be done.

The identified relevant information needs to be evaluated for the purpose of classification, by comparing it with the criteria in Annex I.

The classification of mixtures must take account of all available information about potential occurrence of synergistic and antagonistic effects among the ingredients. Cut-off values ensure that the system is workable and proportionate. A new hazard evaluation is required

[16] Directive 86/609/EEC, OJ L 358, 18.12.1986, p. 1.

when the composition of a mixture is changed outside specified limits, unless it is evident that the change has no effect on the classification.

Agreed classifications must be respected, unless the supplier has sufficient evidence to justify a different classification.

3. LABELLING

The label elements from the GHS are specified, i.e. the name, address and telephone number of the supplier, product identifiers, hazard pictograms, signal words, hazard statements and precautionary statements. To maintain the level of protection of current EU law, supplemental information on hazards not yet included in the GHS must also be mentioned. Furthermore, as is the case today, the nominal quantity in the package, as placed on the market to the general public, has to be indicated. To protect confidential business information, it is possible, as is the case today, to apply for permission to use a name that does not reveal the substance's chemical identity. The Agency established by the REACH Regulation will decide on such applications.

Principles of precedence for labelling are specified..

The supplier has to update the label after changes to the classification, unless the labels are part of an approval decision concerning a biocide or a plant protection product. In the latter case, the applicable special legislation has to be complied with.

To ensure that customers notice hazard information, there are rules on the colours and format of labels and on the location of information on labels.

To reduce the burden on enterprises and to avoid the duplication of transport labels, there are provisions determining which labels to use in case of inner and outer packages.

4. PACKAGING

Safety measures for containers and other packages are set out.

5. HARMONISATION OF CLASSIFICATION AND LABELLING OF SUBSTANCES; THE CLASSIFICATION AND LABELLING INVENTORY

The provisions of Title XI of the REACH Regulation are moved to this Regulation, with certain technical changes.

5.1. Establishing harmonised classification and labelling of substances

For specific hazard classes harmonised classifications can be included in Annex VI, while harmonisation of other hazard classes is possible if there is a need for Community wide action. The applicable procedure is set out, ensuring that expert opinion is taken into account and that stakeholders may comment.

5.2. Notification to the Agency and establishing the classification and labelling inventory

Specific information must be provided for inclusion of a substance in the inventory. As classification and labelling data are part of the information needed for registration under REACH, there is no need to notify the information if a registration has been submitted.

If the classification is changed, as a result of REACH or otherwise, the entry must be updated. It is anticipated that for some substances the classifications will vary. Over time, it is expected that notifiers and registrants will agree on a single entry.

Where the entries differ, enterprises must make every effort to agree a single entry. This reflects the principle of industry self-responsibility and enables authorities to focus resources on substances with properties of very high concern.

The information to be included in the inventory is set out. It will be widely available as a source of information on substances and will encourage industry to come to agreed entries.

6. COMPETENT AUTHORITIES AND ENFORCEMENT

Member States must to appoint the authorities for the application and enforcement of this Regulation. Good cooperation between all competent authorities is essential.

To bundle information on human health, as under current legislation, one body per Member State is responsible for receiving health-related information.

Member States are to take all measures necessary to ensure correct application of this Regulation. To enhance the exchange of practical experience, the Agency's Forum established by the REACH Regulation shall also exchange enforcement information under this Regulation.

Finally, Member States have to establish proportionate sanctions for non-compliance.

7. COMMON AND FINAL PROVISIONS

There are special rules on advertising, to avoid misleading customers.

To be able to retrace their decisions taken in applying this Regulation, suppliers must keep the relevant information, together with any information they are required to keep under the REACH Regulation. Authorities may request this information.

Similar to its role under REACH, the Agency's Secretariat is to prepare guidance and tools for industry as well as guidance for authorities.

Free movement of substances and mixtures that comply with the provisions of the Regulation is guaranteed, while Member States are enabled to address risks to human health and the environment by appropriate provisional measures.

The Commission is empowered to adapt all annexes as well as a number of Articles to technical progress through a Committee procedure, as they relate to scientific and technical matters and do not touch the fundamental rules of the Regulation. The Committee established

by the REACH Regulation shall also assist the Commission under this Regulation. The regulatory procedure with scrutiny has to be applied for adaptations to technical progress. For confirmation or refusal of the provisional measures taken under the safeguard clause and for fees, the ordinary regulatory procedure will be applied, as such decisions do not involve changes to the Regulation.

The findings of the analysis of the potential effects of the GHS Regulation on EU downstream legislation are reflected in the proposal. Directives 67/548/EEC and 1999/45/EC are replaced by this Regulation at the end of the last transitional period set out. References in Community legislation to those Directives and their provisions and classifications will be replaced by references to this Regulation through separate acts. The Regulation specifies which hazard classes or categories trigger obligations under REACH; by doing so, it leaves the current scope of REACH intact.

The obligations under this Regulation apply to the supply of substances. Not all duties apply when the Regulation first enters into force. As the classification of mixtures depends on the classification of substances, the new criteria will have to be applied first to substances, before they are applied to mixtures.

The deadline for mixtures strikes a balance between avoiding too much confusion from the use of a dual system during the transitional period and the need to allow enterprises sufficient time to manage the new workload arising from reclassifying 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 will encourage enterprises to align to the new system in the most efficient way.

For some hazard classes and hazard categories, during the transitional period the table of equivalence which is provided may serve as a first orientation for the results that might follow from the application of the new criteria.

Guidance provided to assist operators in fulfilling the obligations under this Regulation will include a table with references to the specific categories of danger and risk phrases according to Directive 67/548/EEC which should be read as references to specific hazard classes, differentiations and hazard categories in this Regulation.

8. ANNEXES

Annex I

Annex I includes a General Introduction (part 1), the hazard classes and criteria for physical, health and environmental hazards (parts 2, 3 and 4) replacing Annex VI of Directive 67/548/EEC, except for ozone depletion, which is placed in part 5.

Annex II

Part 1 includes the extra labelling provisions from Annex VI to Directive 67/548/EEC not yet covered by the GHS; part 2 contains special rules for labelling certain substances or mixtures, mainly from Annex V to Directive 1999/45/EC. Part 3 provides for child-proof fastenings and

tactile warnings retained from the current EU system. Part 4 contains a special labelling rule for plant protection products.

Annex III

The list of hazard statements is similar to Annex III of Directive 67/548/EEC. Additional hazard statements are required for hazards not currently part of the GHS; thus, R-phrases from the current EU scheme were added as "EUH-statements".

Annex IV

Rules for applying precautionary statements are given. The list of precautionary statements is similar to Annex IV of Directive 67/548/EEC.

Annex V

This reproduces the GHS hazard pictograms and is similar to Annex II of Directive 67/548/EEC.

Annex VI

Part 3 is a list of substances with harmonised classifications for specific hazard class(es) or differentiation(s) and hazard category/ies. As authorities should focus on substances of the highest concern, mainly substances classified for carcinogenicity, germ cell mutagenicity or reproductive toxicity Cat. 1A or 1B, and for respiratory sensitisation will be added, but other effects can be added if justified. Table 3.1 of the Annex includes the entries in Annex I of Directive 67/548/EEC, adapted where necessary to the GHS classification criteria, Table 3.2 contains the unadapted entries taken over from Annex I of Directive 67/548/EEC.

Annex VII

This includes "translation" tables for suppliers of substances and mixtures already evaluated under the current rules for those hazard categories where a simple equivalence exists.

These tables provide an option for suppliers to fulfil their new obligations without having to make an *ab initio* reclassification of their currently self-classified substances and mixtures. Should a supplier choose not to use the table, he must re-evaluate the substance or mixture using the criteria laid down in parts 2 to 5 of Annex I.

2007/0121 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006

(Text with EEA relevance)

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[17]

Having regard to the opinion of the European Economic and Social Committee[18],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[19],

Whereas:

(1) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of chemical substances and mixtures, while enhancing competitiveness and innovation.

(2) The efficient functioning of the internal market for substances and mixtures can be achieved only if requirements for substances and mixtures do not differ significantly from Member State to Member State.

(3) A high level of human health and environmental protection should be ensured in the approximation of legislation on classification and labelling of substances and mixtures, with the goal of achieving sustainable development.

(4) Trade in substances and mixtures is not only an issue of the internal market, but also of the global market. Enterprises should therefore benefit from the global harmonisation of rules for the classification and labelling of substances and mixtures and from consistency between, on the one hand, the rules for classification and labelling for supply and use and, on the other hand, those for transport.

(5) With a view to facilitating worldwide trade while protecting human health and the environment, harmonised criteria for classification and labelling of substances and mixtures have been carefully developed over a period of 12 years within the United

---

17 OJ C

18 OJ C

19 OJ C

Nations (UN) structure, resulting in the Globally Harmonised System of Classification and Labelling of Chemicals, hereinafter "the GHS".

(6) This Regulation follows various declarations whereby the Community confirmed its intention to contribute to the global harmonisation of criteria for classification and labelling for substances and mixtures, not only at UN level, but also through the incorporation of the internationally agreed GHS criteria into Community law.

(7) The benefits for enterprises will increase as more countries in the world adopt the GHS criteria in their legislation. The Community should be at the forefront of this process to encourage other countries to follow and to provide a competitive advantage to industry in the Community.

(8) Therefore it is essential to harmonise the provisions for the classification and labelling of substances and mixtures within the Community, taking into account the classification criteria and labelling rules of the GHS, but also by building on the 40 years of experience obtained through implementation of existing Community chemicals legislation and maintaining the level of protection achieved through the system of harmonisation of classification and labelling, through Community hazard classes not yet part of the GHS as well as through current labelling and packaging rules.

(9) This Regulation is without prejudice to the full and complete application of the Community competition rules.

(10) 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 properly identify and communicate the hazards of their substances and mixtures. Such properties should include physical hazards as well as hazards to human health and to the environment, including hazards for the ozone layer.

(11) This Regulation should, as a general principle, apply to all substances and mixtures supplied in the Community, except where other Community legislation lays down more specific rules on classification and labelling, such as Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[20], Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[21], Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production[22], Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption[23], Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[24],

---

20 OJ L 262, 27.9.1976. Directive as last amended by Commission Directive 2005/80/EC (OJ L 303, 22.11.2005, p. 32).

21 OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).

22 OJ L 184, 15.7.1988, p. 61. Directive as last amended by Regulation (EC) No 1882/2003.

23 OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.

24 OJ L 189, 20.7.1990, p. 17.

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[25], Directive 98/79 of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[26], Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996[27], Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[28], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[29], Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[30] and Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[31] or where substances and mixtures are transported and governed by Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation[32], Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road[33], Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail[34] or Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC[35].

(12) Although ammunitions are not covered by this Regulation, explosives marketed to produce an explosive or pyrotechnic effect may, through their chemical composition, present hazards to health. It is therefore necessary as part of a transparent information process to classify them in accordance with the provisions of the Regulation, as this will also allow to label them in accordance with the international rules used for the transport of dangerous goods.

(13) The terms used in this Regulation should be consistent with those set out in Regulation (EC) No 1907/2006 of the European Parliament and of the Council of

---

25 OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

26 OJ L 331, 7.12.1998, p. 1. Directive as last amended by Regulation (EC) No 1882/2003.

27 OJ L 84, 27.3.1999, p. 1. Decision as last amended by Commission Decision 2006/22/EC (OJ L 91, 29.3.2006, p. 48).

28 OJ L 311, 28.11.2001, p. 1.

29 OJ L 311, 28.11.2001, p. 67.

30 OJ L 31, 1.2.2002, p. 1.

31 OJ L 268, 18.10.2003, p. 29. Regulation as last amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

32 OJ L 373, 31.12.1991, p. 4. Regulation as last amended by Regulation (EC) No 1899/20069 (OJ L 377, 27.12.2006, p. 1).

33 OJ L 319, 12.12.1994, p.7. Directive as last amended by Commission Directive 2006/89/EC (OJ L 305, 4.11.2006, p. 4).

34 OJ L 235, 17.9.1996, p. 25. Directive as last amended by Commission Directive 2006/90/EC (OJ L 305, 4.11.2006, p. 6).

35 OJ L 208, 5.8.2002, p. 10.

18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC of the European Parliament and of the Council and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[36] and with the definitions specified at UN level in the GHS, in order to ensure maximum consistency in the application of chemicals legislation within the Community in the context of global trade. The hazard classes specified in the GHS should be set out in this Regulation for the same reason.

(14) It is especially appropriate to include those hazard classes defined in the GHS which specifically take account of the fact that the physical hazards which may be exhibited by substances and mixtures are to some extent influenced by the way in which they are released.

(15) 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[37] as well as 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[38]. It should maintain the overall current level of protection of human health and the environment provided by those Directives. Therefore, some hazard classes which are covered by those Directives but are not yet included in the GHS, should be maintained in this Regulation. It is also necessary to maintain in this Regulation the concept of "dangerous" as defined by those Directives, which does not include those hazard classes which are part of the GHS but are not covered by Directives 67/548/EEC and 1999/45/EC, to minimise effects on other pieces of Community legislation referring to that concept.

(16) Responsibility for the identification of hazards of substances and mixtures and for deciding on their classification should mainly lie with the suppliers of those substances or mixtures, regardless of whether they are subject to the requirements of Regulation (EC) No 1907/2006. However, there should be a possibility to provide for harmonised classifications of substances for hazard classes of the highest concern which should be applied by all suppliers of such substances and of mixtures containing such substances.

(17) In cases of a decision to harmonise the classification of a substance for a specific hazard class or differentiation within a hazard class by including or revising an entry for that purpose in part 3 of Annex VI to this Regulation, the supplier should apply this harmonised classification, and only self-classify for the remaining, non-harmonised hazard classes or differentiations within the hazard class.

---

36 OJ L 396, 30.12.2006, p. 1.

37 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).

38 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).

(18) 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 in accordance with this Regulation themselves. Where distributors modify the label or the packaging of substances or mixtures, they should also be subject to the obligation to classify the substance or mixture in accordance with the provisions of this Regulation.

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

(20) While the supplier of any substance or mixture should not be obliged to generate new information for the purpose of classification, he should identify all relevant information available to him on the hazards of the substance or mixture and evaluate its quality; in doing so, the supplier should also take into account historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure and effect data and clinical studies. That information should be compared with the criteria for the different hazard classes and differentiations in order for him to arrive at a conclusion as to whether or not the substance or mixture should be classified as hazardous.

(21) While the classification of any substance or mixture may be carried out on the basis of available information, the available information to be used for the purposes of this Regulation should preferably comply with relevant provisions of Regulation (EC) No 1907/2006, transport provisions or international principles or procedures for the validation of information, so as to ensure quality and comparability of the results and consistency with other requirements at international or Community level. The same should apply where the supplier chooses to generate new information.

(22) To facilitate the hazard identification of mixtures, suppliers should base this identification on the data for the mixture itself, where available, except for mixtures with carcinogenic, germ cell mutagenic, reproductive toxic substances or sensitising properties or where the biodegradation or bioaccumulation properties in the hazard class hazardous to the aquatic environment are evaluated. In those cases, as the hazards of the mixture cannot be assessed sufficiently based on the mixture itself, the data for the individual substances of the mixture should normally be used as a basis for the hazard identification of the mixture.

(23) If sufficient information is available on similar tested mixtures, including relevant ingredients of the mixtures, it is possible to determine the hazardous properties of an untested mixture by applying certain rules known as “bridging principles.” Those rules allow characterisation of the hazards of the mixture without performing tests on it, but rather by building on the available information on similar tested mixtures. Where no test data are available for the mixture itself, suppliers should therefore follow the bridging principles to ensure adequate comparability of results of the classification of such mixtures.

(24) The protection of animals falling within the scope of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[39] is of high priority. Accordingly, where the supplier chooses to generate information for the purposes of this Regulation, he should first consider means other than testing on animals within the scope of Directive 86/609/EEC.

(25) New information as regards physical hazards should always be necessary, except if the data are already available or if a derogation is foreseen in part 2.

(26) For the purpose of classification, data should not be generated by means of testing on humans and non-human primates. Available, reliable epidemiological data and experience with regard to the effects of substances and mixtures on humans (e.g. occupational data and data from accident databases) should be taken into account and be given priority over data derived from animal studies when they demonstrate hazards not identified from those 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.

(27) Testing that is carried out for the sole purpose of this Regulation should be carried out on the substance or mixture in the form in which it is used or reasonably can be expected to be used. It should, however, be possible to use, for the purpose of this Regulation, the results of tests that are carried out to comply with other regulatory requirements, including those laid down by third countries, even if the tests were not carried out on the substance or mixture in the form in which it is used or can reasonably be expected to be used.

(28) The criteria for classification in different hazard classes and differentiations are set forth in Annex I, which also contains additional provisions as to how the criteria may be met.

(29) Recognising that the application of the criteria for the different hazard classes to information is not always straightforward and simple, suppliers should apply weight of evidence determinations involving expert judgment to arrive at adequate results.

(30) Specific concentration limits should be assigned to a substance by a supplier in accordance with the criteria referred to in this Regulation, provided the supplier is able to justify the limits and informs the European Chemicals Agency, hereinafter "the Agency", accordingly. Guidance should be provided by the Agency for the purpose of setting the specific concentration limits. In order to ensure uniformity, specific concentration limits should also be included, where appropriate, in cases of harmonised classifications. Specific concentration limits should take precedence over any other concentration limit for the purpose of classification.

(31) For reasons of proportionality and workability, generic cut-off values should be defined, both for impurities, additives and individual constituents of substances and

---

[39] OJ L 358, 18.12.1986, p.1. Directive as last amended by Directive 2003/65/EC (OJ L 230, 16.9.2003, p. 32).

for substances in mixtures, specifying when information on these should be taken into account in determining the hazard classification of substances and mixtures.

(32) To ensure adequate classification of mixtures, available information on synergistic and antagonistic effects should be taken into account for the classification of mixtures.

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

(34) Substances and mixtures classified as hazardous should be labelled and packaged according to their classification, so as to ensure appropriate protection and to provide essential information to their recipients, by drawing the attention to the hazards of the substance or mixture.

(35) The two components used to communicate the hazards of substances and mixtures are labels and the safety data sheets provided for in Regulation (EC) No 1907/2006. The label is the only tool for communication to consumers, but it may also serve to draw attention of workers to the more comprehensive information on substances or mixtures provided in safety data sheets. Since the provisions on safety data sheets are included in Regulation (EC) No 1907/2006 which uses the safety data sheet as the main communication tool within the supply chain of substances, it is appropriate not to duplicate the same provisions in this Regulation.

(36) Workers and consumers worldwide would benefit from a globally harmonised hazard communication tool in the form of labelling. Therefore, the elements to be included in labels should be specified in accordance with the hazard pictograms, signal words, hazard statements and precautionary statements which form the core information of the GHS system. Other information included in labels should be limited to a minimum and should not call into question the main elements.

(37) It is essential that the substances and mixtures placed on the market be well identified, however, the Agency should allow enterprises, where necessary, to describe the chemical identity in a way that does not put the confidential nature of their businesses at risk.

(38) The International Union of Pure and Applied Chemistry (IUPAC) is a long standing global authority on chemical nomenclature and terminology. Identification of substances by their IUPAC name is widespread practice worldwide and provides the standard basis for identifying substances in an international and multilingual context. It is therefore appropriate to use these names for the purposes of this Regulation.

(39) The Chemical Abstracts Service (CAS) provides a system whereby substances are added to the CAS Registry and are assigned a unique CAS Registry Number. Those CAS numbers are used in reference works, databases, and regulatory compliance documents throughout the world to identify substances without the ambiguity of chemical nomenclature. It is therefore appropriate to use the CAS numbers for the purposes of this Regulation.

(40) To limit the information on the label to the most essential information, principles of precedence should determine the most appropriate label elements for cases in which substances or mixtures possess several hazardous properties.

(41) The labelling rules in this Regulation should be without prejudice to Council Directive 91/414/EEC concerning the placing of plant protection products on the market[40] and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market[41].

(42) Rules for the application of labels and the location of information on labels are necessary to ensure that the information on labels can be easily understood. Statements such as "non-toxic", "non-harmful", "non-polluting", "ecological" or other statements inconsistent with the classification are therefore inappropriate and are not to appear on the labels of hazardous substances or mixtures.

(43) This Regulation should set general packaging standards, in order to ensure the safe supply of hazardous substances and mixtures.

(44) Resources of the authorities should be focused on substances of the highest concern. Provision should therefore be made to enable competent authorities or suppliers to submit proposals to the Agency for a harmonised classification of substances classified for carcinogenicity, germ cell mutagenicity or reproductive toxicity categories 1A or 1B, for respiratory sensitisation, or in respect of other effects on a case-by-case basis. The Agency should give its opinion on the proposal while interested parties should have an opportunity to comment. The Commission should decide on the final classification.

(45) In order to take full account of the work and experience accumulated under Directive 67/548/EEC, including the classification and labelling of specific substances listed in Annex I of Directive 67/548/EEC, all existing harmonised classifications should be converted into new harmonised classifications using the new criteria. Moreover, as the applicability of this Regulation is deferred and the harmonised classifications in accordance with the criteria of Directive 67/548/EEC are relevant for the classification of substances and mixtures during the ensuing transition period, all existing harmonised classifications should also be placed unchanged in an Annex to this Regulation. By subjecting all future harmonisations of classifications to the provisions of this Regulation, inconsistencies in harmonised classifications of the same substance under the existing and the new criteria should be avoided.

(46) In order to achieve the functioning of the internal market for substances and mixtures, while at the same time ensuring a high level of protection for human health and the environment, rules should be established for a classification and labelling inventory. The classification and labelling for any substance placed on the market should therefore be notified to the Agency to be included in the inventory.

---

[40] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2007/6/EC (OJ L 43, 15.2.2007, p. 13).

[41] OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2006/140/EC (OJ L 414, 30.12.2006, p. 78).

(47) Different suppliers of the same substance should make every effort to agree on a single classification for that substance except for hazard classes and differentiations subject to a harmonised classification for that substance.

(48) To ensure a harmonised protection for the general public, and, in particular, for persons who come into contact with certain substances, and the proper functioning of other Community legislation relying on classification and labelling, an inventory should record the classification in accordance with this Regulation agreed by manufacturers and importers of the same substance, if possible, as well as decisions taken at Community level to harmonise the classification and labelling of some substances.

(49) The information included in the classification and labelling inventory should benefit from the same degree of accessibility and protection as that afforded by Regulation (EC) No 1907/2006, especially with regard to information which, if disclosed, risks to jeopardise the commercial interests of those concerned.

(50) 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. Member States should put in place effective monitoring and control measures in order to ensure compliance with this Regulation.

(51) 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.

(52) In order to provide focal points for information on hazardous substances and mixtures, Member States should appoint bodies responsible for receiving information relating to health in addition to the competent authorities for the application and enforcement of this Regulation.

(53) 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.

(54) The Forum for the exchange of information on enforcement in the Agency, established by Regulation (EC) No 1907/2006, should also exchange information about the enforcement of this Regulation.

(55) 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 with a view to imposing effective, proportionate and dissuasive penalties for non-compliance with this Regulation, as non-compliance can result in damage to human health and the environment.

(56) Rules should be laid down requiring advertisements for substances meeting the criteria for classification according to this Regulation to mention the associated hazards, in order to protect recipients of substances, including consumers. Advertisements for

mixtures classified as hazardous should mention the type of hazards, for the same reason.

(57) A safeguard procedure should be foreseen to address situations where a substance or a mixture constitutes a risk for human health or the environment, even if it, in compliance with this Regulation, is not classified as hazardous. Should such a situation occur, action at the UN level may be necessary, in view of the global nature of trade in substances and mixtures.

(58) While many of the obligations on enterprises established by Regulation (EC) No 1907/2006 are triggered by classification, this Regulation should not alter the scope and impact of that Regulation. To ensure this, this Regulation maintains the concept of "dangerous" as defined by Directives 67/548/EEC and 1999/45/EC.

(59) It is appropriate to provide for a deferred applicability of this Regulation so that a smooth transition to the new system may be ensured. Moreover, this 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, and because the classification of mixtures depends on the classification of substances, the provisions for the classification of mixtures should only be applied after the reclassification of all substances. If operators choose to apply the classification criteria contained in this Regulation earlier on a voluntary basis, this should be allowed, but to avoid confusion the labelling should in that case comply with the provisions of this Regulation instead of the provisions of Directives 67/548/EEC or 1999/45/EC.

(60) To avoid unnecessary burdens on enterprises, substances and mixtures which are already going through the supply chain when the labelling provisions of this Regulation become applicable to them, should not be required to be relabelled.

(61) Since the objectives of this Regulation, namely harmonising the classification, labelling and packaging rules for substances and mixtures, providing an obligation to classify and establishing a harmonised list of substances classified at Community level as well as a classification and labelling inventory cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(62) The Regulation observes the fundamental rights and principles which are acknowledged in particular in the Charter of Fundamental Rights of the European Union[42].

(63) The measures necessary for the implementation of this Regulation 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[43].

---

42 OJ C 364, 18.12.2000, p. 1.

(64) In particular, power should be conferred on the Commission to adapt this Regulation to technical progress, including incorporating amendments made at UN level to the GHS. In carrying out such adaptations to technical progress the biannual working rhythm at UN level should be considered. Furthermore, powers should be conferred on the Commission for the purpose of deciding on the harmonised classification and labelling of specific substances. Since those measures are of general scope and are designed to amend non-essential elements of this Regulation, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(65) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a (6) of Decision 1999/468/EC for the adoption of adaptations to technical progress.

(66) The Commission should also for the purposes of this Regulation be assisted by the Committee established by Regulation (EC) No 1907/2006, with a view to ensuring a consistent approach to the updating of chemicals legislation,

HAVE ADOPTED THIS REGULATION:

TITLE I
GENERAL ISSUES

Article 1
Subject matter and Scope

1. This Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances and mixtures as defined in points 1 and 2 of Article 3 in Regulation (EC) No 1907/2006 by providing for the following:

   (a) harmonising the classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;

   (b) providing an obligation for suppliers to classify substances and mixtures;

   (c) providing an obligation for suppliers to notify such classifications and for registrants to submit such classifications as part of their registrations to the European Chemicals Agency, hereinafter the Agency;

   (d) establishing a list of substances with their harmonised classifications and labelling at Community level in part 3 of Annex VI;

---

[43] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L200, 22.7.2006, p. 11).

(e) establishing a classification and labelling inventory, which is made up of all notifications, submissions and harmonised classifications referred to in points (c) and (d).

2. This Regulation shall not apply to the following:

(a) radioactive substances and mixtures within the scope of Council Directive 96/29/Euratom[44];

(b) 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;

(c) non-isolated intermediates as defined in point 15(a) of Article 3 in Regulation (EC) No 1907/2006;

(d) 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, germ cell 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[45] is not a substance, mixture or article within the meaning of paragraph 1.

4. This Regulation shall not apply to substances and mixtures in the following forms, which are in the finished state, intended for the final user:

(a) medicinal products as defined in Directive 2001/83/EC;

(b) veterinary medicinal products as defined in Directive 2001/82/EC;

(c) cosmetic products as defined in Directive 76/768/EEC;

(d) medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC;

(e) food or feedingstuffs as defined in Regulation (EC) No 178/2002 including when they are used:

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

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

---

44 OJ L 159, 29.6.1996, p. 1.

45 OJ L 114, 27.4.2006, p. 9.

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

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

5. Save where Article 19 applies, this Regulation shall not apply to cases governed by Regulation (EEC) No 3922/91, Directive 94/55/EC, Directive 96/49/EC or Directive 2002/59/EC.

Article 2
Definitions

For the purpose of this Regulation, the definitions in points 1 to 14, the introductory phrase in point 15 and (a) of that point, points 23 and 24 of Article 3 of Regulation (EC) No 1907/2006 shall apply.

In addition, the following definitions shall apply:

(1) *hazard class* means the nature of the physical, health or environmental hazard;

(2) *hazard category* means the division of criteria within each hazard class, specifying hazard severity;

(3) *supplier* means a manufacturer, importer, downstream user or distributor placing on the market a substance or a mixture;

(4) *competent authority* means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation.

Alloys as defined in point 41 of Article 3 in Regulation (EC) No 1907/2006 shall be considered as mixtures for the purposes of this Regulation.

Article 3
Hazardous substances and mixtures and specification of hazard classes

1. A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex.

Where, in the case of the hazard classes referred to in sections 3.1, 3.4, 3.7, 3.8 and 4.1 of Annex I, those classes are differentiated on the basis of the route of exposure or the nature of the effects, the substance or mixture shall be classified in accordance with such differentiation.

2. A substance or mixture fulfilling the criteria for any of the following hazard classes or categories set out in Annex I is dangerous:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1.

3. The Commission may develop further differentiations for hazard classes on the basis of the route of exposure or the nature of the effects and shall amend the second subparagraph of paragraph 1 as a result. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3).

Article 4

General obligation to classify, label and package

1. Manufacturers, importers and downstream users shall classify substances or mixtures in accordance with Title II before placing them on the market.

Where a substance or mixture is classified as hazardous, it shall be labelled and packaged in accordance with Titles III and IV.

2. For the purposes of this Regulation, the articles referred to in section 2.1 of Annex I shall be classified, labelled and packaged in accordance with the rules for substances and mixtures.

3. Manufacturers, producers of articles and importers shall, in addition to the classification provided for in paragraph 1, classify substances in accordance with Title II where

(a) Articles 6, 7 (1) or (5), 17 or 18 of Regulation (EC) No 1907/2006 provide for registration of a substance;

(b) Articles 7 (2) or 9 of Regulation (EC) No 1907/2006 provide for notification.

4. Where a distributor modifies the original label or packaging provided by any of the actors referred to in paragraph 1 for the purpose of placing a substance or mixture classified as hazardous on the market, the distributor shall fulfil the requirements set out in Titles II, III and IV.

In all other cases, the distributor shall ensure that the labelling or packaging provided by those operators is correct and unchanged.

5. A mixture referred to in part 2 of Annex II not classified as hazardous but containing at least one substance classified as hazardous, shall not be placed on the market, unless it is labelled in accordance with Title III.

6. If a substance is subject to harmonised classification and labelling in accordance with Title V through an entry in part 3 of Annex VI, the supplier shall classify that substance in accordance with that entry, and a classification of the substance in

accordance with Title II shall not be performed for the hazard classes or differentiations covered by that entry.

However, where the substance also falls within one or more hazard classes or differentiations not covered by an entry in part 3 of Annex VI, classification under Title II shall be carried out for those hazard classes or differentiations.

TITLE II
HAZARD CLASSIFICATION

Chapter 1
Identification and examination of Information

Article 5

Identification and examination of available information on substances

1. The supplier of a substance shall identify the relevant available information for the purposes of determining whether the substance entails a physical, health or environmental hazard as set out in Annex I, and, in particular, the following:

   (a) data generated in accordance with any of the methods referred to in Article 8 (3);

   (b) epidemiological data and experience on the effects on humans;

   (c) any other information generated in accordance with section 1 of Annex XI to Regulation (EC) No 1907/2006.

   The information shall relate to the form or physical state in which the substance is used or can reasonably be expected to be used after it is placed on the market.

2. The supplier shall examine the information referred to in paragraph 1 to ascertain whether it is adequate and reliable for the purpose of the evaluation pursuant to Chapter 2.

Article 6

Identification and examination of available information on mixtures

1. The supplier of a mixture shall identify the relevant available information for the purposes of determining whether the mixture entails a physical, health or environmental hazard as set out in Annex I, and, in particular, the following:

   (a) data generated in accordance with any of the methods referred to in Article 8 (3) on the mixture itself or the substances contained in it;

   (b) epidemiological data and experience on the effects on humans for the mixture itself or the substances contained in it;

(c) any other information generated in accordance with section 1 of Annex XI to Regulation (EC) No 1907/2006 for the mixture itself or the substances contained in it.

The information shall relate to the form or physical state in which the mixture is used or can reasonably be expected to be used after it is placed on the market.

2. Subject to paragraphs 3 and 4, where the information referred to in paragraph 1(a) is available for the mixture itself, and the supplier has ascertained that information to be adequate and reliable, he shall use that information for the purposes of the evaluation pursuant to Chapter 2.

3. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'germ cell mutagenicity', 'carcinogenicity' and 'reproductive toxicity' hazard classes referred to in sections 3.5.3.1, 3.6.3.1 and 3.7.3.1 of Annex I, the supplier shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture.

Further, in cases where the available test data on the mixture itself demonstrate germ cell mutagenic, carcinogenic or toxic to reproduction effects which have not been identified from the information on the individual substances, those data shall also be taken into account.

4. For the evaluation of mixtures pursuant to Chapter 2 in relation to the 'biodegradation and bioaccumulation' properties within the 'hazardous to the aquatic environment' hazard class referred to in section 4.1.2.8 of Annex I, the supplier shall only use the relevant available information referred to in paragraph 1 for the substances in the mixture.

5. Where no test data on the mixture itself of the kind referred to in paragraph 1 are available, the supplier shall use other available information on individual substances and similar tested mixtures which may also be considered relevant for the purposes of determining whether the mixture is hazardous, provided that he has ascertained that information to be adequate and reliable for the purpose of the evaluation pursuant to Article 9(4).

Article 7
Animal and human testing

1. Where new tests are carried out for the purposes of this Regulation, tests on animals within the meaning of Directive 86/609/EEC shall be undertaken only where no other alternatives are possible.

2. Tests on humans and non-human primates shall not be performed for the purposes of this Regulation.

Article 8

Generating new information for substances and mixtures

1. For the purposes of determining whether a substance or a mixture entails a health or environmental hazard as set out in Annex I, the supplier may, provided that he has exhausted all other means of generating information including by applying the rules provided for in section 1 of Annex XI to Regulation (EC) No 1907/2006, perform new tests.

2. For the purposes of determining whether a substance or a mixture entails any of the physical hazards referred to in part 2 of Annex I, the supplier shall perform the tests required in that part, unless the data resulting from those tests are already available.

3. The tests referred to in paragraphs 1 and 2 shall be conducted in accordance with one of the following methods:

   (a) the test methods in the fourth 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/Rev.4[46];

   (b) the test methods referred to in Article 13 (3) of Regulation (EC) No 1907/2006;

   (c) in respect of health and environmental hazards as set out in parts 3 and 4 of Annex I, internationally recognised scientific principles or methods validated according to international procedures.

   Where the supplier carries out new ecotoxicological or toxicological tests and analyses, they shall be carried out in compliance with Article 13(4) of Regulation (EC) No 1907/2006.

4. Tests that are carried out for the purposes of this Regulation, shall be carried out on the substance or on the mixture in the form in which it is used or reasonably can be expected to be used after it is placed on the market.

Chapter 2
Evaluation of Hazard Information and Decision on Classification

Article 9

Evaluation of hazard information for substances and mixtures

1. The supplier of a substance or a mixture shall evaluate the information identified in accordance with Chapter 1 by applying to it the criteria for classification for each hazard class or differentiation in parts 2 to 5 of Annex I, so as to ascertain the hazards associated with the substance or mixture.

---

[46] OJ […] The text of the fourth revised edition of the UN RTDG Manual of Tests and Criteria will be published as soon as it is available in all official languages of the Community.

2. In evaluating available test data for a substance or a mixture which have been obtained from test methods other than those referred to in Article 8 (3), the supplier shall compare the test methods employed with those indicated in that Article in order to determine whether the use of those test methods affects the evaluation referred to in paragraph 1.

3. Where the criteria cannot be applied directly to available identified information, the supplier shall carry out an evaluation by applying a weight of evidence determination using expert judgement in accordance with section 1.1.1 of Annex I, weighing all available information having a bearing on the determination of the hazards of the substance or the mixture, and in accordance with section 1.2 of Annex XI of Regulation (EC) No 1907/2006.

4. Where only the information referred to in Article 6(5) is available, the supplier shall apply the bridging principles referred to in section 1.1.3 and in each section of parts 3 and 4 of Annex I for the purposes of the evaluation.

However, where that information does not permit the application of the bridging principles, the supplier shall evaluate the information by applying the other method or methods described in each section of parts 3 and 4 of Annex I.

Article 10

Specific concentration limits and multiplying factors for classification of substances and mixtures

1. Subject to paragraph 3, specific concentration limits whereby a threshold is indicated on or over which the presence of that substance in another substance or in a mixture as an impurity, additive or individual constituent may lead to the classification of the substance or mixture as hazardous may be set by the supplier in the following situations:

(a) where information shows that the hazard of a substance is evident when it is present at a level below the concentrations set for any hazard class in part 2 of Annex I or below the generic concentration limits set for any hazard class in parts 3 to 5 of Annex I;

(b) in exceptional cases, where information shows that a substance classified as hazardous is present at a level above the concentrations set for any hazard class in part 2 of Annex I or above the generic concentration limits set for any hazard class in parts 3 to 5 of that Annex, but there are conclusive data showing that the hazard of the substance is not evident.

2. Subject to paragraph 3, multiplying factors, hereinafter referred to as “m-factors”, describing the severity of acute aquatic toxicity shall be established by the supplier when the acute aquatic toxicity of the substance is below 1 mg/litre for determining the classification of a mixture for environmental hazards.

3. Specific concentration limits or m-factors shall not be set in accordance with paragraph 1 and 2 for hazard classes or differentiations included in part 3 of Annex VI.

4. In setting the specific concentration limit or m-factor the supplier shall take into account any specific concentration limits or m-factors for that substance which have been included in the classification and labelling inventory.

5. Specific concentration limits set in accordance with paragraph 1 shall take precedence over the concentrations in the relevant sections of part 2 of Annex I or the generic concentration limits for classification in the relevant sections of parts 3 to 5 of Annex I.

6. The Agency shall provide further guidance for the application of paragraphs 1 and 2.

Article 11
Cut-off values

1. Where a substance contains another substance, classified as hazardous itself, in the form of an impurity, additive or individual constituent, this information shall be taken into account for the purposes of classification, if the concentration of the impurity, additive or individual constituent is equal to or greater than its cut-off value referred to in paragraph 3.

2. Where a mixture contains a substance classified as hazardous, either as a component or in the form of an impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value referred to in paragraph 3.

3. The cut-off value referred to in paragraphs 1 and 2 shall be the lower of the following:

   (a) the generic cut-off values specified in Table 1.1 of part 1 of Annex I;

   (b) any specific concentration limits set in part 3 of Annex VI or in the classification and labelling inventory referred to in Article 43;

   (c) any concentrations in the relevant sections of part 2 of Annex I or any generic concentration limits for classification in the relevant sections of parts 3 to 5 of Annex I, where the specific concentration limits referred to in point b are not available.

Article 12
Specific cases requiring further evaluation

Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, the supplier shall take them into account for the purposes of classification:

(a) where adequate and reliable information demonstrates that in practice the physical properties of a substance or a mixture other than an organic peroxide differ from those shown by tests;

(b) where conclusive experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable;

(c) where adequate and reliable information demonstrates the potential occurrence of synergistic or antagonistic effects among the substances in a mixture for which the evaluation was decided on the basis of the information for the substances in the mixture.

Article 13
Decision to classify substances and mixtures

If the evaluation undertaken pursuant to Article 9 and Article 12 shows that the hazards associated with the substance or mixture meet the criteria for classification in one or more hazard classes or differentiations in parts 2 to 5 of Annex I, the supplier shall classify the substance or mixture in relation to the relevant hazard class or classes or differentiations by assigning the following:

(a) one or more hazard categories for each relevant hazard class or differentiation;

(b) subject to Article 21, one or more hazard statements corresponding to each hazard category assigned in accordance with (a).

Article 14
Specific rules for the classification of mixtures

1. The classification of a mixture shall not be affected where the evaluation of the information indicates any of the following:

   (a) that the substances in the mixture react slowly with atmospheric gases, in particular oxygen, carbon dioxide, water vapour, to form different substances;

   (b) that the substances in the mixture react very slowly with other substances in the mixture to form different substances;

   (c) that the substances in the mixture may self-polymerize to form oligomers or polymers.

2. A mixture need not be classified for explosive, oxidising, or flammable properties as referred to in part 2 of Annex I provided that any of the following requirements are met:

   (a) none of the substances in the mixture possesses such properties and, on the basis of the information available to the supplier, the mixture is unlikely to present hazards of this kind;

   (b) in the event of a change in the composition of a mixture of known composition, scientific evidence indicates that an evaluation of the information on the mixture will not lead to a change in classification;

(c) where a mixture is placed on the market in the form of an aerosol, it satisfies the provisions of Article 9a of Council Directive 75/324/EEC[47].

Article 15

Review of classification for substances and mixtures

1. Subject to paragraph 3, where the supplier of a substance or mixture may reasonably be expected to have become aware of new scientific or technical information that he has ascertained to be adequate and reliable for the purposes of the evaluation pursuant to this Chapter and that warrants a change in the classification of the substance or mixture, he shall carry out a new evaluation of that information in accordance with this Chapter.

2. Where the supplier introduces a change to a mixture of a known composition, that has been classified as hazardous, he shall carry out a new evaluation in accordance with this Chapter where the change is either of the following:

   (a) a change in the composition of the initial concentration of one or more of the hazardous constituents in concentrations above the limits in Table 1.2 of part 1 of Annex I;

   (b) a change in the composition involving the substitution or addition of one or more constituents in concentrations which meet the cut-off value referred to in Article 11 (3).

   Where the mixture concerned is covered by Directive 91/414/EEC or Directive 98/8/EC the first subparagraph shall not apply.

3. A new evaluation in accordance with paragraphs 1 and 2 shall not be required if there is valid scientific justification that this will not result in a change of classification.

4. The supplier shall adapt the classification of the substance or the mixture in accordance with the results of the new evaluation.

Article 16

Classification of substances included in the classification and labelling inventory

1. A supplier may classify a substance differently from the classification already included in the classification and labelling inventory, provided he submits the reasons for his classification to the Agency together with the notification in accordance with Article 41.

2. Paragraph 1 shall not apply if the classification included in the classification and labelling inventory is a harmonised classification included in part 3 of Annex VI.

---

47 OJ L 147, 9.6.1975, p.40.

TITLE III
HAZARD COMMUNICATION IN FORM OF LABELLING

Chapter 1
Content of the Label

Article 17
General rules

1. A substance or mixture classified as hazardous shall bear a label including the following elements:

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

   (b) the nominal quantity of a substance or mixture in the packages made available to the general public, unless this quantity is specified elsewhere on the package;

   (c) product identifiers in accordance with Article 18;

   (d) where appropriate, hazard pictograms in accordance with Article 19;

   (e) where appropriate, signal words in accordance with Article 20;

   (f) where appropriate, hazard statements in accordance with Article 21;

   (g) where appropriate, precautionary statements in accordance with Article 22;

   (h) where appropriate, a section for supplemental information in accordance with Article 27.

2. Member States may require the use of their official language or languages on the label when substances and mixtures covered by this Regulation are made available to the end user within their territories.

   Suppliers may use more languages on their labels than those required by the Member States, provided that the same particulars appear in all languages used.

Article 18
Product identifiers

1. The label shall include details permitting the identification of the substance or mixture, hereinafter "product identifiers".

   The term used for identification of the substance or mixture shall be the same as that used in the safety data sheet drawn up in accordance with Article 31 of Regulation (EC) No 1907/2006.

2. The product identifier for a substance shall consist of at least the following:

(a) if the substance is included in part 3 of Annex VI, a name and an identification number as given therein;

(b) if the substance is not included in part 3 of Annex VI, but appears in the classification and labelling inventory, a name and an identification number as given therein;

(c) if the substance is not included in part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the Chemical Abstracts Service, hereinafter "the CAS number", together with the name set out in the nomenclature provided by the International Union of Pure and Applied Chemistry, hereinafter "the IUPAC Nomenclature", or the CAS number together with another international chemical name;

(d) if the CAS number is not available, the name set out in the IUPAC Nomenclature or another international chemical name.

Where the name in the IUPAC nomenclature exceeds 100 characters, a common name may be used provided that the notification in accordance with Article 41 includes both the name in the IUPAC Nomenclature and the common name used.

3. The product identifier for a mixture shall consist of both of the following:

(a) the trade name or the designation of the mixture;

(b) the identity of all substances in the mixture that contribute to acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, or specific target organ toxicity (STOT).

Where, in the case referred to in (b), that requirement leads to the provision of multiple chemical names, a maximum of four chemical names shall suffice, unless necessary as a consequence of the severity of the hazards.

The chemical names selected shall identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding hazard statements.

Article 19
Hazard pictograms

1. The label shall include the relevant hazard pictograms consisting of a symbol together with other graphic elements, intended to convey specific information on the hazard concerned.

2. Hazard pictograms shall fulfil the requirements laid down in section 1.2.1 of Annex I and in Annex V.

3. The hazard pictogram relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in parts 2, 3 and 4 of Annex I.

4. The Commission may set hazard pictograms for other hazard classes than those referred to in paragraph 3. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3).

Article 20
Signal words

The following signal words shall be used on the label:

(a) 'danger', indicating the more severe hazard categories;

(b) 'warning', indicating the less severe hazard categories.

Where the signal word 'danger' is used on the label, the word 'warning' shall not appear on the label.

The signal word relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in parts 2 to 5 of Annex I.

Article 21
Hazard statements

1. The label shall include the relevant hazard statements describing the nature of the hazards of a hazardous substance or mixture, including, where appropriate, the degree of hazard.

2. The hazard statement relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in parts 2 to 5 of Annex I.

However, where a substance is included in part 3 of Annex VI, the hazard statement relevant for each specific classification covered by the entry in that part shall be used on the label, together with the hazard statements referred to in the first subparagraph for any classification not covered by that entry.

3. The hazard statements shall be worded in accordance with Annex III.

Article 22
Precautionary statements

1. The label shall include the relevant precautionary statements, whereby a description is provided in the form of a phrase or pictogram of the measure or measures recommended to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use.

2. The precautionary statement relevant for each specific classification is set out in the tables indicating the label elements required for each hazard class in parts 2 to 5 of Annex I.

However, where a substance is included in part 3 of Annex VI, the precautionary statements relevant for each specific classification covered by the entry in that part shall be used on the label, together with the precautionary statements referred to in the first subparagraph for any specific classification not covered by that entry.

3. The precautionary statements shall be selected in accordance with the criteria laid down in part 1 of Annex IV taking into account the hazard statements and the intended or identified use or uses of the substance or the mixture.

4. The precautionary statements shall be worded in accordance with part 2 of Annex IV.

Article 23

Specific rules relating to classification in accordance with part 5 of Annex I

Where a substance or mixture is classified in accordance with part 5 of Annex I the following shall apply:

(a) a hazard pictogram shall not be included on the label;

(b) the signal words, hazard statements and precautionary statements shall be placed in the supplemental information section as referred to in Article 27.

Article 24

Specific rules relating to mixtures not classified as hazardous

A mixture not classified as hazardous but containing at least one substance classified as hazardous shall be labelled in accordance with part 2 of Annex II.

The statements shall be worded in accordance with part 3 of Annex III.

The label shall also include the product identifier referred to in Article 18 and the name, address and telephone number of the manufacturer, importer or downstream user of the mixture concerned.

Article 25

Specific rules relating to certain packaging and certain substances and mixtures

1. The specific provisions on labelling laid down in section 1.3 of Annex I shall apply in respect of the following:

(a) mobile gas cylinders;

(b) gas containers intended for propane, butane or liquefied petroleum gas;

(c) aerosols and containers fitted with a sealed spray attachment and containing substances classified as presenting an aspiration hazard;

(d) metals in massive form, alloys, mixtures containing polymers, mixtures containing elastomers;

(e) explosives, as referred to in point (c) of section 2.1 of Annex I, placed on the market with a view to obtaining an explosive or pyrotechnic effect.

2. The Commission may add further packaging, substances or mixtures to those referred to in paragraph 1 to which specific provisions on labelling shall apply. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3).

Article 26
Request for confidentiality

1. The supplier of a substance or a mixture may submit a request to the Agency to use a product identifier which refers to a substance or mixture either by means of a name that identifies the most important functional chemical groups or by means of a common name, where he can demonstrate that the disclosure on the label of the chemical identity of a substance or mixture puts the confidential nature of his business, in particular his intellectual property rights, at risk

2. Any request referred to in paragraph 1 shall be made in the format referred to in Article 111 of Regulation (EC) No 1907/2006 and shall be accompanied by a fee.

The level of the fees shall be determined by the Commission in accordance with the procedure referred to in Article 54 (2).

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

4. Where the supplier of a mixture, before 1 June 2015, has demonstrated under Article 15 of Directive 1999/45/EC that the disclosure of the chemical identity of a substance puts the confidential nature of his business at risk, he can continue to use the approved alternative name for the purposes of this Regulation.

Article 27
Supplemental information on the label

1. Statements shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous has the physical properties or health properties referred to in sections 1.1 and 1.2 of Annex II.

The statements shall be worded in accordance with sections 1.1 and 1.2 of Annex II and part 2 of Annex III.

2. A statement shall be included in the section for supplemental information on the label where a substance or mixture classified as hazardous falls within the scope of Directive 91/414/EEC.

The statement shall be worded in accordance with part 4 of Annex II and part 3 of Annex III.

3. The supplier may include supplemental information in the section for supplemental information on the label other than that referred to in paragraphs 1 and 2, provided that that information does not make it more difficult to identify the label elements referred to in Article 17(1) (a) to (g) and that it provides further details and does not contradict or cast doubt on the validity of the information specified by those elements.

Article 28

Principles of precedence as regards the hazard pictograms

1. If a substance or mixture is classified within several hazard classes or within several differentiations of one or more hazard classes, the following shall apply in respect of the hazard pictograms to be applied on the label:

(a) if the hazard pictogram "GHS01" applies, the use of the hazard pictograms "GHS02" and "GHS03" shall be optional;

(b) if the hazard pictogram "GHS06" applies, the hazard pictogram "GHS07" shall not appear;

(c) if the hazard pictogram "GHS05" applies, the hazard pictogram "GHS07" shall not appear for skin or eye irritation;

(d) if the hazard pictogram "GHS08" applies, the hazard pictogram "GHS07" shall not appear for skin sensitisation or for skin and eye irritation.

2. If a substance or mixture is classified within several differentiations of one or more hazard classes, the label shall include the most severe hazard pictogram for each hazard class concerned.

In cases where the entry included in part 3 of Annex VI for the substance corresponds to a less severe hazard category than that resulting from the classification pursuant to Title II of that substance in relation to that hazard class, the label shall include the hazard pictogram corresponding to the most severe hazard category.

Article 29

Principles of precedence as regards the hazard statements

If a substance or mixture is classified both within several hazard classes and differentiations of a hazard class, all hazard statements resulting from the classification shall appear on the label, unless there is evident duplication or redundancy.

Article 30

Principles of precedence as regards the precautionary statements

1. Where the selection of the precautionary statements results in certain precautionary statements being redundant or ambiguous or being clearly unnecessary given the specific substance, mixture or packaging, such statements shall be omitted from the label.

2. Where the substance or mixture is sold to the general public, one precautionary statement addressing the disposal of that substance or mixture shall appear on the label, where appropriate.

   In other cases, a precautionary statement addressing the disposal shall not be required, if it is clear that the disposal of the substance or mixture or the packaging does not present a hazard to human health or the environment.

3. Not more than six precautionary statements shall appear on any label, unless necessary as a consequence of the severity of the hazards.

Article 31

Exemptions from labelling for small or otherwise unsuitable packaging

1. For packaging containing 125 ml or less, hazard and precautionary statements need not be indicated on the label, if the substance or mixture is classified as:

   (a) Flammable Gas of category 2;

   (b) Flammable Liquid of category 2 or 3;

   (c) Flammable Solid of category 1 or 2;

   (d) Substances which in contact with water emit Flammable Gases of categories 2 or 3;

   (e) Oxidising Liquid of category 2 or 3;

   (f) Oxidising Solid of category 2 or 3;

   (g) Acutely Toxic of category 4, if the substances or mixtures are not supplied to the general public;

   (h) Skin Irritant of category 2;

   (i) Eye Irritant of category 2;

(j) Acutely Aquatic Hazardous of category 1;

(k) Chronically Aquatic Hazardous of category 1,2, 3 and 4.

2. Where the Commission so requests, the Agency shall prepare and submit to the Commission draft exemptions from the obligations to label provided for in Articles 17 and 34 as follows:

(a) where the packaging is either too small or otherwise unsuitable for affixing the label, the conditions for applying the label elements;

(b) where packaging contains a quantity other than 125 ml which does not entail a risk to workers or human health or the environment, the quantities and the appropriate exemptions from the labelling requirements for substances and mixtures classified as follows:

(i) Flammable Gases;

(ii) Oxidising Gases;

(iii) Flammable Liquids ;

(iv) Flammable Solids ;

(v) Substances which in contact with water emit Flammable Gases;

(vi) Oxidising Liquids;

(vii) Oxidising Solids;

(viii) Acutely Toxic of category 4;

(ix) Skin Irritant of category 2;

(x) Eye Irritant of category 2;

(xi) Hazardous to the Environment.

Article 32

Exemption from labelling for substances and mixtures sold to the general public

Packaging destined for the general public on which it is physically impossible to apply a label in accordance with Article 34, shall be exempted from the obligation to bear a label, provided that such packaging is accompanied by precise and clear instructions for use, including, where appropriate, instructions for its disposal, and provided that it contains substances or mixtures classified in accordance with the following hazard classes and categories in Annex I:

(a) Section 3.1, acute toxicity category 1, 2 or 3;

(b) Section 3.2, skin corrosion category 1;

(c) Section 3.8, specific target organ toxicity (STOT) – single exposure category 1;

(d) Section 3.9, specific target organ toxicity (STOT) – repeated exposure category 1.

Article 33
Updating information on labels

The supplier of a substance or a mixture shall update the label without delay following any change to the classification and labelling of the substance or mixture.

The supplier of a mixture referred to in Article 24 shall update the label without delay following any change to the classification of the substance and the labelling of the mixture.

This Article shall be without prejudice to Directives 91/414/EEC and 98/8/EC.

Chapter 2
Application of Labels

Article 34
General rules for the application of labels

1. Labels shall be firmly affixed to one or more surfaces of the packaging immediately containing the substance or mixture and shall be readable 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 label elements referred to in Article 17 (1) shall be clearly and indelibly marked. They shall stand out clearly from the background and be of such size and spacing as to be easily read.

4. The shape and the size of a hazard pictogram as well as the dimensions of the label shall be as set out in section 1.2.1 of Annex I.

5. A label shall not be required when the label elements referred to in Article 17 (1) are shown clearly on the packaging itself. In such cases, the requirements of this Chapter applicable to a label shall be applied to the information shown on the packaging.

Article 35
Location of information on the label

1. The hazard pictograms, signal word, hazard statements and precautionary statements shall be located together on the label.

2. The supplier may decide the order of the hazard and precautionary statements on the label, unless otherwise specified.

3. The supplemental information shall be placed in the supplemental information section as referred to in Article 27 and the location of that section shall not make it more difficult to identify the elements specified in Article 17 (1).

4. In addition to its use in hazard pictograms, colour may be used on other areas of the label to implement special labelling requirements.

5. Label elements resulting from the requirements provided for in Annex XVII of Regulation (EC) No 1907/2006, Article 16 of Directive 91/414/EEC and Article 20 of Directive 98/8/EC shall be placed in the section for supplemental label information referred to in Article 27.

6. The Commission may adopt measures adding to paragraph 5 other Community acts requiring additional labelling elements. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3).

Article 36

Specific rules for labelling of outer packaging, inner packaging and single packaging

1. Where both an outer and an inner packaging is used and the outer packaging does not bear a pictogram in accordance with rules on the transport of dangerous goods provided for in Regulation (EEC) No 3922/91, Directive 94/55/EC, Directive 96/49/EC or Directive 2002/59/EC, both the outer and the inner packaging shall be labelled in accordance with this Regulation.

   However, if the outer packaging bears a pictogram in accordance with rules on the transport of dangerous goods, only the inner packaging shall be labelled in accordance with this Regulation.

2. In case of a single packaging, the packaging shall be labelled in accordance with this Regulation and in accordance with rules on the transport of dangerous goods referred to in paragraph 1. However, where those rules provide for a pictogram relating to the same hazard, the hazard pictogram resulting from the application of this Regulation shall not appear on the packaging. Moreover, where those rules provide for other label elements, the corresponding label elements resulting from the application of this Regulation shall not appear.

TITLE IV
PACKAGING

Article 37

Packaging

1. Substances and mixtures classified as hazardous shall be contained in packaging that shall satisfy the following requirements:

   (a) the packaging 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 shall not be susceptible to damage by the contents, or liable to form dangerous compounds with the contents;

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

(d) packaging in the form of containers fitted with replaceable fastening devices shall be so designed that the container can be refastened repeatedly without the contents escaping.

2. Packaging in the form of containers containing a hazardous substance or a mixture sold or made available to the general public shall not have either a shape or graphic decoration likely to attract or arouse the active curiosity of children or to mislead consumers, or a presentation or a designation used for foodstuff or animal feeding stuff or medicinal or cosmetic products.

Where such containers meet the requirements in section 3.1.1 of Annex II they shall have a child-resistant fastening in accordance with sections 3.1.2, 3.1.3 and 3.1.4.2 of Annex II.

Where such containers meet the requirements in section 3.2.1 of Annex II they shall bear a tactile warning of danger in accordance with section 3.2.2 of Annex II.

TITLE V
HARMONISATION OF CLASSIFICATION AND LABELLING OF SUBSTANCES AND THE CLASSIFICATION AND LABELLING INVENTORY

Chapter 1
Establishing Harmonised Classification and Labelling of Substances

Article 38
Harmonisation of classification and labelling of substances

1. A substance that fulfils the criteria set out in Annex I for the following may be subject to harmonised classification and labelling in accordance with Article 39:

(a) respiratory sensitisation, section 3.4, category 1;

(b) germ cell mutagenicity, section 3.5, category 1A, 1B or 2;

(c) carcinogenicity, section 3.6, category 1A, 1B or 2;

(d) reproductive toxicity, section 3.7, category 1A, 1B or 2;

2. Where a substance fulfils the criteria for other hazard classes or differentiations than those referred to in paragraph 1, a harmonised classification and labelling in accordance with Article 39 shall be possible on a case-by-case basis, if justification is provided demonstrating the need for such action at Community level.

Article 39

Procedure for harmonisation of classification and labelling of substances

1. A competent authority of a Member State may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or m-factors.

   The proposal shall follow the format set out in part 2 of Annex VI and contain the relevant information provided for in part 1 of Annex VI.

2. A supplier of a substance may submit to the Agency a proposal for harmonised classification and labelling of that substance and, where appropriate, specific concentration limits or m-factors, provided that there is no entry in part 3 of Annex VI for such a substance in relation to the hazard class or differentiation covered by that proposal.

   The proposal shall be drawn up in accordance with the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006 and it shall follow the format set out in part B of the Chemical Safety Report of section 7 of that Annex. It shall contain the relevant information provided for in part 1 of Annex VI to this Regulation. Article 111 of Regulation (EC) No 1907/2006 shall apply.

3. Where the proposal of the supplier concerns the harmonised classification and labelling of a substance in accordance with Article 38 (2), it shall be accompanied by the fee determined by the Commission in accordance with the procedure referred to in Article 54 (2).

4. The Committee for Risk Assessment of the Agency set up pursuant to Article 76 (1) (c) of Regulation (EC) No 1907/2006 shall adopt an opinion on any proposal submitted pursuant to paragraphs 1 or 2 within 12 months of receipt of the proposal, giving the parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission.

5. Where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it shall, within 6 months of receipt of the opinion referred to in paragraph 4, include that substance together with the relevant classification and labelling elements in Table 3.1 of part 3 of Annex VI and, where appropriate, the specific concentration limits or m-factors.

   A corresponding entry shall be included in Table 3.2 of part 3 of Annex VI subject to the same conditions, until 31 May 2015.

   That measure, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 54 (4).

Article 40

Content of opinions and decisions for harmonised classification and labelling in Annex VI; accessibility of information

1. Any opinion referred to in Article 39 (4) and any decision according to Article 39 (5) shall at least specify for each substance:

   (a) the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI to Regulation (EC) No 1907/2006;

   (b) the classification of the substance referred to in Article 38, including a statement of reasons;

   (c) the specific concentration limits or m-factors, where applicable;

   (d) the labelling elements for the substance;

   (e) any other parameter enabling an assessment to be made of the health or environmental hazard of mixtures containing the hazardous substance in question or of substances containing such hazardous substances as impurities, additives and constituents, if relevant.

2. The information referred to in Article 118(2) of Regulation (EC) No 1907/2006 shall not be disclosed in the opinion or in the decision referred to in Article 39(4) and (5) of this Regulation respectively. Article 119 of Regulation (EC) No 1907/2006 shall apply.

Chapter 2
Notification of the Agency and Establishing the Classification and Labelling Inventory

Article 41

Obligation to notify the Agency

1. Any manufacturer or importer, or group of manufacturers or importers, hereinafter "the notifiers", who places on the market a substance subject to registration in accordance with Regulation (EC) No 1907/2006 or a substance classified as hazardous on its own or in a mixture above the concentration limits specified in Directive 1999/45/EC or in this Regulation, where relevant, which results in the classification of the mixture as hazardous, shall notify to the Agency the following information in order for it to be included in the inventory referred to in Article 43:

   (a) the identity of the notifier or notifiers responsible for placing the substance or substances on the market as specified in section 1 of Annex VI to Regulation (EC) No 1907/2006;

   (b) the identity of the substance or substances as specified in section 2.1 to 2.3.4 to Annex VI of Regulation (EC) No 1907/2006;

(c) the classification of the substance or substances in accordance with Article 13;

(d) where a substance has been classified in some but not all hazard classes or differentiations, an indication of whether this is due to lack of data,inconclusive data, or data which are conclusive although insufficient for classification;

(e) specific concentration limits or m-factors, where applicable, in accordance with Article 10 of this Regulation together with a justification using the relevant parts of sections 1, 2 and 3 of Annex I to Regulation (EC) No 1907/2006;

(f) the labelling elements for the substance or substances in accordance with Title III of this Regulation.

The information referred to in (a) to (e) shall not be notified, if it has been submitted to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006.

The manufacturer or importer shall submit this information in the format specified pursuant to Article 111 of Regulation (EC) No 1907/2006.

2. The information listed in paragraph 1 shall be updated and notified to the Agency by the notifier or notifiers concerned when, pursuant to the review in Article 15(1), a decision to change the classification and labelling of the substance has been taken.

3. For substances placed on the market before 1 December 2010, notifications shall be made in accordance with paragraph 1 before that date.

Article 42
Agreed entries

Where the notification in Article 41 (1) results in different entries on the inventory referred to in Article 43 for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory. The notifiers shall inform the Agency accordingly.

Article 43
The classification and labelling inventory

1. The Agency shall establish and maintain a classification and labelling inventory in the form of a database.

The information notified pursuant to Article 41 (1) shall be included in the inventory, as well as information submitted as part of registrations under Regulation (EC) No 1907/2006.

Information in the inventory which corresponds to the information referred to in Article 119 (1) of Regulation (EC) No 1907/2006 shall be publicly accessible. The Agency shall grant access to the other information on each substance in the inventory to the notifiers and registrants who have submitted information on that substance in accordance with Article 29(1) of Regulation (EC) No 1907/2006. It shall grant access to such information to other parties subject to Article 118 of that Regulation.

2. The Agency shall update the inventory when it receives updated information in accordance with Article 41 (2) or Article 42.

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

(a) whether, in respect of the entry, there is a harmonised classification and labelling;

(b) whether, in respect of the entry, it is a joint entry between registrants of the same substance as referred to in Article 11 (1) of Regulation (EC) No 1907/2006;

(c) whether it is an agreed entry of two or more notifiers or registrants in accordance with Article 42;

(d) if the entry differs from another entry on the inventory for the same substance.

The information referred to in (a) shall be updated where a decision is taken in accordance with Article 39 (5).

TITLE VI
COMPETENT AUTHORITIES AND ENFORCEMENT

Article 44
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 45

Appointment of bodies responsible for receiving information relating to health

1. 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 physical effects.

2. The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet medical demand by formulating preventative and curative measures, in particular in case of emergency.

   The information shall not be used for other purposes.

3. The appointed bodies shall have at their disposal all the information required from the suppliers responsible for marketing to carry out the tasks for which they are responsible.

Article 46

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 first July on the results of the official controls, and other enforcement measures taken. The first report shall be submitted by … [3 years after entry into force]. The Agency shall make those reports available to the Commission which shall take them into account for its report under Article 117 of Regulation (EC) No 1907/2006.

3. The Forum referred to in Article 76 (1) (f) of Regulation (EC) No 1907/2006 shall exchange information about the enforcement of this Regulation.

Article 47

Penalties for non-compliance

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

TITLE VII
COMMON AND FINAL PROVISIONS

Article 48
Advertisement

1. Any advertisement for a substance classified as hazardous shall be prohibited if no mention is made therein of the hazard class or hazard category concerned.

2. Any advertisement for a mixtures classified as hazardous or covered by Article 24 which allows a member of the general public to conclude a contract for purchase without first being informed of those hazards through the label for that mixture shall mention the type or types of hazard indicated on the label.

   The first subparagraph shall be without prejudice to Directive 97/7/EC of the European Parliament and of the Council.

Article 49
Obligation to maintain information and requests for information

1. Any supplier of a substance or mixture shall assemble and keep available all the information required for the purposes of classification and labelling under this Regulation for a period of at least 10 years after he last supplied the substance or the mixture.

   The supplier shall keep this information together with the information required in Article 36 of Regulation (EC) No 1907/2006.

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 the first subparagraph of paragraph 1 to it.

   However, where that information is available to the Agency as part of a registration pursuant to under Regulation (EC) No 1907/2006 or a notification pursuant to Article 41 of this Regulation, the Agency shall use that information and the competent authority shall address itself to the Agency.

Article 50
Tasks of the Agency

1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.

2. The Secretariat of the Agency shall undertake the following tasks:

   (a) providing technical and scientific guidance and tools where appropriate for the operation of this Regulation by industry;

(b) providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities.

Article 51
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 and, where appropriate, with Community acts adopted in implementation of this Regulation.

Article 52
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. Within 60 days of receipt of the information from the Member State, the Commission in accordance with the regulatory procedure referred to in Article 54 (2) either authorise the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.

3. In the case of an authorisation as referred to in paragraph 2, the competent authority of the Member State concerned shall in accordance with the procedure laid down in Article 39 submit a proposal to the Agency for harmonised classification and labelling, within three months of the date of the Commission decision.

Article 53
Adaptations to technical progress

The Commission may adjust and adapt Articles 12, 14, 23, 27 to 32 and 37 (2) second and third subparagraph and Annexes I to VII to technical progress. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 54 (3). On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 54 (4).

Article 54
Committee procedure

1. The Commission shall be assisted by the Committee instituted by Article 133 of Regulation (EC) No 1907/2006.

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

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

3. Where reference is made to this paragraph, Article 5a (1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. Where reference is made to this paragraph, Article 5a (1), (2), (4) and (6), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

Article 55
Amendment to Directive 67/548/EEC

Directive 67/548/EEC is amended as follows:

(1) Article 4 is amended as follows:

(a) paragraph 3 is replaced by the following:

"3. Where an entry containing the harmonised classification and labelling for a particular substance has been included in part 3 of Annex VI of Regulation (EC) No … of the European Parliament and of the Council*, the substance shall be classified in accordance with that entry and paragraphs 1 and 2 shall not apply to the danger categories covered by that entry."

(b) paragraph 4 is deleted;
* OJ L …,

(2) in Article 5, paragraph 2 is replaced by the following:

"2. The measures in the first subparagraph of paragraph 1 shall apply until the substance is listed in part 3 of Annex VI of Regulation (EC) No … for the danger categories covered by that entry or until a decision not to list it has been taken in accordance with the procedure laid down in Article 39 of Regulation (EC) No ….";

(3) the text of Article 6 is replaced by the following:

"Manufacturers, distributors and importers of substances which appear in the EINECS but for which no entry has been included in part 3 of Annex VI of Regulation (EC) No … shall carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label dangerous substances according to the rules laid down in Articles 22 to 25 and the criteria in Annex VI.";

(4) in Article 23, paragraph 2 is amended as follows:

(a) in point (a), the words "Annex I" are replaced by the words "part 3 of Annex VI to Regulation (EC) No …";

(b) in point (c), the words “Annex I” are replaced by the words “part 3 of Annex VI to Regulation (EC) No …”;

(c) in point (d), the words “Annex I” are replaced by the words “part 3 of Annex VI to Regulation (EC) No …”;

(d) in point (e), the words “Annex I” are replaced by the words “part 3 of Annex VI to Regulation (EC) No …”;

(e) in point (f), the words "Annex I" are replaced by the words “part 3 of Annex VI of Regulation (EC) No …”;

(5) Annex I is deleted.

Article 56
Amendment to Regulation (EC) No 1907/2006

Regulation (EC) No 1907/2006 is amended as follows:

(1) Article 14 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) point (b) is replaced by the following:

"(b) the specific concentration limits and multiplying factors, hereinafter referred to as “m-factors”, that have been set in part 3 of Annex VI to Regulation (EC) No … of the European Parliament and of the Council*;”;

(ii) point (e) is replaced by the following:

"(e) the specific concentration limits and m-factors given in an agreed entry in the classification and labelling inventory established under Title V of Regulation (EC) No …;”;

(b) from 1 December 2010, in paragraph 4, the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …";

(c) from 1 June 2015, paragraph 2 is amended as follows:

(i) points (a) and (b) are replaced by the following:

“(a) the applicable concentrations and generic concentration limits defined in each of the parts 1 to 5 of Annex I to Regulation (EC) No … of the European Parliament and of the Council*;”;

* OJ L …

(b) the specific concentration limits and m-factors that have been set in part 3 of Annex VI to Regulation (EC) No …;”;

(ii) Points (c) and (d) are deleted;
* OJ L …

(2) Article 31 is amended as follows:

(a) the following paragraph 10 is added:

“10. From 1 December 2010 until 1 June 2015, the safety data sheets for substances shall contain the classification according to both Directive 67/548/EEC and Regulation (EC) No ….

Where substances and mixtures are classified in accordance with Regulation (EC) - No … during the period from its entry into force until 1 December 2010 or 1 June 2015, that classification shall be added in the safety data sheet together with the classification in accordance with Directives 67/548/EEC and 1999/45/EC respectively.”;

(b) from 1 December 2010, in paragraph 1, point (a) is replaced by the following:

"(a) where a substance or mixture meets the criteria for classification as dangerous in accordance with Article 3 (2) of Regulation (EC) No … or Article 2 (2) of Directive 1999/45/EC; or";

(c) from 1 June 2015, paragraphs 1 and 3 are amended as follows:

(i) in paragraph 1, point (a), the words "or Article 2(2) of Directive 1999/45/EC" are deleted;

(ii) paragraph 3 is amended as follows:

The introductory phrase is replaced by the following:

"The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as dangerous in accordance with Titles I and II of Regulation (EC) No …, but contains:";

- point (b) is replaced by the following:

"(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is carcinogenic category 2 or toxic to reproduction category 2 or persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or";

(3) from 1 December 2010, in Article 40, in paragraph 1, the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …";

(4) in Article 56, paragraph 6, point (b) is amended as follows:

(a) from the entry into force of this Regulation, it is replaced by the following:

"(b) for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in part 3 of Annex VI to Regulation (EC) No … which result in the classification of the mixture as dangerous.";

(b) from 1 June 2015, it is replaced by the following:

"(b) for all other substances, below the cut-off values specified in Article 11 (3) of Regulation (EC) No … which result in the classification of the mixture as dangerous.";

(5) from 1 December 2010, in Article 57, paragraphs (a), (b) and (c) are replaced by the following:

"(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of part 3 of Annex I to Regulation (EC) No …;

(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of part 3 of Annex I to Regulation (EC) No …;

(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B in accordance with section 3.7 of part 3 of Annex I to Regulation (EC) No …;";

(6) in Article 59, paragraphs 2 and 3 are amended as follows:

(a) in paragraph 2, the second sentence is replaced by the following:

"The dossier may be limited, if appropriate, to a reference to an entry in part 3 of Annex VI to Regulation (EC) No ….";

(b) in paragraph 3, the second sentence is replaced by the following:

"The dossier may be limited, if appropriate, to a reference to an entry in part 3 of Annex VI to Regulation (EC) No ….";

(7) Article 65 is amended as follows:

(a) from 1 December 2010, the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …";

(b) from 1 June 2015, the words "and Directive 1999/45/EC" are deleted;

(8) from 1 December 2010, Article 68 (2) is replaced by the following:

"For a substance on its own, in a mixture or in an article which meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII

shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.";

(9) in Article 76, in point (c) of paragraph 1, the words "Title XI" are replaced by "Title V of Regulation (EC) No …";

(10) Article 77 is amended as follows:

(a) in paragraph 2, the first sentence of point (e) is replaced by the following:

"(e) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list established in accordance with Regulation (EC) No ….;"

(b) in paragraph 3, point (a), the words "Titles VI to XI" are replaced by "Titles VI to X";

(11) Title XI is deleted;

(12) from 1 December 2010, Article 119 paragraphs 1 and 2 are amended as follows:

(a) in paragraph 1, point (a), the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …";

(b) in paragraph 2, point (g), in the introductory phrase, the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …";

(13) from 1 December 2010, in Article 138 (1) in paragraph 1, the second sentence of the introductory phrase is replaced by the following:

"However, for substances meeting the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, in accordance with Regulation (EC) No …, the review shall be carried out by 1 June 2014.";

(14) from 1 December 2010, Annex III is amended as follows:

(a) point (a) is replaced by the following:

"(a) substances for which it is predicted (i.e. by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for category 1A or 1B classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity or the criteria in Annex XIII;";

(b) in point (b), point (ii) is replaced by the following:

"(ii) for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any health or environmental hazard classes or differentiations under Regulation (EC) No ….";

(15) from 1 December 2010, in Annex V, point 8., the words "Directive 67/548/EEC" are replaced by "Regulation (EC) No …";

(16) Annex VI is amended as follows:

(a) from 1 December 2010, sections 4.1 and 4.2 are amended as follows:

(i) Section 4.1 is amended as follows:

– the first subparagraph is replaced by the following:

"The hazard classification of the substance(s), resulting from the application of Title I and II of Regulation (EC) No … for all hazard classes and categories in that Regulation;";

– the second subparagraph is replaced by the following:

"In addition, for each entry, the reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification);";

(ii) Section 4.2 is replaced by the following:

"4.2. The resulting hazard label for the substance(s), resulting from the application of Title III of Regulation (EC) No …;";

(b) From 1 June 2015, section 4.3 is replaced by the following:

"4.3. Specific concentration limits, where applicable, resulting from the application of Article 10 of Regulation (EC) No ….";

(17) from 1 December 2010, in Annex XIII, the second and third indents of point 1.3 are replaced by the following:

– "the substance is classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2), or

– there is other evidence of chronic toxicity, as identified by the classifications STOT (repeated exposure), category 1 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) according to Regulation (EC) No …"

(18) Annex XV, sections I and II are amended as follows:

(a) section I is amended as follows:

(i) the first indent is deleted;

(ii) the second indent is replaced by the following:

"-the identification of CMRs, PBTs, vPvBs, or a substance of equivalent concern in accordance with Article 59,";

(b) in section II, point 1 is deleted;

(19) Annex XVII is amended as follows:

(a) from 1 December 2010, the table is amended as follows:

(i) in the column "Designation of the substance, of the groups of substances or of the preparation", entries 3., 28., 29., 30. and 40. are replaced by the following:

"3. Liquid substances or mixtures, which are regarded as dangerous according to Regulation (EC) No … and Directive 1999/45/EC.;

28. Substances which appear in Annex VI to Regulation (EC) No … classified as carcinogen category 1A or 1B and listed as follows :

– Carcinogen category 1A listed in Appendix 1

– Carcinogen category 1B listed in Appendix 2

29. Substances which appear in Annex VI to Regulation (EC) No … classified as germ cell mutagen category 1A or 1B and listed as follows:

– Mutagen category 1A listed in Appendix 3

– Mutagen category 1B listed in Appendix 4

30. Substances which appear in Annex VI to Regulation (EC) No … classified as toxic to reproduction category 1A or 1B and listed as follows:

– Reproductive toxicant category 1A listed in Appendix 5

– Reproductive toxicant category 1B listed in Appendix 6

40. Substances classified as flammable gases category 1, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in part 3 of Annex VI to that Regulation or not.";

(ii) in the column " Conditions of restriction", in entry 28, the first indent of point 1. is replaced by the following:

"– either the relevant specific concentration limit specified in part 3 of Annex VI of Regulation (EC) No …, or";

(b) from 1 June 2015, the column " Conditions of restriction" of the table is amended as follows:

(i) in entry 28, the second indent of point 1. is replaced by the following:

"– the relevant generic concentration limit specified in part 3 of Annex I of Regulation (EC) No ….";

(ii) in entry 30., point 2 (d) is replaced by the following:

"(d) artists' paints covered by Regulation (EC) No ….";

(20) Appendices 1 to 6 are amended as follows:

(a) the Foreword is amended as follows:

(i) in the section entitled “Substances”, the words “Annex I of Directive 67/548/EEC” are replaced by “part 3 of Annex VI to Regulation …”;

(ii) in the section entitled “Index number”, the words “Annex I of Directive 67/548/EEC” are replaced by “part 3 of Annex VI to Regulation …”;

(iii) in the section entitled “Notes”, the words “Annex I of Directive 67/548/EEC” are replaced by “part 3 of Annex VI to Regulation …”;

(iv) Note A is replaced by the following:

“The name of the substance must appear on the label in the form of one of the designations given in part 3 of Annex VI to Regulation (EC) No ….

In that part, use is sometimes made of a general description such as "... compounds" or "... salts". In this case, the manufacturer or any other person who places such a substance on the market is required to state on the label the correct name, due account being taken of paragraph 1.1.1.6 of part 1 of Annex VI of Regulation (EC) No ….

Regulation (EC) No … also requires that the appropriate label elements to be used for each substance shall be those shown in part 3 of Annex VI to that Regulation.

For substances belonging to one particular group of substances included in part 3 of Annex VI to Regulation (EC) No …, the appropriate label elements to be used for each substance shall be those shown in the appropriate entry in that part.

For substances belonging to more than one group of substances included in part 3 of Annex VI to Regulation (EC) No …, the appropriate label elements to be used for each substance shall be those shown in both the appropriate entries given in that part. In cases where two different classifications are given in the two entries for the same hazard class or differentiation, the classification reflecting the more severe classification shall be used."

(v) Note D is replaced by the following:

"Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in part 3 of Annex VI to Regulation (EC) No ….

However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the manufacturer or any person who places such a substance on the market must state on the label the name of the substance followed by the words "non-stabilised"."

(vi) Note H is replaced by the following:

"The classification and label shown for this substance applies to the hazard or hazards indicated by the hazard statement or hazard statements in combination with the hazard classification shown. The requirements of Article 4 of Regulation (EC) No … on manufacturers, distributors and importers of this substance apply to all other hazard classes, differentiations and categories.

The final label shall follow the requirements of section 1.2 of Annex I of Regulation (EC) No …."

(vii) Note K is replaced by the following:

"The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1 % w/w 1,3-butadiene (Einecs No 203-450-8). If the substance is not classified as a carcinogen or mutagen, at least the precautionary statements (102-)210-403 should apply. This note applies only to certain complex oil-derived substances in part 3 of Annex VI to Regulation (EC) No …."

(viii) Note S is replaced by the following:

"This substance may not require a label according to Article 17 (see section 1.3 of Annex I of Regulation …)."

(b) in Appendix 1, the title is replaced by the following:

"Point 28 – Carcinogens: category 1A";

(c) in Appendix 2, the title is replaced by the following:

"Point 28 – Carcinogens: category 1B";

(d) in Appendix 3, the title is replaced by the following:

"Point 29 – Mutagens: category 1A";

(e) in Appendix 4, the title is replaced by the following:

"Point 29 – Mutagens: category 1B";

(f) in Appendix 5, the title is replaced by the following:

"Point 30 – Reproductive toxicants: category 1A";

(g) in Appendix 6, the title is replaced by the following:

"Point 30 – Reproductive toxicants: category 1B";

(21) the word « preparation » or "preparations" within the meaning of Article 3 (2) of Regulation (EC) 1907/2006 is replaced by the word « mixture » or "mixtures" respectively throughout the text.

Article 57
Repeal

Directive 67/548/EEC and Directive 1999/45/EC are repealed with effect from 1 June 2015.

Article 58
Transitional provisions

1. Until 1 December 2010, substances shall be classified, labelled and packaged in accordance with Directive 67/548/EEC.

   Until 1 June 2015, mixtures shall be classified, labelled and packaged in accordance with Directive 1999/45/EC.

2. By way of derogation from Article 60 and from paragraph 1 of this Article, the substances and mixtures classified in accordance with paragraph 1 may, as regards the period before 1 December 2010 and 1 June 2015 respectively, be classified and labelled in accordance with this Regulation. In that case, the provisions on labelling in Directives 67/548/EEC and 1999/45/EC shall not apply.

3. From 1 December 2010 until 1 June 2015, substances shall be classified in accordance with both Directive 67/548/EEC and this Regulation. They shall be labelled and packaged in accordance with this Regulation.

4. Substances and mixtures that have been classified and placed on the market before 1 December 2010 and 1 June 2015 respectively shall not be required to be labelled and packaged in accordance with this Regulation.

Article 59
Reclassification

Where a substance has already been classified in accordance with Directive 67/548/EEC before 1 December 2010, the suppliers shall from that date reclassify such a substance in accordance with Title II of this Regulation or may adapt the classification by using the conversion table in Annex VII.

Article 60
Entry into force

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

Titles II, III and IV shall apply in respect of substances from 1 December 2010 and in respect of mixtures from 1 June 2015.

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*